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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
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March 12, 2014

Re: NIH FOI Case No. 42070
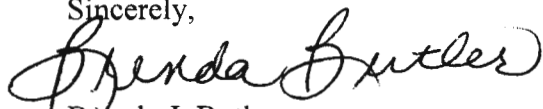   HHS FOI Case No. 14-0464

This is the final response to your January 5, 2014, Freedom of Information Act (FOIA) request addressed to the Freedom of Information/Privacy Acts Division, Department of Health and Human Services (HHS). Your request was referred to this office on January 8, 2014, because of our responsibilities under the FOIA. You requested an electronic copy of the National Institutes of Health (NIH) Manual Chapters found on the NIH Office of Management Assessment website.

We searched the files of the NIH Office of Management Assessment (OMA) for records responsive to your request. That search produced the enclosed computer disc with 51 Manual Chapters consisting of approximately 1,010 pages. Please be advised that Manual Chapter 6304-2 titled "Establishment of New Activities and Activity Codes" has been renumbered and is now Manual Chapter 54101, which is provided on the enclosed disc. You should also be aware that the content of six Manual Chapters has been superseded by the "NIH Grants Policy Statement" (GPS) which is located on the NIH website at: http://grants.nih.gov/grants/policy/nihgps_2013/. Enclosed is a cross reference guide for these few chapters.

As it pertains to the remaining Manual Chapters, you may access them on the OMA website at: http://oma1.od.nih.gov/manualchapters/scripts/mcs/browse.asp. We are not providing copies because the FOIA does not require agencies to provide requesters with records that are already publicly available either on the agency's website, internet, or other public source. If you have any questions about the information we have provided, please feel free to contact our office on 301-496-5633 or at nihfoia@mail.nih.gov.

In certain circumstances, provisions of the FOIA allow us to recover part of the cost of complying with your request. Because the cost is below our $25 minimum fee, there is no charge for the enclosed materials.

Sincerely,

Brenda J. Butler
Freedom of Information Specialist, NIH

Enclosures:
  1 CD
  GPS Cross Reference Guide

NIH POLICY MANUAL

1745 - NIH Information Technology (IT) Privacy Program

Issuing Office: OD/OM/OMA (301) 402-6201 and CIT/ODCIO (301) 496-1111
Release Date: 7/12/07

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1. **Explanation of Material Transmitted:**

   This chapter outlines responsibilities for complying with the NIH IT Privacy Program, and ensuring the privacy and protection of personal information contained in all NIH IT systems. This policy also applies to NIH IT systems that are developed, operated and/or maintained by contract personnel.

   Additional guidance for meeting privacy requirements can be found at http://oma.od.nih.gov/ms/privacy/.

2. **Filing Instructions:**

   Remove: N/A..

   Insert: NIH Manual 1745 dated 7/12/07.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- Privacy and Privacy Act, contact the NIH Senior Official for Privacy (SOP), Division of Management Support, Office of Management Assessment, OM at (301) 402-6201.
- On-line information, enter this URL: http://oma.od.nih.gov/ms/privacy/

A. Purpose:

This policy applies to all employees and contractors of the National Institutes of Health (NIH) and establishes the importance of protecting the privacy of the information maintained, stored, or transmitted/passed through NIH information technology (IT) systems, and those developed, operated and/or maintained by contractors on behalf of the NIH.

Note: All links to federal legislation, mandates, and guidance can be found in Section E: References.

B. Responsibilities:

Certain personnel within NIH have been designated with responsibility for ensuring compliance with Federal law and policies pertaining to privacy.

1. <u>NIH Director</u>
   - Responsible for providing privacy protections commensurate with the risk and magnitude of harm resulting from unauthorized access, use, disclosure, disruption, modification, or destruction of the following:
     - Information collected or maintained by or on behalf of NIH.
     - Information systems used or developed, maintained and/or operated by NIH or a contractor of NIH.
   - Comply with applicable requirements of, including but not limited to, the Privacy Act of 1974, as amended, the E-Government Act of 2002, OMB Circulars and directives, Departmental policy and guidelines, and other material referenced or cited in this manual chapter (see Section E);
   - Oversee the integration of privacy management processes with NIH strategic and operational planning processes; and
   - Ensure that the NIH Senior Official for Privacy (SOP), in coordination with the NIH Chief Information Officer (CIO), NIH Chief Information Security Officer (CISO) and other senior NIH officials, report to the NIH Director

through the Deputy Director of Management (DDM) on the effectiveness of NIH privacy compliance efforts, including progress of remedial actions.

2. <u>NIH Senior Official for Privacy (SOP)</u>

- o Support the roles and responsibilities of the HHS Senior Agency Official for Privacy as appropriate;

- o Report to HHS CISO and current NIH Director through the Director of the Office of Management Assessment (OD/OM/OMA) regarding the effectiveness of the NIH IT privacy program (defined in Office of Management and Budget (OMB) M-05-08, "Designation of Senior Agency Officials for Privacy.")

- o Ensure NIH is in compliance with all Federal laws, regulations and policies regarding privacy management and oversee its execution by:
  - Instituting, reviewing, and updating NIH privacy policies and procedures;
  - Ensuring that NIH employees, contractors, and all other personnel using NIH information systems receive mandatory training regarding privacy procedures;

- o On an annual basis, generate and approve NIH's Privacy Management submission for inclusion in the HHS Federal Information Security Management Act and Agency Privacy Management (FISMA) Report;

- o Support quarterly President's Management Agenda (PMA) activities through compliance with E-Government Act privacy impact assessment (PIA), and Privacy Act Systems of Records Notice (SORN) requirements.

- o Oversee and review NIH PIA process for completeness and accuracy;

- o Establish a framework to facilitate the development and maintenance of PIAs for all NIH systems;

- o Manage and update an ongoing inventory of PIAs for all NIH information systems, when a major change occurs in systems, or when systems are in development;

- o Ensure compliance with the [NIH Manual 1745-1](#);

- o Track privacy awareness training completed by NIH personnel and contractors;
- o Develop/incorporate NIH privacy guidance into NIH and system-level documentation to ensure consistency with Department policy and guidance;
- o Coordinate with the website owners and managers to ensure that web-based privacy compliance requirements are met across the NIH; and
- o Coordinate with the NIH CISO, Information Systems Security Officer (ISSO), Incident Response Team (IRT), NIH Police, and the affected IC's Privacy Coordinator as needed in the event of a privacy breach to ensure that reporting and subsequent investigations are accomplished according to NIH, Department and OMB requirements.

3. <u>NIH Chief Information Officer (CIO)</u>
- o
  Coordinate with the NIH SOP and NIH ICs and the Office of the Director (OD) to ensure all employees comply with this policy;
- o Upon request, provide updates for the HHS CIO regarding NIH's privacy compliance;
- o Establish and implement IT security policies, procedures, and practices, consistent with OMB and Departmental requirements to safeguard the privacy of the information maintained, stored, or transmitted/passed through systems;
- o Ensure that senior NIH officials provide IT security controls to safeguard privacy information maintained in IT systems that support the operations and assets under their control; and
- o Designate NIH's SOP (defined in the HHS Information Security Program Privacy Policy Memorandum).

4. NIH Chief Information Security Officer (CISO)
- o Coordinate with the NIH CIO, SOP and other NIH and HHS officials, etc. in the event of a breach to ensure that proper reporting and remedial actions are taken;

- Maintain and oversee the NIH Incident Response Team (IRT);
- Ensure than all Federally-mandated information security measures in support of privacy are implemented;
- Coordinate with the NIH SOP to integrate and implement privacy into security policies, procedures, and practices consistent with Departmental requirements;
- Assist in the incorporation of security and privacy considerations within acquisition documents, and help to ensure that contractor compliance is maintained;
- Assist the NIH SOP to develop and maintain a framework to facilitate the development and maintenance of PIAs;
- Coordinate with the NIH SOP to conduct general privacy awareness and role-based training activities with parallel security training; and
- Ensure that security awareness education is mandatory for all NIH employees and contractors who are using, operating, supervising, or managing NIH computer systems;

5. <u>NIH Privacy Act Officer</u>
- Oversee, develop, and implement NIH's compliance with the Privacy Act;
- Coordinate as necessary with the NIH SOP to ensure 90% of systems subject to the Privacy Act have a SORN to comply with the President's Management Agenda;
- Review NIH Privacy Act SORNs:
    - prior to publication;
    - biennially, in accordance with OMB Circular A-130; and
    - to ensure that SORNs meet the requirements of the Privacy Act
- Submit Privacy Act SORNs to the Federal Register for publication;
- Maintain an NIH SORN website to post current SORNs per the guidance of the Department Privacy Act Officer;
- Manage NIH Privacy Act training and/or awareness programs; and
- Collaborate with [IC Privacy Coordinators](#) to ensure that system owners/managers understand the Privacy Act requirements and their

related responsibilities.

6. <u>IC Privacy Coordinator</u>
    o Advise ICs on inquiries regarding the privacy laws and policies;
    o Distribute privacy memoranda and bulletins to NIH personnel so that they are informed of current OMB, HHS and NIH privacy policies and procedures;
    o Ensure that system owners/managers maintain privacy notices, policies, and procedures for all applicable IT systems as appropriate;
    o Assist NIH CISO and IC ISSO in performing security reviews for IT systems that are subject to the Privacy Act;
    o Assist the NIH Privacy Act Officer as necessary with biannual SORN reviews;
    o Coordinate with the NIH SOP on the annual requirement, and satisfactory completion of, privacy awareness training for IC staff and contractors;
    o Respond to requests for access to records from individuals whose personally identifiable information (PII) resides in a Privacy Act system of records; and
    o Maintain awareness of privacy laws, regulations, and issues.

7. <u>NIH Senior Information Systems Security Officers (Senior ISSO)</u>
    o Provide assistance to IC ISSOs on implementing Federal law and policies regarding privacy issues in IT systems; and
    o Serve as NIH Incident Response Team (IRT) Coordinator, whose responsibilities include supporting activities related to safeguarding privacy information such as:
        ▪ Informing IC ISSOs of IT-related privacy incidents and acting as liaison between ICs and SOP for tracking incident reporting;
        ▪ Investigating privacy breaches occurring in IT systems and developing appropriate safeguards to prevent such breaches; and
        ▪ Coordinating investigations with the NIH CIO, CISO, SOP, and NIH Police in the event of an IT system breach.

8. <u>NIH IC Information Systems Security Officer (ISSO)</u>

- o Report incidents involving breaches to PII contained in NIH IT systems to the NIH IRT;
- o Ensure proper IT security protection is used to protect PII critical to the program's mission;
- o Have knowledge of Federal government and Departmental laws, regulations and policies and procedures regarding privacy;
- o Institute security technologies to ensure the safety of privacy information maintained, stored, and/or transmitted/passed in NIH IT systems;
- o Collaborate with NIH IT business owners to determine appropriate security controls and resources for implementation;
- o Coordinate with IC system owners to establish security categorization for IC systems and data in accordance with National Institute of Standards and Technology (NIST) standards and guidelines; and
- o Assist the NIH CISO in ensuring that all Federally-mandated information security measures in support of privacy are implemented:
    - Enforcing logical access controls that provide privacy protection by preventing unauthorized access, alteration, loss, disclosure;
    - Maintaining availability of information and disclosure of information about privacy policies and practices to the public for all applicable IT systems as appropriate;
    - Reviewing contracts for systems under NIH CISO control to ensure privacy is appropriately addressed in contract language; and
    - Ensuring privacy controls are functioning properly within each IT system and that privacy needs are captured in NIH's plans of action and milestones (POA&Ms).

9. Designated Approving Authority (DAA)/ Accrediting Authority
    - o Use the security accreditation process to determine the privacy risk and provide protection commensurate with a system's sensitivity or confidentiality requirements;
    - o Use Certification Authority (CA) analysis to determine whether to accept a privacy risk or to implement countermeasures; and

- Ensure that NIH sensitive information and PII is protected from unauthorized access in all forms at rest or in transit.

10. <u>IC System Owner/Manager</u> *(in coordination with knowledgeable privacy and security personnel as needed)*
    - Serve as point of contact (POC) for the system to whom privacy issues may be addressed;
    - Collaborate with the ISSO, IC Privacy Coordinator, data owner, and system/network administrator to determine and implement appropriate privacy policies and controls;
    - Coordinate with NIH IT personnel to delegate system-level privacy requirements;
    - Collect, modify, use, and disclose the minimum PII necessary to complete the mission-related, required and/or permitted program task consistent with organizational policy;
    - Develop additional system rules of behavior for systems under their responsibility, if rules are not covered under the NIH IT Rules of Behavior;
    - Complete, maintain and submit all PIAs on all systems under their responsibility to the SOP for approval and transmission to HHS;
    - Collaborate with the IC ISSO to perform risk assessments of the privacy technologies used to secure information in the system;
    - Coordinate with IC Privacy Coordinators and ISSOs to ensure privacy and security requirements are in place for facilities that process, transmit, or store sensitive information based on the level of privacy risk;
    - Coordinate with IC ISSOs to establish sensitivity and criticality levels for IC systems and data in accordance with NIST standards and guidelines;
    - Assist in the development, activation, and execution of an implementation plan for any new instances of a system-to-system interconnection;
    - Keep track of the location of Privacy Act records;
    - Approve/deny/track access to, and amendments of, records;
    - Ensure records are complete, accurate, timely and relevant;
    - Ensure that users are made aware of their privacy responsibilities when

accessing systems that contain personal information;

- o Submit Privacy Act annual report data to the IC Privacy Coordinator;
- o Inform staff of the annual requirement to take privacy awareness training;
- o Comply with the NIH Records Schedule;
- o Assist in the mitigation of privacy weaknesses identified through the system PIA process into the system Plan of Action and Milestones (POA&M);
- o Ensure PII collected is fulfilling its stated purpose; and
- o Coordinate with the IC Privacy Coordinator as necessary to provide appropriate written privacy notification to individuals whose PII is being collected regarding:
  - Consent to collect PII prior to its submission;
  - Use/disclosure practices of PII prior to its submission; and
  - Major changes that occur to a system that may affect the status or usage of PII contained within the system.

11. Data Owners *(in coordination with privacy and IT security personnel as needed)*
- o Ensure NIH system owners/managers are aware of the sensitivity of the data being handled; and
- o Ensure data is not processed on an NIH system without the appropriate level of privacy controls.

12. System/Network Administrators
- o Implement and enforce appropriate privacy requirements for all IT systems or networks;
- o Patch privacy vulnerabilities in IT systems and report related privacy incidents;
- o Ensure that the privacy posture of the network is maintained during all network maintenance, monitoring activities, installations or upgrades, and throughout day-to-day operations;
- o Implement technical privacy controls on systems; and
- o Protect data during an incident by isolating the related system(s) connected to the network until assurance can be made that the problem

has been adequately resolved.

13. <u>Contracting Officers</u>

    o Include Department's privacy considerations in contracts dealing with IT acquisitions;

    o Maintain the integrity and quality of the proposal evaluation, negotiation, and source selection processes while ensuring that all privacy terms and conditions of the contract are met; and

    o Obtain contractual assurances from third parties to ensure that the third party will protect PII in a manner consistent with the privacy practices of the Department and applicable laws and policies, before enabling access to PII .

14. <u>Administrative Officers (AO)</u>

    o Notify appropriate IC ISSO and Human Resources (HR) point of contact when NIH personnel are separated from the Department. If NIH ISSO is not available, the personnel officer should contact the NIH Senior ISSO.

15. <u>Supervisors</u>

    o Ensure personnel comply with privacy policies and provide the personnel, financial, and physical resources required to protect privacy;

    o Ensure that employees complete all required privacy and IT security training within the mandated time frame;

    o Review employee requests for telework to ensure that all proper privacy and security measures are in place;

    o Ensure that the AO is aware of all employee or contractor separations from the Department; and

    o Pursue disciplinary actions against personnel who violate the NIH IT Rules of Behavior and system-specific Rules of Behavior.

16. <u>Users and Employees</u>

    o Comply with the Departmental and NIH privacy polices, standards, and procedures;

    o Be aware of special privacy requirements for accessing, protecting, handling, and using data;

- o Report potential or occurring privacy incidents to IC ISSO and Privacy Coordinator;
- o Seek guidance from supervisors when implementing privacy policies;
- o Ensure NIH data is appropriately marked to indicate the sensitivity of the data;
- o Ensure sensitive privacy data is not stored on laptop computers or other portable devices unless they are encrypted with standards commensurate with the sensitive level of the data are being used, or otherwise approved through a waiver of the encryption requirement;
- o Read, acknowledge, sign, and comply with all privacy requirements in the NIH IT Rules of Behavior and system-specific Rules of Behavior before gaining access to government systems and networks;
- o Implement specific safeguards to prevent fraud, waste, or abuse of the systems, networks, and data authorized to use;
- o Agree to not disable, remove, install with intent to bypass, or otherwise alter privacy settings or administrative settings designed to protect privacy controls on NIH IT resources; and
- o Complete all required privacy and IT security awareness training, as applicable.

C. Policy:

The following privacy controls and procedures are to be followed along with any other policy requirements defined within [NIH Manual 1745-1](#):

1. General Requirements
   a. NIH must integrate and explicitly identify funding for privacy control technologies and programs into IT investment and budgeting plans, establish consistent methodologies for determining privacy control costs for all NIH systems and networks, and ensure that any NIH system that is reported as a FISMA system maps to an OMB Exhibit 300 ("Planning, Budgeting, Acquisition, and Management of Capital Assets") and/or

Exhibit 53 ("Agency IT Investment Portfolio");

b. IC system owners/managers must incorporate review of privacy controls into the annual assessment schedule of controls (operational, management, and technical) on all systems, networks and interconnected systems for which they have management oversight to ensure that adequate and effective IT privacy controls are implemented to prevent unauthorized collection, access, use, disclosure, disruption, modification or destruction of information;

c. All NIH employees and contractors must be made aware of privacy risks associated with their activities and of applicable privacy legislation via privacy awareness, training, and education;

d. NIH must establish and maintain an incident response capability to include preparation, identification, containment, eradication, recovery, and follow-up capabilities to ensure effective recovery from privacy breaches

e. NIH must establish and implement plans for emergency response, continuity of operations, and post-disaster recovery of information systems. These plans must take into account privacy protection requirements; and

f. NIH, coordinated through the NIH SOP, must conduct an independent review of its privacy program to determine its effectiveness:

- At least every three years; or
- When changes in legislation, regulation, related guidance, contractual obligations, internal preferences, market expectations, public expectations, HHS guidance requires the review of the program

2. **System Requirements**

a. Privacy reviews and controls must be implemented throughout the system development life cycle;

b. Written authorization from management (e.g. DAA/AO) must be obtained prior to connecting with other systems and/or sharing PII. Obtain an individual's written authorization if NIH intends to use, modify, or disclose

PII in a manner inconsistent with the SORN, under which it was collected. Ensure that the terms and conditions of the information sharing agreement do not conflict with or otherwise contradict NIH's IT Privacy policies, procedures, controls, and standards or applicable legislation, regulation, or guidance, and its other contractual obligations;

c. NIH must capture all privacy program and system weaknesses that require mitigation in POA&Ms in accordance with the standards and guidelines set forth by OMB Memorandum (M)02-01 ("Guidance for Preparing and Submitting Security Plans of Action and Milestones") and the HHS CISO;

d. NIH must ensure that system PIAs are included in all Certification and Accreditation (C&A) packages;

e. PIAs are to be updated when a major change occurs that affects the data in the system and/or poses a risk to the data. (See Section D6 for definition of a major change.) (**Note**: For more information regarding PIA requirements, please see [NIH Manual 1745-1](#);

f. All NIH systems and networks must implement the appropriate management security policies to ensure the adequate protection of PII;

g. When technically feasible, all NIH systems and networks must generate audit logs that show addition, modification, and/or deletion of PII and the unique user identifier of the person initiating the access, modification, or deletion. Audit logs must be protected from unauthorized modification, access, or destruction and be recorded, retained, and regularly analyzed by IC system owners/managers to identify unauthorized activity; and

h. Appropriate implementation of technology products evaluated and approved by the NIH CISO is required for all NIH systems used to store, process, display, or transmit sensitive information or PII.

3. **Personnel Requirements**

NIH must enforce compliance with executive, legislative, and technical requirements to ensure that only appropriate personnel are granted access to sensitive, personal information or system privileges;

a. All NIH system users are required to read, acknowledge, and comply with their roles and responsibilities and privacy rules of each system;

b. New NIH users must receive initial privacy awareness training before being granted permanent access to NIH systems and networks. Access to administrative systems, such as electronic or online training, can be granted for new employees as needed. All NIH users must receive annual training in privacy as part of their annual awareness training requirements; and

c. All NIH employees must comply with [NIH Manual 1745-1](#).

D. Definitions:

1. Accreditation: The official management decision given by a senior agency official to authorize operation of an information system and to explicitly accept the risk to agency operation (including mission, function, image, or reputation), agency assets, or individuals based on the implementation of an agreed-upon set of security controls (Defined in NIST SP 800-37, "Guide for the Security Certification and Accreditation of Federal Information Systems," Appendix B).

2. Certification: A comprehensive assessment of the management, operational, and technical security controls in an information system made in support of security accreditation, to determine the extent to which the controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting the security requirements for the system (Defined in NIST SP 800-37, Appendix B).

3. Confidentiality: Preserving authorized restrictions on information access and disclosure, including means for protecting personal privacy and proprietary information (Defined in NIST SP 800-53, "Recommended Security Controls for Federal Information Systems, Appendix B).

4. Data Owner: The authority, individual, or organization that has original responsibility for the data by statute, executive order, or directive (Defined in the HHS Information Security Program Policy).

5. <u>Information in Identifiable Form (IIF):</u> Information in an information system or online collection:

   o That directly identifies an individual (e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc); or

   o By which an agency intends to identify specific individuals in conjunction with other data elements, i.e., indirect identification. (These data elements may include a combination of gender, race, birth date, geographic identifier, and other descriptors.) (M-03-22, "OMB Guidance for Implementing Privacy Provisions of the E-Government Act of 2002," Attachment A, Section II.)

   Note: The acronyms of IIF and personally identifiable information (PII) are often used interchangeably.

6. <u>Major Change:</u> any change that is made to the system environment or operation of the system. The following are examples of major changes as defined by M-03-22 ("OMB Guidance for Implementing Privacy Provisions of the E-Government Act of 2002," Attachment A, Section II.):

   o Conversions: When converting paper-based methods to electronic systems;

   o Anonymous to Non-Anonymous: When the system's function, as applied to an existing information collection, changes anonymous information into IIF;

   o Significant System Management Changes: When new uses of an existing information system, including application of new technologies, significantly change how IIF is managed in the system;

   o Significant Merging: When agencies adopt or alter business processes so that government databases holding IIF are merged, centralized, matched with other databases, or otherwise significantly manipulated;

   o New Public Access: When user-authenticating technology (e.g., password, digital certificate, biometric) is newly applied to an electronic information system that members of the public can access;

Commercial Sources: When agencies systematically incorporate into existing information systems, databases of IIF purchased or obtained from commercial or public sources;

- o New Interagency Uses: When agencies work together on shared functions involving significant new uses or exchanges of IIF;

- o Internal Flow or Collection: When alteration of a business process results in significant new uses or disclosures of information or incorporation into the system of additional IIF; and

   Alteration in Character of Data: When new IIF added to a collection raises the risk to personal privacy, such as the addition of health or privacy information.

7. OPDIV Senior Official for Privacy: A title extended by the Department to each OPDIV to effectively meet the reporting requirements outlined in OMB M-06-20, "Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management". (Defined in Secure One HHS Information Security Program: Privacy Impact Assessment (PIA) Guide).

8. Plan of Action and Milestones (POA&M): A tool that identifies tasks that need to be accomplished. POA&Ms identify resources required to accomplish the elements of the plan, any milestones in meeting the tasks, and scheduled completion dates for the milestones (Defined in OMB M-02-01, "Guidance for Preparing and Submitting Security Plans of Action and Milestones").

9. Personally Identifiable Information (PII): Any information about an individual maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and information which can be used to distinguish or trace an individual's identity, such as their name, social security number, date and place of birth, mother's maiden name, biometric records, etc., including any other personal information which is linked or linkable to an individual. (Defined in OMB M-06-19, "Reporting Incidents Involving Personally Identifiable Information & Incorporating Cost for Security in Agency Information Technology Investments.")

Note: The acronyms of PII and information in identifiable form (IIF) are often used interchangeably.

10. <u>Privacy Impact Assessment (PIA):</u> A methodology that provides information technology (IT) security professionals with a process for assessing whether appropriate privacy policies, procedures, and business practices—as well as applicable administrative, technical and physical security controls—have been implemented to ensure compliance with Federal privacy regulations. (Defined in Secure One HHS Information Security Program: Privacy Impact Assessment (PIA) Guide.)

11. <u>Risk:</u> The net mission impact considering (1) the probability that a particular threat-source will exercise (accidentally trigger or intentionally exploit) a particular information system vulnerability and (2) the resulting impact if this should occur. IT-related risks arise from legal liability or mission loss due to:

   o Unauthorized (malicious or accidental) disclosure, modification, or destruction of information;

   o Unintentional errors and omissions;

   o IT disruptions due to natural or man-made disasters; or

   o Failure to exercise due care and diligence in the implementation and operation of the information system.

   (Defined in NIST SP 800-30, "Risk Management Guide for Information Technology Systems," Appendix E).

12. <u>Risk Assessment:</u> The process of identifying risks to agency operations (including mission, functions, image, or reputation), agency assets, or individuals by determining the probability of occurrence, the resulting impact, and additional security controls that would mitigate this impact. Part of risk management, synonymous with risk analysis, and incorporates threat and vulnerability analyses. (Defined in NIST SP 800-53, Appendix B).

13. <u>Senior Agency Official for Privacy:</u> An individual selected by the Department (HHS) to

have agency-wide (HHS) oversight in implementing and ensuring compliance to privacy legislation. (Established in OMB M-05-08, "Designation of Senior Agency Officials for Privacy").)

14. <u>Sensitive Information:</u> Information is considered sensitive if the loss of confidentiality, integrity, or availability could be expected to have a serious, severe or catastrophic adverse effect on organizational operations, organizational assets, or individuals. Further, the loss of sensitive information confidentiality, integrity, or availability might: (i) cause a significant or severe degradation in mission capability to an extent and duration that the organization is unable to perform its primary functions; (ii) result in significant or major damage to organizational assets; (iii) result in significant or major financial loss; or (iv) result in significant, severe or catastrophic harm to individuals that may involve loss of life or serious life threatening injuries. (Defined in HHS Memorandum ISP-2007-005, "Departmental Standard for the Definition of Sensitive Information").

15. <u>System:</u> An organized assembly of IT resources and procedures integrated and regulated by interaction or interdependence to accomplish a set of specified functions. (Defined in Secure One HHS Information Security Program: Privacy Impact Assessment (PIA) Guide).

16. <u>Threat:</u> Any circumstance or event with the potential to adversely impact agency operations (including mission, functions, image, or reputation), agency assets, or individuals through an information system via unauthorized access, destruction, disclosure, modification of information, and/or denial of service. (Defined in NIST SP 800-53, Appendix B).

E. References:

1. Privacy Act of 1974 as amended, 5 U.S.C. 552a at: http://www.usdoj.gov/foia/privstat.htm
2. E-Government Act of 2002 at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ347.107.pdf
3. Computer Matching and Privacy Protection Act of 1988 (Public Law 100-53) at: http://www.whitehouse.gov/omb/inforeg/final_guidance_pl100-503.pdf

4. Computer Security Act of 1987 (Public Law 100-235) at:
   http://csrc.nist.gov/ispab/csa_87.txt

5. Children's Online Privacy Protection Act of 1998, (15 U.S.C. 6501 et seq.), an implementing regulations (16 CFR Part 312) at:
   http://www.ftc.gov/ogc/coppa1.shtm

6. OMB Circular A-130, "Management of Federal Information Resources," at:
   http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html

7. OMB Memorandum M-99-18, "Privacy Policies on Federal Web Sites," at:
   http://www.whitehouse.gov/omb/memoranda/m99-18.html

8. OMB Memorandum M-00-13, "Privacy Policies an Data Collection on Federal Web Sites," at: http://www.whitehouse.gov/omb/memorana/m00-13.html

9. OMB Memorandum M-02-01, "Guidance for Preparing and Submitting Security Plans of Action and Milestones," at:
   http://www.whitehouse.gov/omb/memoranda/m02-01.html

10. OMB Memorandum M-03-22, "OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002," at:
    http://www.whitehouse.gov/omb/memoranda/m03-22.html

11. OMB Memorandum M-05-08, "Designation of Senior Agency Official for Privacy," at: http://www.whitehouse.gov/omb/memoranda/fy2005/m05-08.pdf

12. OMB Memorandum M-06-16, "Protection of Sensitive Agency Information," at:
    http://www.whitehouse.gov/omb/memoranda/fy2006/m06-16.pdf

13. OMB Memorandum M-06-19, "Reporting Incidents Involving Personally Identifiable Information and Incorporating the Cost for Security in Agency Information Technology Investments," at:
    http://www.whitehouse.gov/omb/memoranda/fy2006/m06-19.pdf

14. OMB Memorandum M-06-20, "FY2006 Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management," at:
    http://www.whitehouse.gov/omb/memoranda/fy2006/m06-20.pdf

15. OMB Memorandum M-06-25, "FY 2006 E-Government Act Reporting Instructions," at: http://www.whitehouse.gov/omb/memoranda/fy2006/m06-25.pdf

16. OMB Circular A-11, Exhibit 300, "Planning, Budgeting, Acquisition, and

Management of Capital Assets," at:

http://www.whitehouse.gov/omb/circulars/a11/current_year/s300.pdf

17. OMB Circular A-11, Exhibit 53, "Information Technology and E-Government," at:

http://www.whitehouse.gov/omb/circulars/a11/current_year/s53.pdf

18. National Institute of Standards and Technology Special Publication 800-30, "Risk Management Guide for Information Technology Systems," at:

http://csrc.nist.gov/publications/nistpubs/800-30/sp800-30.pdf

19. National Institute of Standards and Technology Special Publication 800-37, "Guide for the Security Certification and Accreditation of Federal Information Systems," at: http://csrc.nist.gov/publications/nistpubs/800-37/SP800-37-final.pdf

20. National Institute of Standards and Technology Special Publication 800-53, "Recommended Security Controls for Federal Information Systems," at:

http://csrc.nist.gov/publications/nistpubs/800-53/SP800-53.pdf

21. Federal Enterprise Architecture Program Management Office, "The Federal Enterprise Architecture Security and Privacy Profile," at:

http://cio.gov/documents/Security_and_Privacy_Profile_v2.pdf

22. NIH Manual 1743, "Keeping and Destroying Records," at:

http://oma.od.nih.gov/manualchapters/management/1743/

23. NIH Manual 1745-1, "NIH Privacy Impact Assessments," at:

http://oma.od.nih.gov/manualchapters/management/1745-1/

24. NIH Manual 2805, "NIH Web Page Privacy Policy," at:

http://oma.od.nih.gov/manualchapters/management/2805/

25. NIH Information Technology General Rules of Behavior, at:

http://irm.cit.nih.gov/security/nihitrob.html

26. HHS Information Security Program Privacy Policy Memorandum, at:

http://intranet.hhs.gov/infosec/docs/policies_guides/ISPPM/Infosec_Program_Privacy_Policy_memo.doc

27. Secure One HHS: "Information Assurance and Privacy: Privacy Impact Assessment (PIA) Guide," at:

http://intranet.hhs.gov/infosec/docs/policies_guides/PIA/PIA_Guide.doc

28. Secure One HHS : "Information Security Program Policy," at:

29. HHS Memorandum ISP-2007-005, "Departmental Standard for the Definition of Sensitive Information," at: http://intranet.hhs.gov/infosec/policies_memos.html

F. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743 ,"Keeping and Destroying Records", Appendix 1, "NIH Records Control Schedule," Section 8000-F.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. The IC Records Officer should be contacted for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests.

Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

G. Management Controls:

The purpose of this manual issuance is to provide guidance to NIH employees in meeting requirements related to privacy legislation.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter:

   Overview of this policy will be carried out by the Office of Management Assessment (OMA) in coordination with, as it relates to IT Security, the Office of the Deputy Chief Information Officer (ODCIO).

2. Frequency of Review:

   Reviews will be ongoing. Appropriate management controls must be in place at all times for NIH. NIH system owners/managers and contractors managing NIH systems are also responsible for ensuring compliance with the privacy policy within the ICs.

3. Method of Review:

   Every three years, OMA will survey a sample of NIH ICs for compliance with these policies and prepare the necessary review reports. External reviews may be used as alternative reviews for this purpose.

4. Review Reports:

   Reports will be sent through the NIH CIO to the Deputy Director for Management (DDM), and circulated to NIH privacy stakeholders as deemed appropriate by the NIH SOP. Reports should indicate the effectiveness of the controls in place, and indicate any internal management control issues that should be brought to the attention of the report recipient(s).

NIH POLICY MANUAL

1745-1 - NIH Privacy Impact Assessments

Issuing Office: OD/OM/OMA (301) 496-2832 and OD/OCIO (301) 496-1168

Release Date: 12/20/11

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1. **Explanation of Material Transmitted:** This manual chapter outlines responsibilities for complying with the National Institutes of Health (NIH) policy on conducting privacy impact assessments (PIA) on all Information Technology (IT) Systems and Third-Party Websites and Applications (TPWAs) owned, operated or controlled by NIH, in addition to those set forth by the Department of Health & Human Services (HHS), Titles II and III of the Electronic Government (E-Gov) Act of 2002, and Office of Management and Budget (OMB) guidance. This policy also applies to NIH IT Systems and the use of TPWAs that are developed, operated and/or maintained on behalf of NIH by contract personnel.

2. **Filing Instructions:**

   Remove: NIH Manual 1745-1, dated 7/12/07.
   Insert: NIH Manual 1745-1, dated 12/20/11.

PLEASE NOTE: For information on:

- The Privacy Act of 1974 as amended, OMB and HHS guidance related to privacy, and the privacy mandates contained in the E-Gov Act and Federal Information Security Management Act (FISMA), contact the NIH Senior Official for Privacy (SOP), Division of Management Support (DMS), Office of Management Assessment (OMA) at (301) 496-2832.

- The content of this chapter and resources, publications, and privacy guidance provided

by the NIH Office of the Senior Official for Privacy (OSOP) are available online at http://oma.nih.gov/dms/programs/privacy/SitePages/Home.aspx.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-4606, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This manual chapter establishes policies and procedures based upon requirements and guidance set forth by the Federal Government, OMB, and HHS to conduct PIAs for all identified IT Systems, and for uses of TPWAs within NIH's Institutes and Centers (ICs).

B. Responsibilities:

PIAs provide a documented process to identify and protect employee and public citizens' personally identifiable information (PII). They ensure that the government has considered necessary safeguards for the PII passing through or being collected, maintained, or disseminated in its IT Systems and TPWAs. Personnel have been identified as leads responsible for assisting in the completion and/or review process of PIAs.

1. **HHS Senior Agency Official for Privacy (SAOP)**
   a. Ensure there is a framework to facilitate the development and maintenance of PIAs;
   b. Review and approve PIAs prior to posting them to HHS.gov for public review;
   c. Coordinate policy with Departmental Privacy Act points of contact as needed;
   d. Establish Departmental PIA policy and procedures; and
   e. Manage the development and submission of the FISMA privacy management report.
2. **NIH Senior Official for Privacy (SOP)**

a. Establish an NIH policy framework to facilitate the development and maintenance of PIAs;

b. Ensure that all NIH staff comply with this policy;

c. Ensure the oversight of this policy is carried out through a coordinated effort between OMA and the NIH Office of the Chief Information Officer (OCIO);

d. Coordinate training for IC Privacy Coordinators and other key stakeholders on the conduct and review of PIAs and their requirements, as needed;

e. Review completed PIAs and attest that they are completed accurately;

f. Promote PIAs to the Department and submit them to the SAOP once complete, or seek revisions from the NIH PIA Author if errors are found;

g. Track and maintain all PIA reporting activities in the Department's PIA online reporting tool;

h. Support the HHS SAOP in ad hoc privacy reporting activities as necessary, including the maintenance of the annual and quarterly FISMA and SAOP reporting activities; and,

i. Make recommendations to senior level officials with budgetary authority to allocate proper resources to mitigate privacy weaknesses found in IT and TPWA Systems as documented in their corresponding PIAs.

3. **NIH Chief Information Security Officer (CISO)**

a. Ensure that oversight of this policy is carried out through a coordinated effort between OMA and the OCIO;

b. Provide oversight for the security controls necessary to support NIH privacy requirements;

c. Ensure that all NIH Certification and Accreditation (C&A) packages include updated and completed PIAs;

d. Facilitate reporting of privacy and security requirements to the Department and HHS Office of the Inspector General (IG) auditors; and,

e. Collaborate with the NIH SOP to generate the annual and quarterly FISMA and Agency Privacy Management Report submissions for transmission to

the Department.

4. **NIH Privacy Act (PA) Officer**

   a. Serve as a point of contact (POC) at NIH for issues related to the Privacy Act;

   b. Maintain awareness of privacy laws, regulations, and issues within NIH; and,

   c. Collaborate with IC Privacy Coordinators to conduct information training sessions for IT Systems and TPWA Users regarding new legislation and procedures relating to the Privacy Act, E-GOV Act, and FISMA.

5. **NIH Web Master**

   a. Coordinate with the NIH SOP to determine uses of TPWAs that are subject to OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies*, and OMB Memorandum M-10-23, *Guidance for Agency Use of Third Party Websites and Applications*, HHS policy and implementing guidance, and any subsequent federal law or guidance that revises or updates OMB guidance; and,

   b. Work with the NIH SOP to develop and review PIAs for TPWAs in accordance with OMB guidance and HHS policy and implementing guidance.

6. **IC Privacy Coordinator**

   a. Coordinate completion, review, and approval of PIAs within each IC;

   b. Track and monitor the PIA requirements and reporting progress for the IC;

   c. Respond to IT System and TPWA System User inquiries regarding privacy related federal legislation and guidance, HHS and NIH policy and guidance; and,

   d. Complete the final review of a PIA before its promotion to the NIH SOP.

7. **IC Information Systems Security Officer (ISSO)**

   a. Assist the IC Privacy Coordinator, IT System and TPWA System User with the completion of PIAs by answering any questions pertaining to security; and,

   b. Provide guidance and support to ICs to implement IT security controls that

enhance privacy compliance.

8. **IC IT System and TPWA Owner/User**

   a. Serve as a PIA Author or identify the staff within the IC with sufficient knowledge of the characteristics of the IT Systems to complete the PIA;

   b. Maintain responsibility for ensuring compliance with the PIA policy for IT Systems and TPWAs under their responsibility within the IC;

   c. Serve as a POC for specific systems or TPWAs to whom PIA questions may be directed;

   d. Refer complex PIA questions and privacy issues to the IC Privacy Coordinator as appropriate;

   e. Respond to inquiries regarding the function, content and disclosure practices of IT Systems and TPWAs;

   f. Maintain responsibility for the accuracy of information contained in the PIAs in the current PIA online reporting tool;

   g. Coordinate with appropriate NIH privacy and security stakeholders to complete PIAs;

   h. Notify the IC Privacy Coordinator or ISSO of a new use of an IT System or TPWA, when a major change occurs to the IT System or TPWA that may potentially affect PII and how it is used;

   i. Identify any additional resources needed to complete PIAs;

   j. Update NIH management on the progress of PIA completion; and,

   k. Consult with IC ISSO on questions/concerns related to security controls.

C. Policy Requirements:

1. PIAs are required to be conducted on all IT Systems and each use of TPWA, whether already in existence, development, or undergoing modification, as defined by the E-Government Act of 2002, OMB guidance, HHS policy and supporting guidance.

2. NIH ICs must update any PIAs for any and all IT Systems and TPWAs that undergo a major change, as defined in Office of Management and Budget (OMB)

Memoranda M-03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.*

3. A PIA is a living document that must be updated in conjunction with a C&A package. All IT System PIAs must also be updated when a **major change** occurs within the IT System (see list of "Major Changes" under Section D. Definitions).

4. Reviews of IT System and TPWA PIAs must be completed periodically, as set forth by the Department, to ensure that changes in the management, operational, or technical controls affecting the PII within the IT System or use of TPWA, will be addressed as necessary.

5. All PII collected on an individual must be the minimum amount necessary and must be kept up to date. A privacy policy and notice regarding the usage of PII must be clearly displayed on all IT System or TPWA websites prior to the collection of PII.

6. Individuals must receive notification when a major change occurs to the IT System or to the use of a TPWA that may potentially affect their PII and how it is used.

7. All personnel using/operating IT Systems and TPWAs must be trained, educated, and made aware of their responsibilities for protecting any PII stored on those systems. All NIH staff (employees and contractors) must complete mandatory NIH Information Security and Privacy Awareness Training and annual refresher training available at http://irtsectraining.nih.gov.

8. All portions of the PIA must be populated in the PIA online reporting tool, as appropriate, and be 100% complete and accurate prior to promotion to the NIH SOP.

9. All IT System and TPWA PIAs must be submitted through appropriate IC channels, to the NIH SOP upon completion. The NIH SOP will submit them to the Department for quarterly and annual review. The PIA Summary will be made publicly available on the Department's PIA Internet site (http://www.hhs.gov/pia/nih/index.html).

10. All IT Systems subject to the Privacy Act must cite an appropriate Privacy Act Systems of Records Notice (SORN). The SORN informs the public what

information is collected, how it is used, how individuals may gain access to information about themselves, and other specific details.

11. All new and updated IT Systems and TPWAs collecting, maintaining, and/or disseminating PII must:

    a. Have policies in place with regard to the collection, retention and destruction of PII; and

    b. Include a complaint process for individuals who believe their PII has been used inappropriately or is inaccurate.

D. Definitions:

1. **Awareness, Training, and Education:** Includes (1) awareness programs that set the stage for training by changing organizational attitudes towards realization of the importance of security and the adverse consequences of its failure; (2) teaching people the skill that shall enable them to perform their jobs more effectively; and (3) education is more in-depth than training, and is targeted for security professionals and those whose jobs require expertise in IT security (defined in NIST SP 800-12, *An Introduction to Computer Security: The NIST Handbook*).

2. **E-Government Act of 2002:** Title II of the E-Government Act of 2002 requires federal agencies to conduct PIAs before developing or procuring IT Systems that collect, maintain, or disseminate PII. Once completed, the agency's Chief Information Officer (CIO), or an equivalent official, must review the Privacy Impact Assessments (PIAs). Additional requirements include making PIAs publicly accessible and posting a machine-readable privacy notice on publicly facing websites (defined in the HHS Cybersecurity Program's guidance entitled, *Standard Operating Procedures for Completing a Privacy Impact Assessment*, and in the *E-Government Act of 2002* (E-GOV) Section 208, (44 U.S.C. Chapter 36) (Public Law 107-347 Title II) (December 17, 2002)).

3. **Federal Information Security Management Act (FISMA) of 2002:** Title III of E-Government Act: Provides (1) a comprehensive framework for information

security standards and programs and (2) uniform safeguards to protect the confidentiality of information provided by the public for statistical purposes. This act defines terms such as information security and information technology and the responsibilities of federal agencies regarding information security. This act also outlines the requirements for annual independent evaluations, which evaluate the effectiveness of an agency's security program and practice (defined in HHS-OCIO's *Policy for Information Systems Security and Privacy* (IS2P) and *Federal Information Security Management Act (FISMA) of 2002*, (44 U.S.C. Chapter 35) (Public Law 107-347, Title III) (December 17, 2002)).

4. **Information Technology:** Any equipment or interconnected system or subsystem of equipment that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by an executive agency. Equipment is considered used by an executive agency if used directly or is used by a contractor under a contract with the executive agency, which: (i) requires the use of such equipment, or (ii) requires the use, to a significant extent, of such equipment in the performance of a service or the furnishing of a product. Information technology includes computers, ancillary equipment, software, firmware and similar procedures, services (including support services), and related resources (defined in 44 U.S.C., Section 3502), the *Clinger-Cohen Act of 1996*).

5. **IT System:** A discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (defined in NIST Special Publication 800-53, Revision 3, entitled *Recommended Security Controls for Federal Information Systems and Organizations*).

6. **Major Change:** Any change that is made to the IT system environment or operation of the system. PIAs should be conducted following any major changes, including, but not limited to:
   a. Conversions: A conversion from *paper-based methods to electronic Systems*;

b. Anonymous to Non-Anonymous: When the system's function, as applied to an existing information collection, changes anonymous information into PII;

c. Significant System Management Changes: In the case that new uses of an existing IT system, including application of new technologies, significantly change the process of managing PII in the system;

d. Significant Merging: When agencies adopt or alter business processes so that government databases holding PII are merged, centralized, matched with other databases, or otherwise significantly manipulated;

e. New Public Access: When user-authenticating technology (e.g., password, digital certificate, biometric) is newly applied to an electronic information system, which can be accessed by the public;

f. Commercial Sources: When PII is obtained from commercial or public sources and is systematically integrated into the existing information Systems databases;

g. New Interagency Uses: When agencies work together on shared functions involving significant new uses or exchanges of PII;

h. Internal Flow or Collection: When alteration of a business process results in significant new uses or disclosures of information or incorporation into the system of additional PII; and

i. Alteration in Character of Data: When new PII added to a collection raises the risk to personal privacy, such as the addition of health or privacy information.

(defined in OMB Memorandum M-03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*).

7. **Personally Identifiable Information (PII):** Information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as

date and place of birth, mother's maiden name, etc. (defined in OMB M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*).

8. **Privacy Act Record:** Any item, collection, or group of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph (defined in the Privacy Act of 1974).

9. **Privacy Act System of Records Notice (SORN):** All Systems with Privacy Act information contained within them are required to publish a "Records Notice" in the Federal Register that informs the public what information is contained in the system, how it is used, how individuals may gain access to information about themselves, and other specific aspects of the system (defined in the HHS Cybersecurity Program's guidance entitled *Standard Operating Procedures for Completing a Privacy Impact Assessment (PIA)*).

10. **Privacy Impact Assessment (PIA):** An analysis of how information is handled: (i) to ensure handling conforms to applicable legal, regulatory, and policy requirements regarding privacy, (ii) to determine the risks and effects of collecting, maintaining and disseminating information in identifiable form in an electronic information system, and (iii) to examine and evaluate protections and alternative processes for handling information to mitigate potential privacy risks (defined in OMB Memorandum M-03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*).

11. **Senior Agency Official for Privacy (SAOP):** An individual selected by the Department to have agency-wide oversight in implementing and ensuring compliance with privacy legislation (defined in OMB M-05-08, *Designation of Senior Agency Officials for Privacy*).

12. **System of Records:** A group of records under the control of any agency where information is retrieved by the name of the individual, by some identifying number or symbol, or by other identifiers assigned to the individual (defined in the HHS

Cybersecurity Program's document entitled *Standard Operating Procedures for Completing a Privacy Impact Assessment (PIA) Guide*).

13. **Third-Party Websites or Applications:** Web-based technologies that are not exclusively operated or controlled by a government entity, or web-based technologies that involve significant participation of a nongovernment entity. Often these technologies are located on a ".com" website or other location that is not part of an official government domain. However, TPWAs can also be embedded or incorporated on an agency's official website (defined in OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Websites and Applications*).

14. **Website:** A collection of interlinked web pages (on either Internet or intranet sites) with a related topic, usually under a single domain name, which includes an intended starting file called a "home page." From the home page, access is gained to all the other pages on the website (defined in the HHS Cybersecurity Program's document entitled *Standard Operating Procedures for Completing a Privacy Impact Assessment (PIA) Guide*).

E. References:

Laws:

1. Privacy Act of 1974, (5 U.S.C. 552a, as amended) (Public Law 93-579) (December 31, 1974):
   http://www.justice.gov/opcl/privstat.htm
2. Paperwork Reduction Act (PRA) of 1995, (44 U.S.C. 3501) (Public Law 104-13) (May 22, 1995):
   http://www.cio.gov/documents/paperwork_reduction_act_1995.html
3. Clinger-Cohen Act of 1996, (40 U.S.C. Section 1401) (Public Law 104-106) (February 10, 1996) (also known as the Information Technology Management Reform Act):
   http://www.cio.gov/Documents/it_management_reform_act_feb_1996.html
4. Computer Matching and Privacy Protection Act of 1988, (5 U.S.C. 552a(o))

(Public Law 100-53) (October 18, 1988):

http://www.whitehouse.gov/omb/inforeg/final_guidance_pl100-503.pdf

5. Computer Security Act of 1987, (15 U.S.C. Chapter 7, 40 U.S.C. Section 1441) (Public Law 100-235) (January 8, 1988):

http://www.cio.gov/documents/computer_security_act_jan_1998.html

6. E-Government Act of 2002 (E-GOV) Section 208, (44 U.S.C. Chapter 36) (Public Law 107-347 Title II) (December 17, 2002):

http://www.mda.mil/global/documents/pdf/egov_act2002.pdf

7. Federal Information Security Management Act (FISMA) of 2002, (44 U.S.C. Chapter 35) (Public Law 107-347, Title III) (December 17, 2002):

http://csrc.nist.gov/drivers/documents/FISMA-final.pdf

Federal Regulations:

1. 45 CFR, Part 5b, HHS Privacy Act Regulations:
   http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d8c05a9cf0b3dd219f61ecf068cb7260&rgn=div5&view=text&node=45:1.0.1.1.7&idno=45

National Institute of Standards and Technology (NIST) References:

1. Guide to NIST Information Security Documents:
   http://csrc.nist.gov/publications/CSD_DocsGuide.pdf

2. NIST Special Publications (SP), Complete list of NIST Publications:
   http://csrc.nist.gov/publications/PubsSPs.html

3. NIST SP 800-53 Rev 3, Recommended Security Controls for Federal Information Systems and Organizations (August 2009):
   http://csrc.nist.gov/publications/nistpubs/800-53-Rev3/sp800-53-rev3-final_updated-errata_05-01-2010.pdf

4. NIST SP 800-122, Guide to Protecting the Confidentiality of Personally Identifiable Information (PII) (April 2010):

http://csrc.nist.gov/publications/nistpubs/800-122/sp800-122.pdf

Office of Management and Budget Guidance:

OMB Circulars:

1. Office of Management and Budget Circular A-11, Section 53, Information Technology and E-Government:
   http://www.whitehouse.gov/omb/circulars/a11/current_year/s53.pdf
2. OMB Circular A-130, Management of Federal Information Resources (November 28, 2000):
   http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html

OMB Memoranda:

Calendar Year 2011

1. M-11-02, Sharing Data While Protecting Privacy (November 3, 2010):
   http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-02.pdf

Calendar Year 2010

2. M-10-23, Guidance for Agency Use of Third-Party Websites and Applications (June 25, 2010):
   http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-23.pdf
3. M-10-22, Guidance for Online Use of Web Measurement and Customization Technologies (June 25, 2010):
   http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-22.pdf
4. M-10-15, FY 2010 Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management (April 21, 2010):
   http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-

[15.pdf](15.pdf)

5. M-10-06, Open Government Directive (December 8, 2009): http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf

Calendar Year 2007

6. M-07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information (May 22, 2007): http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-16.pdf

Calendar Year 2006

7. M-06-19, Reporting Incidents Involving Personally Identifiable Information Incorporating the Cost for Security in Agency Information Technology Investments (July 12, 2006): http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2006/m06-19.pdf

8. M-06-16, Protection of Sensitive Agency Information (June 23, 2006): http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2006/m06-16.pdf

9. M-06-15, Safeguarding Personally Identifiable Information (May 22, 2006): http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2006/m-06-15.pdf

Calendar Year 2005

10. M-05-08, Designation of Senior Agency Officials for Privacy (February 11, 2005): http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-08.pdf

11. M-03-22, OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002 (September 30, 2003):
http://www.whitehouse.gov/omb/memoranda_m03-22/

HHS Privacy Policy and Guidance:

1. HHS General Administration Manual, Chapter 45-10, Privacy Act – Basic Requirements and Relationships:
http://www.hhs.gov/hhsmanuals/gam/chapters/45-10.pdf

2. HHS General Administration Manual, Chapter 45-13, Safeguarding Records Contained in Systems of Records:
http://www.hhs.gov/hhsmanuals/gam/chapters/45-13.pdf

3. HHS Privacy Impact Assessment (PIA) Standard Operating Procedures:
http://oma.od.nih.gov/ms/privacy/Privacy_Impact_Assessment_SOP_Final_02102009.doc

4. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P):
http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP/pol_for_info_sys_sec_and_priv_7-07-2011.pdf

5. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P) Handbook:
http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP/pol_for_info_sys_sec_and_priv_hndbk_20110707.pdf

6. HHS-OCIO Policy for Privacy Impact Assessment (PIA):
http://www.hhs.gov/ocio/policy/20090002.001.html

7. Privacy in the System Development Lifecycle (SDLC):
http://intranet.hhs.gov/it/docs/privacy/PSDLC/Privacy_in_SDLC.html

NIH Policy, Provisions and Guidelines:

1. NIH Manual Chapter 1743, Keeping and Destroying Records:

http://oma.od.nih.gov/manualchapters/management/1743/

2. NIH Manual Chapter 1745, NIH Information Technology (IT) Privacy Program:
   http://oma.od.nih.gov/manualchapters/management/1745/

3. NIH Manual Chapter 1825, Information Collection from the Public:
   http://oma.od.nih.gov/manualchapters/management/1825/

4. NIH Manual Chapter 2804, NIH Public-Facing Web Management Policy:
   (pending release)
   http://oma.od.nih.gov/manualchapters/management/2804/

5. NIH Manual Chapter 2805, NIH Web Privacy Policy:
   http://oma.od.nih.gov/manualchapters/management/2805/

6. NIH Manual Chapter 2809, NIH Social and New Media Policy:
   http://oma.od.nih.gov/manualchapters/management/2809/

F. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, Section 8000-F, in accordance with the specific schedule item as applied to the kind of records.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the

same information requests as original messages and documents.

G. Internal Controls:

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:**

   Oversight of this policy will be carried out through a coordinated effort between the Office of Management Assessment (OMA) and Office of the Chief Information Officer (OCIO).

2. **Frequency of Review:**

   Reviews will be ongoing. Appropriate internal controls must be in place at all times for NIH systems. NIH System Owners/Managers and contractors managing NIH Systems are responsible for ensuring compliance with the PIA policy within the ICs.

3. **Method of Review:**

   Annually, OMA and the OCIO prepare a report for signature by the NIH Director that provides information on the status of NIH PIAs for compliance with these policies. External reviews are also used for this purpose.

4. **Review Reports:**

   Annually and quarterly, FISMA reports are sent to the NIH Director for signature and submitted to the Department Senior Agency Official for Privacy (SAOP). Reports indicate that controls are in place and working well, and indicate any internal management control issues that require the attention of the report recipient.

NIH POLICY MANUAL

2800 – NIH Policy on Information Security Policy Development

Issuing Office: OD/OCIO – 301-496-1168; http://ocio.nih.gov

Release Date: 6/23/11

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1. **Explanation of Material Transmitted:** This chapter contains information that establishes standards of procedure, content, uniform format, and style for all NIH information security policies.

2. **Filing Instructions:**

   Remove: None.

   Insert: NIH Manual Chapter 2800, dated 6/23/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-4606, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

The purpose of this policy is to designate responsibility and ensure consistency in information security policy development, review, and approval. This policy establishes standards of procedure, content, uniform format, and style for all NIH information security policies that meet the criteria established under Section H. 1.

B. Background:

NIH is a very diverse agency with many internal organizations that make and implement information security policy. Establishing information security policy-level requirements in a uniform manner yields consistent practices. This policy is meant to establish a standard set of NIH information security policy development criteria by which compliance can be measured and reported.

A formal and structured development and review process ensures that all stakeholders are involved and that the result is a policy that has wide organizational buy-in and is consistent with other policies and the overall mission of the agency.

C. Scope:

This policy applies to all NIH Institutes and Centers (ICs) and to organizations who are involved with NIH information security policy on behalf of the NIH through contractual relationships. This policy does not supersede any other applicable law or higher level agency directive, or any existing labor management agreements in effect as of the effective date of this policy.

Agency officials shall apply this policy to employees, Fellows, volunteers, special volunteers, contractor personnel, interns, and other non-government employees/staff, who are involved in the development of NIH information security policy, by incorporating references in contracts or memorandums of agreement.

D. Policy:

1. All NIH information security policy:
    a. shall be issued under the purview of the NIH Chief Information Officer (CIO), who is the primary authority at NIH for approving and implementing NIH information security policies.
    b. shall be consistent with HHS and Office of Management and Budget (OMB) policies or have an approved waiver.
    c. shall be developed in a collaborative effort and use a wide distribution during the development and review periods to gather a broad perspective of input.
    d. shall include the parameters for compliance and reporting, if applicable.

e. shall be developed or modified to address Federal and HHS security mandates, policies and requirements, NIH security needs, and IC recommendations, as appropriate.

f. must be applied uniformly across NIH unless a waiver signed by the NIH CIO or NIH Chief Information Security Officer (CISO) (as appropriate) is in place.

g. implementations and waived exceptions are subject to oversight and monitoring by the NIH Office of the CIO (OCIO).

h. that conflicts with the provisions of other NIH information security policies must have any conflicting information clearly stated in the policy statement. This only applies to special circumstances or situations that are clearly spelled out and the reason(s) for the conflict is noted. The NIH CISO should be notified of this conflict and the reason(s) prior to issuing final policy.

i. shall be checked and verified as Section 508 compliant prior to posting on an NIH website, to a shared document directory or distributed in electronic form.

j. shall be accessible from the NIH CIO website, http://ocio.nih.gov

2. All information security policy approved and issued at the IC level:

a. must also be developed or revised in compliance with this and any other relevant NIH policies and be in writing.

b. must be implemented in a manner where compliance can be reported in the designated format described in the compliance section (Section I) of this policy, e.g., where implementation is not centrally controlled. Where local control is acceptable and approved, the OCIO must have access to information on the oversight and monitoring of the implementation of the policy within the IC.

c. that is based on an existing NIH security policy(s), shall reference the NIH policy(s) that it is augmenting.

d. cannot supersede or be less restrictive than NIH policy without a waiver from the NIH CIO or CISO that includes approved compensating controls.

e. shall be developed and modified in accordance with the guidelines provided in Appendix A.

E. References:

1. Computer Security Act of 1987, P.L. 100-235, 101 Stat. 1724,

http://www.nist.gov/cfo/legislation/Public Law 100-235.pdf

2. Federal Information Security Management Act of 2002 (FISMA),
   http://csrc.nist.gov/drivers/documents/FISMA-final.pdf

3. HHS-OCIO Policy for Information Systems Security and Privacy,
   http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP/pol_for_info_sys_sec_and_priv_9-22-2010.pdf

4. HHS Security of Information Technologies Memorandum, dated November 10, 2009, Delegation of Authority

5. HHS-OCIO Policy for IT Policy Development
   http://www.hhs.gov/ocio/policy/#OCIOpolicy

6. OMB Circular A-130, Management of Federal Information Resources,
   http://www.whitehouse.gov/sites/default/files/omb/circulars/a130/appendix_iii.pdf

7. Section 508 of the Rehabilitation Act of 1973, as amended in 1998 (29 U.S.C. 794d),
   http://www.access-board.gov/sec508/guide/act.htm

8. NIH Enterprise Information Security Plan,
   https://ocio.nih.gov/InfoSecurity/Policy/Documents/EISP_FINAL.doc

9. NIH IT Security Policy template,
   https://ocio.nih.gov/InfoSecurity/Policy/Documents/FIPS-200-SSP-Extended-Outline.doc

10. NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, http://oma.od.nih.gov/manualchapters/management/1743/

11. NIH Office of the Chief Information Officer website, http://ocio.nih.gov/

12. NIH Delegations of Authority, Program: General; No 42 "National Institutes of Health Information Technology Security Program,"
    http://www.delegations.nih.gov/DOADetails.aspx?id=3304

F. Definitions:

The NIH Master Glossary of Information Security Terms which contains definitions of all information security terms is located at http://ocio.nih.gov/security/ISSO Glossary.doc.

G. Responsibilities:

1. **NIH Chief CIO or their designee(s) are responsible for:**
   a. Acting as the primary authority at NIH for developing, approving, and implementing NIH information security policies;
   b. Ensuring NIH information security is in compliance and conformance with Public Laws, regulations, Office of Management and Budget (OMB) and Government Accountability Office (GAO) regulations, policies, standards, procedures, and instructions concerning agency operations and reviews;
   c. Ensuring that NIH information security policy drafts are disseminated for IC review and comment;
   d. Ensuring that final approved NIH information security policy is disseminated to the appropriate IC communities.

2. **NIH CISO or their designee(s) are responsible for:**
   a. Monitoring enforcement of this policy and approving exceptions to this policy via the formal waiver process. Facilitating and coordinating all NIH information security policies developed by NIH or on behalf of NIH;
   b. Creating and distributing draft and final NIH information security policies;
   c. Coordinating with the NIH Information Technology Management Committee (ITMC) and other security groups during the development and review of NIH information security policies;
   d. Determining, in collaboration with the NIH Deputy CIO, which NIH security policies should be developed or revised as NIH Manual Chapters.

3. **IC Chief Information Officers (IC CIOs) or their designee(s) are responsible for:**
   a. Selecting employees to participate in groups to help develop or revise NIH information security policies and to review IT policies and provide timely comments;
   b. Providing resources for developing and implementing IC policies (when warranted).

4. **IC Information System Security Officers (IC ISSOs) or their designee(s) are responsible for:**
   a. Reviewing information security policy developed (or revised) at the NIH level to determine impact on IC and advising IC CIO if IC level policy is needed.
   b. Assisting the IC CIO in developing IC security policy that augments NIH policy

or where there is no existing NIH policy, as needed.

H. Procedures:

NIH level information security policies will follow the process outlined below:

1. Determine which process should be used to develop or revise the NIH level information security policy. The following criteria should be considered in making this determination:

    a. The policy will be developed (or revised) as an official Manual Chapter format and processed through the NIH OD Office of Management Assessment (OMA) for publication in the [NIH Manual System](#) if it meets all of the following criteria:

        i.   The policy is not targeted solely toward ISSOs, system administrators, or otherwise restricted audiences;

        ii. The policy does not contain sensitive information that should not be publicly accessible;

        iii. The policy is not overly technical and would therefore be understandable by a majority of the general NIH population.

        NOTE: The NIH CISO, in consultation with the NIH Deputy CIO, will make the final decision on whether or not a policy meets these criteria.

    b. The policy will be developed (or revised) as an official OCIO information security policy for publication on an internal NIH information security policy website if the proposed policy does not meet the criteria above to be issued as an NIH Manual Chapter policy.

2. Assign a Point of Contact (POC)/lead for each policy and associated document(s) (such as standards or guidance) being developed or reviewed.

3. Identify the Subject Matter Expert(s) (SME) that need to be contacted during the review process and have the document lead send the first internal draft to them for their input. Keep SMEs in the loop as comments come in.

4. Review applicable OMB, HHS, National Institutes of Standards and Technology (NIST) and other Federal laws and regulations to determine if the NIH information security policy under development will be in compliance with those mandates. If there is a

deviation from HHS policy, such that the NIH policy is less restrictive than the HHS policy, a waiver must be submitted to HHS by the NIH CISO. A more restrictive policy does not require a waiver.

5. Consult with the Office of General Counsel, the NIH Senior Official for Privacy, or the Office of Human Resources (HR), when appropriate, to address legal, privacy, or HR implications contained in the policy.

6. Prepare a Request for Comment (RFC) to distribute or post the new or revised draft policy for review.

   At a minimum, the following process shall be followed:

   a. The NIH CISO shall review all final drafts before they are sent out to the NIH security community (ITMC and ISSO groups) for comments.
   b. The drafts shall be posted so that all applicable NIH users have access to the document.
   c. The "first draft" notification is distributed to the NIH security community (ITMC and ISSO email groups) and others, as applicable. Use the standard email template for notification.
      i. The normal review time for a "first draft" is two weeks from day of issue.
      ii. All comments submitted via the policy comment matrix (Appendix B) are sent to the NIH Information Security and Awareness Office (ISAO) Policy mailbox (nihisaopolicy@nih.gov).
   d. All comments are consolidated in the NIH-combined policy comment matrix.
   e. The comments are reviewed for content and a determination is made on whether or not they should be included in the policy.
   f. A "second draft" is developed based on comments (and reviewed by the NIH CISO) and sent back out to the NIH security community within two weeks, along with the NIH-combined policy comment matrix, using the "second draft" email template.
      i. The normal review time for a "second draft" is two weeks from day of issue.
      ii. All IC comments submitted via the policy comment matrix are sent to the

NIH ISAO Policy mailbox.

g. All comments are consolidated in the NIH-combined policy comment matrix.

h. The comments are reviewed for content and a determination is made on whether or not they should be included. Disposition of comments submitted for the second and any subsequent drafts will be documented and will be published on the security policy website.

i. If no major changes are required, a notification email (last call) is sent stating that the policy is going to the NIH CIO/CISO for signature and that a notification will be sent out when it has been signed. If this is to be a Manual Chapter policy, the OCIO Manual Chapter Liaison shall be provided a copy of the final draft of the policy for review and to submit to OMA for their review. Changes resulting from those reviews are incorporated into the draft policy.

j. The NIH Enterprise Information Security Policy (EISP) is updated to reflect applicable changes.

k. If major changes are still required, a "third draft" is sent out for comment. (This should be the exception rather than the rule.) The formal review process in steps f, g, and h are then followed. If major changes are required, or there is significant disagreement with the policy, the NIH CIO and CISO will decide how to proceed, usually in consultation with relevant constituents.

7. When the document has been approved for final, it is given to the NIH CIO/CISO, through the NIH Deputy CIO, for signature. If the policy is to be issued as an NIH Manual Chapter, the policy will be submitted to the NIH OD Office of Management Assessment (OMA) by the OCIO Manual Chapter Liaison for publication in the NIH Manual System.

8. If the policy has been published in the NIH Manual System, all links on the OCIO security web pages will point to that version. If the policy is published by OCIO, a copy of the signed policy is posted to the OCIO information security policy website.

9. A notification email, which includes a link to the document, is sent to the NIH security community (ITMC and ISSO email groups) and others in the NIH community, as applicable.

NOTE: The above process will also be used for information security standards and guidance,

as applicable.

I. Compliance and Oversight:

As stated in Section D of this policy, the NIH CIO is the primary authority at NIH for approving and implementing NIH information security policies and has the responsibility and authority for management of the NIH IT security program as delegated by the HHS Secretary, HHS CIO and the NIH Director.

All NIH approved information security policies shall be consistent with HHS and OMB policies, in order of precedence, or have an approved waiver. The NIH Enterprise Information Security Plan (EISP) shall be updated to reflect new NIH information security policies.

IC-level policies:

IC-level policies that are written to supplement an NIH-level policy will detail in the Compliance Section how the IC will ensure and report compliance to the OCIO, if applicable. These details should include the method of implementation, ensuring and reporting compliance, the format of the compliance report, and what alternative methods of reporting will be acceptable, if applicable. Language must be included that requires approval of the alternative method by the NIH CIO or NIH CISO and allows for subsequent monitoring and oversight by the NIH CIO. The cost and burden of compliance with an IC-specific policy that relates to an NIH policy, lies with the IC.

If an IC-specific policy does not relate to an NIH Policy, then it will include a Compliance Section containing details of the requirements for IC compliance.

In cases where an IC-specific policy existed before the development of an NIH policy, the IC-specific policy shall be made compliant with the NIH policy as soon as possible but not later than within six (6) months.

The parameters and suggested wording for the compliance requirements in a policy are included in the NIH Information Security Policy Template which can be found at http://sps.nihcio.nih.gov/InfoSec/SPS/Security_Policies_Under_Review/Policy%20Template_v8.docx.

J. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the [NIH Manual Chapter 1743](#), "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section 1100 – "General Administration," Item 1100-B-1, "Policy Files," Section 2300 – "Personnel," Item 2300-410-2-b, "Employee Training," and General Records Schedule 24, "Information Technology and Management Records," all items that apply.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management Manual Chapter. Contact your IC Records Liaison for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

K. Internal Controls:

The purpose of this manual issuance is to establish standards of procedure, content, uniform format, and style for all NIH Information Security Policies.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** NIH OCIO/ Information Technology and Security Awareness Office.
2. **Frequency of Review (in years):** Ongoing review occurring at least annually. Review will include a periodic assessment of IT security policies to determine if changes are required.
3. **Method of Review:** This review will be part of the periodic review and annual

assessment of the IT Management Process of the ICs.

Type of Review: Review of the controls associated with this chapter shall be part of IT security certification and accreditation process.

4. **Review Reports are sent to:** NIH CIO.

Appendix A – Guidelines for NIH Information Security Policy Development and Revision:

The following guidelines shall be followed during policy development, revision, and review to ensure the use of standard language, content, and format:

a. Ensure that the policy is in writing and appropriately defines the organizational and staff responsibilities and accurately reflects who shall perform the functions described.

b. Evaluate the policy prior to development (or revision) to determine whether or it meets the criteria for inclusion in the NIH Manual System. (See section H. Procedures)

c. Ensure that the policy contains only the most necessary policy information. Associated details should be written as a Standard, Procedure or Guidance document, or as an appendix to the policy, as applicable.

d. Use plain language when possible and/or suggested language from the governing policy or template, when applicable.

e. Where possible, language with legal, privacy, or HR implications that has already been approved by the Office of General Counsel, Privacy, and HR departments will be used. If that language needs to be updated or changed, or if there is not applicable language for this policy, then those departments will be consulted to approve the new policy language.

f. Update policies when there are significant changes, e.g., reviews should be done if HHS or federal directives require a change in policy. [If the policy was issued as an NIH Manual Chapter, revision and re-approval procedures must follow the NIH Manual Chapter process.]

g. Review all policies at least annually to determine if any other changes are needed, e.g., organization titles, contact information, etc.

h. Policy reviews that are done should be documented on the Record of Changes page

and have the CIO or CISO sign an updated approval sheet.

i. Develop and revise all policies using the appropriate official NIH information security policy template depending as follows:

1. OCIO-issued information security policies are to be prepared in accordance with http://sps.nihcio.nih.gov/InfoSec/SPS/Security_Policies_Under_Review/Policy%20Template_v8.docx. (This template is based on the HHS Policy template) or ,

2. NIH Manual Chapter-issued information security policies are to be prepared in accordance with

   http://oma.od.nih.gov/manualchapters/mc/examples/manualchapters/

j. Policies that were developed in advance of this policy shall be re-written and reformatted in the appropriate format (OCIO or NIH Manual Chapter) when they are revised for reissuance.

k. Use the "Comment Matrix" to collect and document reviewer comments during the development and revision processes. The Comment Matrix template is located at http://sps.nihcio.nih.gov/InfoSec/SPS/Security_Policies_Under_Review/Comment%20matrix%20for%20security%20policies.doc or at Appendix B of this policy.

l. Maintain a record of changes page in the document with enough detail to show what substantive information has been changed, unless it is a full rewrite. If it is a full rewrite, keep a copy of the old document for audit purposes.

m. Have all documents reviewed and remediated as necessary for Section 508 compliance.

n. Post all approved policies on an internal or external web site, as appropriate. The "signed" approval sheet should not be posted with the document, but filed appropriately.

Appendix B – Information Security Comments Matrix :

REVIEWER COMMENTS ON

[**Policy Name**]

This document provides comments on the [policy name] dated [policy date].

The following categories have been established for the comments in Table 1:

1. **Administrative** comments correct what appear to be inconsistencies between sections, typographical errors, or grammatical errors.
2. **Substantive** comments are provided because sections in the publication appear to be or are potentially incorrect, incomplete, misleading, or confusing.
3. **Major** comments are significant concerns that may result in a non-concurrence of the entire document if not satisfactorily resolved. This category may be used with a general statement of concern with a subject area, thrust of the document, etc., followed by detailed comments on specific entries in the publication which, taken together, constitute the concern.
4. **Critical** comments *will* cause non-concurrence with the publication if concerns are not satisfactorily resolved.

Table 1: Specific Observations and Comments

Pg. #	Ref. #/ Section	Specific Comment	Submitted By	Category	Response

General Comments:

Contacts, if applicable:

NIH POLICY MANUAL

2803 – NIH Staff E-Mail List Policy

Issuing Office: CIT 301 402-4452

Release Date: 11/13/01

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1. **Explanation of Material Transmitted:** The NIH Staff E-Mail List Policy has been updated to clarify requirements and to ensure consistency with the HHS IRM Policy for Use of Broadcast Messages, Spamming, and Targeted Audiences (dated 1/8/01).

2. **Filing Instructions:**

   Remove: NIH Manual Chapter 2803 dated 12/07/99.
   Insert: NIH Manual Chapter 2803 dated 11/13/01.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OA, at 301 496-2832.

- On-line information, enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

The purpose of the NIH Staff E-Mail List is to facilitate the communication of important mission-related information of interest to the broad NIH community.

B. Scope:

The NIH-STAFF E-Mail List encompasses the entire NIH community of approximately 32,000 people. The creation of such a large volume of unsolicited e-mail involves significant transmission and usage costs, as well as a significant labor cost to read and process these messages. Further, it is recognized that an excessive use of this list could diminish its value as an effective channel of communication to convey critical information. For these reasons, screening of messages is required to assure that this resource is used prudently.

This policy applies to NIH-generated e-mail. It does not apply to HHS or other agency e-mail broadcasts approved by the Assistant Secretary for Budget, Technology, and Finance (ASBTF), which NIH is required to send to the NIH community. On occasion, NIH may be asked to distribute messages to NIH employees from other HHS Operating Divisions (OPDIVs). In accordance with the [HHS IRM Policy for Use of Broadcast Messages, Spamming, and Targeted Audiences](#) (dated January 8, 2001), the requesting OPDIV's Chief Information Officer (CIO) or designated approving official will present the request to the NIH CIO or designated approving officials (NIH-STAFF List Moderators) who will determine if the subject is of sufficiently broad interest to the NIH community and meets the criteria set forth in the NIH policy. The NIH-STAFF List Policy is consistent with the HHS IRM Policy as far as what type of message is appropriate and what is not.

In times of local or national emergency, the NIH-STAFF List Moderators may choose to restrict usage of the NIH-Staff E-mail List to messages related to the emergency operations of NIH and the safety of NIH employees.

C. Who May Submit Messages:

- NIH employees in fulfillment of their official duties if the message is of broad interest to the NIH community.

- Official representatives of NIH Chartered or Sponsored Organizations in

support of goals related to the NIH mission.

- Employees from other HHS OPDIVs if the message has approval from their CIO or designated approving official and is of sufficiently broad interest to the NIH community.

D. Responsibility for Clearance - A Two Part Process :

1. **IC Review or Other HHS OPDIV Review**

   NIH Executive Officers shall designate two [Reviewing Officials](#) to review and approve all messages generated from within their respective areas, including messages by any NIH chartered, sanctioned, or sponsored groups. Each submission to the NIH-STAFF E-Mail List must first be reviewed and approved by one of the designated IC Reviewing Officials in accordance with the criteria set forth below to determine whether the message warrants being distributed outside of the IC. The Reviewing Official is responsible for ensuring that IC records are maintained to document review and clearance of messages, including both review by internal officials and officials in appropriate subject matter offices to which the message relates (e.g., Equal Employment Opportunity, Human Resources, Office of Research Services, etc.).

   Messages from other HHS OPDIVs must have the approval of their CIO or designated approving official and meet the criteria set forth in NIH-STAFF List Policy.

2. **NIH Review**

   After review and approval by one of the IC Reviewing Officials or HHS OPDIV designee, the message is reviewed by the NIH-STAFF List Moderators to determine appropriateness for distribution NIH-wide in accordance with the criteria set forth below. Even though the NIH-STAFF Moderators retain final authority to determine the appropriateness of any

NIH-STAFF List message, they will work with the ICs in a collegial manner to help them reach their goals.For example, the Moderators may suggest alternative methods for advertising events at NIH.

E. Criteria to be Used for Screening Messages:

1. **The following criteria will be used in determining the appropriateness of a message:**
   - Is the message of sufficiently broad interest or importance to the NIH community to justify posting it to all employees?
   - Are other mailing lists, or other vehicles for disseminating information, such as print media, more appropriate because of the limited focus of the message's interest or target audience? (See Section J., "Alternatives for Disseminating Information.")
   - Does the message involve security, public affairs, legal, or other issues that require handling in a different context?
   - Are the contents of the message accurate, timely, and complete so that additional correction or clarification messages are not needed?

2. **Elements of a Good Message:**
   - Contains a descriptive title in the subject line.
   - Is short and concise.
   - References a website, if available, for detailed information, and includes the full web address. (Attachments are not allowed.) Includes point of contact information, i.e., name, telephone number, and e-mail address.
   - Includes language on the provision of reasonable accommodations for individuals with disabilities.

3. **Reasonable Accommodation Language:**

   Providing reasonable accommodations for individuals with disabilities is a requirement for the NIH office that is sponsoring a lecture, conference

or event. *

Any announcement advertising a lecture, conference, or event that is open to all employees or members of the public and does not require prior registration, must have the following statement:

"Sign language interpreters will be provided. Individuals with disabilities who need reasonable accommodation to participate in this (event/training/conference/program) should contact (name and office, telephone number, TTY number and/or the Federal TTY Relay number (1-800-877-8339), and e-mail address)."

For events where registration is required in advance, the following language should be used:

"Individuals with disabilities who need sign language interpreters and/or reasonable accommodation to participate in this (event/training/conference/program) should contact (name and office, telephone number, TTY number and/or the Federal TTY Relay number (1-800-877-8339), and e-mail address). Requests should be made at least 5 days in advance of the event."

For information on how to provide reasonable accommodations for your event, please contact your IC EEO Officer or the NIH Office of Equal Opportunity and Diversity Management.

* For further information on providing reasonable accommodations, see the HHS and/or NIH versions of "Accessing Opportunity: The Plan for the Employment of People With Disabilities in the Federal Government." Also see NIH Manual 2204, "Reasonable Accommodations," which can be found at http://oma.od.nih.gov/manualchapters/management/2204/

4. **Categories Of Appropriate Messages:**
    - One-time lectures related to the mission of NIH, e.g., a lecture by

a visiting scientist or dignitary as part of the NIH Director's Wednesday Afternoon Lectures.

- Official security warnings, instructions, or information, e.g., an announcement concerning heightened security related to a demonstration on the NIH campus.

- Notice of public events of special interest to the broad NIH community, e.g., public television programs about NIH, or that NIH was involved in producing; Research Day; or NIH Library Open House.

- Requests for assistance where the relevant audience is the broad NIH community, e.g., requests for blood donations of a particular type when the Blood Bank is running low, official Federal CFC announcements. CFC is the only authorized solicitation of federal employees for money.

- Information about general employee benefit programs, e.g., information about the Health Fair, or Open Season announcements.

- Information about administrative matters affecting the broad NIH community, e.g., how to communicate with NIH's contract travel agency by e-mail, information about major scheduled NIHnet outages for upgrades, or significant construction disruptions to NIH campus traffic.

- NIH Chartered Organization announcements or activities of interest to the broad NIH community, e.g., information or events for the education or participation of the broad NIH community.

5. **Categories Of Inappropriate Messages:**
    - Notices of routine and recurring events, meetings, lectures, or organizational activities that focus on specific target audiences or that can be delivered through the NIH Calendar of Events, World Wide Web pages, the CALENDAR mailing list on LISTSERV, or some other more limited mailing list.

- Routine notices about ongoing NIH operational activities and announcements of new websites.
- Commercial announcements or solicitations of any kind.
- Requests for assistance that focus on a specific/specialized audience, e.g., a researcher's request for a certain compound or equipment.
- Personal matters such as leave donation requests, retirement announcements, birth or death announcements, and job location changes.
- The solicitation of funds, or publicizing of fundraising events, for private charities.
- Announcements of a political (e.g., lobbying Congress on behalf of causes, individuals, or organizations; promoting or conducting political activities), religious, or other similarly sensitive nature.
- Non-government matters, e.g., selling a used car, or non-government survey or seminar.
- Repeated announcements about a specific event, e.g., reminders for upcoming events and incremental announcements of a major relocation of personnel.
- Security warnings, instructions, or information by a person other than the responsible security officials.

F. The Process of Message Review and Posting:

To accommodate the review and approval process, submissions to the list are held by the NIH-STAFF E-Mail List for review before they are posted. The review process can last from several hours to two business days. When submitting a message, allow for review time. When the message is submitted to the NIH-STAFF E-Mail List via the online form on the NIH-STAFF website, a copy is automatically sent to an IC Reviewing Official for internal clearance. No message will be posted until the NIH-STAFF list moderators receive this clearance. However, internal clearance does not guarantee that the message

will be distributed. The NIH-STAFF list moderators retain final authority to determine the appropriateness of any NIH-STAFF message.

Only one message per event or subject is usually permitted. Unless the message is of unusual importance, broadcast messages will be sent after normal business hours, when e-mail traffic is lower. Generally, notices will be distributed the evening after the moderators have approved the message, and will be seen by most NIH employees the next business day. In some cases, the message may be disapproved and not posted at all. If your message is not approved for distribution, you will receive an explanation from the Moderators.

G. Instructions for Submitting an NIH-STAFF E-Mail Message:

1. Point your web browser at the [NIH-STAFF online submission form](#).
2. Fill out the online form completely. Cutting and pasting of text from other applications is allowed. However, special formatting (bold text, fancy fonts, columns, etc.) will not be preserved. Attachments are NOT permitted.
3. Include a descriptive subject on the Subject: line. ("Seminar" or "Message to NIH Staff" is not sufficient.)
4. In the body of the message, include an e-mail address and telephone number that can be used to request additional information. When the message includes a World Wide Web address (URL), include the entire address so that recipients will see the address as a clickable hyperlink.
5. If you cut and paste text into the message field, avoid using embedded tabs in your text. Tabs tend to change size when pasted into the web page, and may alter the appearance of your text.
6. Indicate whether your message should be sent to DC-area employees only by checking the appropriate button at the bottom of the form.
7. Prior to submitting your message, please ensure that all appropriate IC officials or sponsoring NIH organization(s) reviews the message for appropriateness, accuracy and completeness. This will often expedite

review by the NIH-STAFF E-Mail List Moderators.

8. When you have completed filling out the online form, click the submit button to submit your message. The message text will be automatically formatted for you, and a copy will be submitted to the appropriate Reviewing Official. You will receive email notification that your message has been submitted.

9. Submit the message at least 2 business days before you want it to be distributed. Generally, messages will be posted one day after approval by the moderators. However, there is no guarantee that moderators will be able to review and approve a message on a specific date. The moderators cannot "hold" a message for later posting.

10. If you wish to send additional rationale for why the message should be posted, type it in the "Comments" field.

11. The person sending the message can expect to receive numerous "out of office" replies in his or her mailbox.These can be ignored or deleted. The sender may wish to create a rule in his/her email client that will divert all replies to the message to a special folder, or automatically delete them. Note that some people may reply to the sender of the message, even if the e-mail address in the message is different.

H. Time-Critical Messages:

E-mail broadcasts, while faster than desk-to-desk paper distribution, are not instantaneous. Further, there is no guarantee about when someone will read his or her e-mail.

NOTE: E-mail broadcasts should not be relied upon as the sole mechanism for emergency announcements. Notices of fire alarms, bomb threats, and other such events will also be handled through more immediate mechanisms as appropriate.

If your posting is time-critical (i.e., it must go out immediately rather than after business hours), you can request urgent handling of your message. Check

"YES" at the bottom of the form in response to the question, "Is this an urgent message that cannot wait for overnight distribution?" You will be prompted to justify in writing why your message requires urgent handling. Urgent messages still require internal clearance; it may be helpful to call your IC Reviewing Official (or the OEO Reviewing Official, if you selected OEO in the "IC" field) to expedite clearance of your request.

Once approved, messages may take an hour or longer to be distributed. If you do not see your urgent announcement in your mailbox within an hour and a half after submitting it, please contact the NIH IT Service Desk to request assistance through one of the following methods:

NIH IT SERVICE DESK

[Submit a request online](#) (click link)

Phone:
301-496-4357 (local)
866-319-4357 (toll-free)
301-496-8294 (TTY)

Web:
[ITServiceDesk.nih.gov](#)

I. Rules for Corrections, Updates or Changes:

Normally, only one message will be allowed per subject. Therefore, messages should be carefully reviewed for accuracy prior to sending. To avoid burdening the NIH community with unnecessary e-mail due to corrections and updates, it is important that the sender of the message ensure the accuracy and completeness of the message with all appropriate parties prior to original dissemination.

J. Alternatives for Disseminating Information:

While the NIH-STAFF E-mail List is a useful tool for disseminating information to the NIH community, other options exist and in many cases may be more appropriate at targeting the desired audience. Some examples include: The NIH Record; the NIH Calendar of Events (Yellow Sheet); the NIH Recreation and Welfare Newsletter; the NIH Home Page; the NIH Calendar of Biomedical Meetings and Events; the NIH Catalyst; the Deputy Director for Intramural Research's (DDIR) Bulletin Board; web-based special interest groups; and e-mail lists targeted to specific groups.

Information on how to promote an event at NIH–e.g., newsletters, bulletin boards, posters, calendars: http://www.nih.gov/employee/advert.htm

Information on the criteria used to determine if a special promotion for an event can be run on the NIH home page: http://www.nih.gov:/news/postevnt.htm

K. For Further Information:

For further information, please call the NIH IT Service Desk (See Section H above) or send e-mail to NIH-STAFF-MODERATORS@LIST.NIH.GOV.

L. Records Retention and Disposal:

All records (**e-mail** and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, *NIH Records Control Schedule.*" Official records should be maintained in accordance with the retention schedule applicable to the given subject matter of the message. Note: All e-mail suitable for NIH-wide dissemination are considered official records. The originator of the message is responsible for maintaining the official record.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. **These records must be**

maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significant periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

M. Internal Controls:

Adequate and reasonable internal controls have been included in the approval process required of both IC approving officials and NIH staff moderators. If CIT determines that ICs are not following this policy, they will ensure that the appropriate IC officials are notified and the issue is resolved.

NIH POLICY MANUAL

2804 – Public-facing Web Management Policy

Issuing Offices: OCPL (301-496-5787), OMA (301-496-2832), and OCIO (301-496-1168)

Release Date: 04/09/12 – Partial Revision: 02/06/13*

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1. **Explanation of Material Transmitted:** This chapter provides policy on the creation and management of Public-facing Web sites and new media properties, which includes NIH hosted social media sites, Web applications and mobile Web sites.

   *Partial revision on 02/06/13: This Chapter has been updated to remove IC responsibilities concerning E-Government Act and NOFEAR Act requirements related to Public-facing Web sites previously in Section D.4 and D.13. Although the NIH and its ICs support these activities for the Department of Health and Human Services (HHS), the requirements of these Acts are for "executive agencies" (i.e., HHS).

2. **Filing Instructions:**

   Insert: Manual Issuance 2804, dated 04/09/12 – updated 02/06/13.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing offices listed above.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-2832, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This chapter provides policy on the creation and management of Public-facing Web sites and new media properties, which includes NIH hosted social media sites, Web applications and mobile Web sites.

B. Scope:

This policy applies to all Public-facing Web sites and new media properties that are funded by the National Institutes of Health (NIH), its Institutes and Centers (ICs) and Offices of the Director (OD), whether they are created and hosted by NIH staff or by contract personnel, within the NIH domain or externally. Existing Public-facing Web sites and new media properties funded by NIH should be brought into compliance within 30 days of this chapter publication.

C. Background:

The advent of the Internet has fundamentally changed the ways in which NIH communicates and operates with the public. It is critical for NIH to meet expectations for online interactions while maintaining public trust and protecting the reputation and the information resources of the ICs, NIH, HHS and the Federal Government.

D. Policy:

NIH recognizes the Web as a transformative tool for communications and operations and, therefore, encourages ICs and OD offices to use the Web to further the NIH mission. To support these efforts and ensure a consistent level of quality across all NIH Web and new media properties, the ICs and OD offices shall comply with the following policies and

guidelines for Web development and management:

1. **Branding:**

    a. **Domain Names:** NIH ICs and OD offices shall, in compliance with HHS policy, ensure that all Web sites reside in the .gov domain unless they obtain a waiver to reside outside the .gov domain. NIH ICs and OD offices shall use .gov domain names for Public-facing Web sites that are funded by NIH per HHS Policy for Internet Domain Names. HHS policy states that the use of .com .org, .edu, .net, .biz, .tv, or other domain names requires a HHS waiver (See http://www.hhs.gov/policies/webpolicies/200501.html). Public-facing Web sites that do not contain 'NIH' in the Web site address, but are controlled and operated by NIH directly or through contract or other agreement affiliated with NIH, such as www.cancer.gov, shall also obtain a HHS waiver.

    ICs and OD offices may request a top-level NIH domain name (i.e., .nih.gov) through the Center for Information Technology (CIT) (http://www.net.nih.gov/DNS/). The requests are evaluated to determine whether the requested name is relevant and appropriate to the resource it describes and whether the requestor has official, sanctioned authority for the requested topic area.

    Many Web sites exist that resemble government Web sites or appear to provide "official" government information. They can mislead the public into believing and acting on erroneous information. Visitors looking for official government information must be confident they are getting government information. Using domains that are exclusive to the government is one way to provide assurance to citizens that Federal public Web sites are

legitimate official government sites.

b. **NIH Name and Logo Use:** NIH ICs and OD offices that use the names, symbols, logos or identifying marks of NIH, its components, offices or programs shall, in accordance with NIH policy, obtain approval as described in NIH Manual Chapter 1186, "Use of NIH Names and Logos" (http://oma.od.nih.gov/manualchapters/management/1186/). ICs are required to submit a request to the NIH Office of Communications and Public Liaison (OCPL) for review and approval before the NIH logo or name may be used.

2. **Privacy and Personally Identifiable Information (PII):** NIH ICs and OD offices shall ensure each Web property is compliant with NIH Manual Chapter 2805, "NIH Web Privacy Policy" (http://oma.od.nih.gov/manualchapters/management/2805).

3. **Records Management and Freedom of Information Act (FOIA):**

a. **Records Management:** NIH ICs and OD offices shall maintain Web records and documents in the same manner in which they maintain hardcopy "official" documents for their IC or OD offices. Proper records management and the schedules for records maintenance and disposition shall be in accordance with HHS policy and the NIH Manual Chapter 1743, "Keeping and Destroying Records" (http://oma.od.nih.gov/manualchapters/management/1743). See http://www.archives.gov/records-mgmt/policy/managing-web-records-index.html for further information.

b. **Freedom of Information Act (FOIA):** NIH ICs and OD offices shall ensure public access to, and dissemination of, records that are created and maintained by the IC and OD office, as prescribed by FOIA and the NIH FOIA Office. Each IC has a FOIA

Coordinator and shall maintain a FOIA information page that is accessible through the IC's Public-facing Web site.

4. **Open Government:** NIH ICs and OD offices should enable openness, transparency and collaboration by publishing Web content and data in open, industry standard formats, e.g., Portable Document Format (PDF), etc. The open format shall allow information to be retrieved, downloaded, indexed and searched by commonly used Web search applications per the Open Government Directive.

5. **Accessibility:** NIH IC and OD office Web sites shall be accessible to all individuals in accordance with Section 508 of the Rehabilitation Act of 1973, as amended. Each IC shall ensure that (1) individuals with disabilities who are Federal employees have access to and use of information and data that is comparable to the access to and use of the information and data by Federal employees who are not individuals with disabilities; and (2) individuals with disabilities who are members of the public seeking information or services from a Federal department or agency have access to and use of information and data that is comparable to the access to and use of the information and data by such members of the public who are not individuals with disabilities. All Web tools and services acquired using NIH funds, e.g., under a contract, shall be Section 508 compliant. If there are extenuating circumstances that prevent acquisition of a compliant tool or service, NIH components have the option of requesting a temporary or long-term accommodation or exception from the comparable access requirement. Requests shall be appropriately documented and submitted through their respective IC Section 508 Coordinator for the approval of the NIH Section 508 Coordinator. All exceptions or accommodations shall be approved in advance of their use.

When considering the use of various third-party sites for information or

services that are of comparable value (e.g., multiple sites that provide bus schedules), NIH components shall give preference to third-party sites that are Section 508 compliant and/or accessible to persons with disabilities.

6. **Plain Language:** NIH ICs and OD offices shall comply with the Plain Writing Act of 2010, which requires the Federal Government to write in simple, easy-to-understand language. Specifically, the Act defines "plain writing" as writing that the intended audience can readily understand because the writing is clear, concise, well-organized and follows best practices for plain writing. Furthermore, the Act specifies that plain writing shall be used in any writing that is relevant to obtaining Federal benefits or services or complying with Federal requirements.

7. **Copyright:** NIH ICs and OD offices shall ensure that content that is produced by Federal staff and made available on an NIH Public-facing Web site is in the public domain and does not include copyright notices. ICs and OD offices shall have written permission or a license to post documents or other materials produced by private individuals or organizations and the usage terms need to be followed and should be evaluated and renewed as needed.

8. **Government Paperwork Elimination Act (GPEA):** NIH ICs and OD offices shall, whenever practicable, use electronic forms, electronic filing, and electronic signatures to conduct official business with the public.

9. **Non-Governmental Sites, Applications, and External Linking:** NIH ICs and OD offices may utilize third-party, non-governmental sites or embedded application ("widgets") within a government Web site to engage the public or disseminate information (such as embedding a YouTube video on an IC Web site). Furthermore, ICs and OD offices may establish a presence on or link to a third-party site, such as Facebook, GovLoop or LinkedIn, in support of their mission. Links to external sites should be clearly marked, so that users are aware that they are exiting the

NIH site.

Each IC and OD office shall assess the risk of utilizing third-party applications or sites according to guidelines described in NIH Manual Chapter 2809, "NIH Social and New Media Policy." (http://oma.od.nih.gov/manualchapters/management/2809/).

10. **Limited English Proficiency:** NIH IC and OD office Public-facing Web sites shall provide appropriate access for people with limited knowledge of English. ICs shall determine if their Web content requires translation per Department of Justice guidance described in Executive Order 13166 (http://www.justice.gov/crt/lep/13166/eolep.pdf).

11. **Search:** NIH ICs and OD offices shall provide a search function on all Public-facing Web sites. The search application shall allow users to search among public files within that IC or OD office's Web domain.

12. **Government Accountability and Security:**

    a. **Lobbying:** NIH ICs and OD offices shall not use Web and new media properties for direct or indirect lobbying efforts. The content, data and applications shall not be used or designed to influence a member of Congress, a jurisdiction or an official of any government to favor, adopt or oppose, by vote or otherwise, any legislation, law, etc. before or after the introduction of any bill, measure, or resolution proposing such legislation, law, etc.

    b. **Security:** NIH ICs and OD offices shall maintain their Web servers in line with National Institute of Standards and Technology (NIST) Special Publication 800-44, "Guidelines on Securing Public Web Servers" and other associated guidance from NIST (http://csrc.nist.gov/publications/nistpubs/800-44-ver2/SP800-44v2.pdf (PDF Document, 142 pages)) and HHS/NIH policy.

E. Definitions and Additional Information/Requirements:

1. **Child and Children:** Unless the context otherwise provides, it means individuals under the age of 13 per the Children's Online Privacy Protection Act (COPPA) of 1998.
2. **Contract:** Includes any contract, written or oral, subject to the Federal Acquisition Regulations.
3. **Cookies:** A text file, saved in a browser's directory or folder, which is stored in the computer's memory while the browser is running. The cookie usually goes unnoticed to the user and expires at some point. Using the cookie, the site can collect user preferences. In this file various types of information can be stored, from pages visited on the site, to information voluntarily given to the site. The browser records the cookie onto a "cookie list."

   The Office of Management and Budget Memo [M-10-22, Guidance for Online Use of Web Measurement and Customization Technologies](#) (PDF Document, 9 pages) allows Federal agencies to use cookies.

   Basically there are two types of cookies used on Web sites:
   a. **"Persistent cookies"** collect and maintain information for later use. They can track the activities of users over time and across different Web and new media properties. These are capable of capturing personal information that can be retrieved by individual identifiers (e.g., name, SSN, etc.) and may therefore be covered by the Privacy Act. Use of persistent cookies requires pre-approval.
   b. **"Session cookies"** do not fall within the scope of this policy. Exempted "session" cookies include those that retain

information only during the session or for the purpose of completing a particular online transaction, without any capacity to track users over time and across different Web sites.

4. **Disclaimer:** A statement that NIH is not responsible for the information or material included on (1) the NIH Web site that was derived from other non-NIH sources and (2) external Web pages. A disclaimer is also used to avoid giving a user the impression that NIH is endorsing information or a commercial product described on an NIH page or at an external site linked to an NIH page. Notice regarding inclusion of information which may be copyrighted, disclaimers, endorsement (general and external links), liability, and medical information may be used, as appropriate, for individual IC Web sites. Sample disclaimers are available at https://ocio.nih.gov/aboutus/Pages/disclaimer.aspx. In determining appropriate statements, careful consideration should be given to the nature of the specific site and its potential risk.

5. **Exit Page:** An intermediary page the user sees before proceeding to third-party Web sites, and which notifies the user that they are leaving NIH-managed Web pages.

6. **Kid's Pages:** NIH Web sites directed to children under the age of 13.

7. **Personal Identifier:** A name, or the identifying number, symbol, or other unique identifier, such as Social Security Number or User ID Number assigned to an individual.

8. **Personally Identifiable Information (PII):** Information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place

of birth, mother's maiden name, etc. (Defined in OMB [M-07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information]( )).

9. **The Privacy Act of 1974, as amended:** Protects the privacy of individuals by establishing "Fair Information Practices" for the collection, maintenance, use, and dissemination of information by federal agencies. The Privacy Act is the most significant milestone in the history of the protection of the privacy of personal information held by the Federal Government. Many subsequent laws, regulations, and guidance build upon the principles first articulated in the Privacy Act. (Privacy Act of 1974, as amended, 5 U.S.C. 552a).

10. **Privacy Policy:** "Privacy Policy" is described in OMB Memorandum [M-99-18, Privacy Policies on Federal Web Sites]( ) and is further explained in OMB Memorandum [M-03-22, OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002]( ) . The Privacy Policy should be a consolidated explanation of the agency's general privacy-related practices that pertain to its official Web site and its other online activities.

11. **Third-Party Web Sites or Applications:** "Third-party Web sites or applications" refers to Web-based technologies that are not exclusively owned, operated or controlled by a government entity, or Web-based technologies that involve significant participation of a nongovernment entity. Often these technologies are located on a ".com" Web site or other location that is not part of an official government domain. However, third-party applications can also be embedded or incorporated on an agency's official Web site.

12. **Web 2.0/Social Media Technology:** Web 2.0 technologies refer to a second generation of the World Wide Web as an enabling platform for Web-based communities of interest, collaboration, and interactive services. These technologies include those that exist

today (listed below) as well as emerging new media technologies that will be developed in the future.

   a. **Blogs:** Web sites where regular entries are made (such as in a journal or diary) and presented in reverse chronological order. Provides the ability to disseminate a message or information to a worldwide audience.

   b. **Cloud Computing:** Uses Internet hosted servers/applications rather than locally installed servers/applications.

   c. **Social Networking Sites:** Web sites that connect people or entities through online communities. Users can establish pages with their profiles and find other people or groups they know or look for other members with similar interests or affiliations. Examples include Facebook and Twitter.

   d. **Video and multimedia sharing:** Web sites that use videos, images, and audio libraries to share information. YouTube is an example.

   e. **Wikis:** Collections of Web pages that encourage users to contribute or directly modify the content.

   f. **Podcasting:** Publishing digital media files on the Web so they can be downloaded onto computers or portable listening devices. Users can subscribe to a "feed" of new media files and download them automatically as they are posted.

   g. **RSS Feed:** Really Simple Syndication and Rich Site Summary publish frequently updated (syndicated) works to multiple venues.

   h. **Mashups:** Web sites that combine content from multiple sources for an integrated experience.

13. **Web Measurement and Customization Technologies:** These technologies are used to remember a user's online interactions with a Web site or online application in order to conduct measurement and

analysis of usage or to customize the user's experience. (Defined in OMB Memorandum [M-10-22, Guidance for Online Use of Web Measurement and Customization Technologies](#))

a. **Single-Session Technologies** - These technologies remember a user's online interactions within a single session or visit. Any identifier correlated to a particular user is used only within that session, is not later reused, and is deleted immediately after the session ends.

b. **Multi-Session Technologies** - These technologies remember a user's online interactions through multiple sessions. This approach requires the use of a persistent identifier for each user, which lasts across multiple sessions or visits.

F. Responsibilities:

NIH ICs and OD offices shall review and be familiar with the provisions of this policy prior to posting new or revised Web content to ensure compliance. The following are officials with responsibilities associated with this policy. Note that this is not a comprehensive list.

1. **NIH Chief Information Officer (CIO)** – The official responsible for oversight of IT management at NIH. Specific to this policy, the NIH CIO is responsible for:

   a. Approving non- .gov domain name requests prior to submission to HHS.

   b. Approving Section 508 exception and accommodation requests.

2. **NIH Chief Information Security Officer (CISO)** – The NIH official responsible for the NIH Information Security Program and ensuring that

the implementation of this policy at NIH is consistent with all other Federal, HHS, and NIH rules and regulations. (NIH Security policies, guidelines and regulations can be found at: https://ocio.nih.gov/InfoSecurity/Policy/Pages/default.aspx.)

3. **IC Web Site Owner/Administrator** – The IC or OD office official who serves as the principal contact responsible for IC Web product development and Web project management. The IC/OD Web Site Owner/Administrator is responsible for ensuring adherence to this and other HHS and NIH Web policies

4. **IC Contracting/Project Officer** – The IC or OD Office official who oversees the development of the documentation and discussions of assigned contracts for award and administration, performs the final review of contract actions, and provides final signature authority. The IC/OD Contracting/Project Officer is responsible for ensuring any contractual agreements to design, develop, and/or implement Web sites comply with this and other applicable policies.

G. Procedures:

Public-facing Web sites and new media activities shall follow appropriate procedures and clearances. In most cases, the procedures to be followed for print publication apply unless one is posting content that has already been cleared for public use.

For other types of less formal Public-facing Web site content, such as blogs, micro blogging, and replies to comments in public online space, activities should be coordinated through the appropriate supervisory channels. In most cases, the following offices should be contacted: (1) IC or OD communication office to ensure appropriate content procedures are being followed, (2) IC or OD CIO office to learn if any security procedures need to be followed and (3) IC or OD FOIA and Privacy liaisons to learn if

any FOIA and Privacy procedures are required.

When using third party online applications on a Public-facing Web site or new media property, any polices or procedures associated with that service must be followed.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual Chapter 1743,"Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, in accordance with the specific schedule item as applied to the kind of records.

Web 2.0 Information: A challenge associated with the use of Web 2.0 technologies, including government blogs and wikis and Web pages hosted by commercial providers, is the question of whether information exchanged through these technologies constitute federal records pursuant to the Federal Records Act. According to the guidance, records generated when a user interacts with an agency Web site may form part of a set of official agency records. National Archives and Records Administration (NARA) guidance indicates that content created with interactive software on government Web sites is owned by the government, not the individuals who created it, and is likely to constitute agency records and should be managed as such. NARA issued "Guidance on Managing Web Records" to help agencies make decisions on what records generated by these technologies should be considered agency records: http://www.archives.gov/records-mgmt/pdf/managing-web-records-index.pdf (PDF Document, 28 pages).

NIH e-mail messages. NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks

that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

I. Internal Controls:

The purpose of this manual issuance is to provide guidance to ICs and OD offices in meeting requirements related to privacy and the protection of personal information on NIH Public-facing Web site pages.

1. Office Responsible for Reviewing Internal Controls Relative to this Chapter:
    Oversight of this policy will be carried out through a coordinated effort between the Office of Management Assessment (OMA), Office of the Chief Information Officer (OCIO), and Office of Communications and Public Liaison (OCPL).

2. Frequency of Review:
    Reviews will be ongoing. Appropriate internal controls shall be in place before a Web page may be activated. Webmasters, content mangers, and developers responsible for NIH Web pages and products are responsible

for ensuring compliance with NIH policy.

3. Method of Review:

   Each year, a workgroup of members from OMA, OCIO and OCPL will survey a sample of NIH Web sites for compliance with NIH policy. External reviews may be used as alternative reviews for this purpose.

4. Review Reports:

   Reports will be sent to the NIH Deputy Director for Management (DDM), and circulated to NIH privacy stakeholders, as deemed appropriate by OMA, OCIO and OCPL. Reports should indicate that controls are in place and working well, or indicate any internal management control issues that require the attention of the report recipient(s).

J. References:

Laws and Regulations

1. Privacy Act of 1974, 5 United States Code, Section 552a:
   http://www.justice.gov/opcl/privstat.htm
2. Privacy Act Regulations, Code of Federal Regulations (CFR) Title 45, part 5:
   http://law.justia.com/cfr/title45/45-1.0.1.1.7.html
3. Freedom of Information Regulations, Code of Federal Regulations (CFR) Title 45, part 5 (FOIA):
   http://www.access.gpo.gov/nara/cfr/waisidx_10/45cfr5_10.html
4. Freedom of Information Act, 5 U.S.C. Section 552:
   http://www.usdoj.gov/oip/foia_guide07/text_foia.pdf (PDF Document, 13 pages)
5. Department of Justice Executive Order 13166 (Limited English Proficiency):
   http://www.justice.gov/crt/lep/13166/eo13166.html
6. Government Paperwork Elimination Act (GPEA)/Paperwork

Reduction Act, 44 U.S.C. Section 3501:

http://www.archives.gov/federal-register/laws/paperwork-reduction/

7. Memorandum from the Office of the Attorney General; March 19, 2009:

www.usdoj.gov/ag/foia-memo-march2009.pdf (PDF Document, 3 pages)

8. Section 207(f)(1)(b)(iv) of the E-Gov Act of 2002, Public Law 107–347:

http://www.archives.gov/about/laws/egov-act-section-207.html

9. OMB Circular A-130:

http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html

10. Open Government Directive:

http://www.whitehouse.gov/open/documents/open-government-directive

11. OMB Implementation of the Government Paperwork Elimination Act:

http://www.whitehouse.gov/omb/fedreg/gpea2.html

12. Prohibition of Lobbying, Title 18 U.S.C. Section 1913:

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+18USC1913

13. Section 508 of the Rehabilitation Act, 29 U.S.C. Section 794d:

http://www.section508.gov/

Policies, Guidance, and Office Contacts

14. NIH FOIA Office:

http://www.nih.gov/icd/od/foia/index.htm

15. NIH Information Security Policies, Guidelines and Regulations:

https://ocio.nih.gov/InfoSecurity/Policy/Pages/default.aspx

16. HHS Policy for Internet Domain Names:

http://www.hhs.gov/policies/webpolicies/200501.html

17. HHS Web Records Management Policy:

    http://www.hhs.gov/web/policies/webpolicies/webrecords.html and

    http://www.newmedia.hhs.gov/standards/

18. OMB Memo on Policies for Federal Agency Public Web Sites:

    http://www.whitehouse.gov/omb/memoranda/fy2005/m05-04.pdf

    (PDF Document, 5 pages)

Manual Chapters:

19. NIH Manual Chapter 2805, "NIH Web Privacy Policy:"

    http://oma.od.nih.gov/manualchapters/management/2805

20. NIH Manual Chapter 2809, "NIH Social and New Media Policy:"

    http://oma.od.nih.gov/manualchapters/management/2809

21. NIH Manual Chapter 1743, "Keeping and Destroying Records:"

    http://oma.od.nih.gov/manualchapters/management/1743

NIH POLICY MANUAL

2805 – NIH Web Privacy Policy

Issuing Office: OMA 301-496-2832; OCPL 301-496-5787; and OCIO 301-496-1168

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1. **Explanation of Material Transmitted:** This chapter establishes policies and procedures for ensuring the privacy and protection of personal information collected, stored, used, maintained and disseminated via NIH Web sites. This policy applies to NIH Internet Web sites that are developed and/or maintained by NIH staff or by contract personnel. This revision includes new privacy requirements for emerging web-based technologies that are not exclusively operated or controlled by NIH, or which involve the significant participation of a non-government entity. Often these technologies are located on a ".com" Website or other location that is not part of the NIH official government domain. They may include Third-Party Websites or Applications (TPWAs) and Web Measurement and Customization Technologies embedded or incorporated on NIH Websites.

2. **Filing Instructions:**

    Remove: Manual Issuance 2805, dated 12/18/01.
    Insert: Manual Issuance 2805, dated 08/08/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing offices listed above.

- NIH Manual System, contact the Division of Management Support, OMA on 301-496-2832, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This chapter establishes policies and procedures for ensuring the privacy and protection of personal information collected, stored, used, maintained and disseminated via NIH Web sites. This policy applies to NIH Internet Web sites that are developed and/or maintained by NIH staff or by contract personnel. This policy does not apply to internal agency activities (such as on intranets, applications, or interactions that do not involve the public) or to activities that are part of authorized law enforcement, national security, or intelligence activities.

B. Background:

The Web is a powerful tool for conveying information about the activities, objectives, policies and programs of the Federal Government and NIH. It is important that visitors to federal Web sites know that their private information is appropriately protected by the agency when they are accessing these sites, and that agency staff understand their responsibility to safeguard the personally identifiable information (PII) made available, whether solicited or unsolicited, to the agency.

Potential consequences for not adequately protecting privacy in the government include criminal and civil penalties, negative impact on individuals where PII is collected and not appropriately used, reduced mission effectiveness and loss of credibility, confidence, and trust in NIH.

C. Policy:

1. **General Requirements**

    Privacy Policy – A Web privacy policy shall be clearly posted on all NIH top-level/principal Web sites, including NIH and Institute/Center (IC) level sites, major on-line public resource sites and any other known major public facing entry points, as well as any Web page that collects or posts personal information. (See URL: http://www.nih.gov/about/privacy.htm)

    Privacy Notice/Statement – A comprehensive online privacy notice discusses the

information collected through the Web site and typically covers the effective date, scope, information collected (both actively and passively), information uses, choices available, how to modify information or preferences, how to contact or register a dispute, and how policy changes will be communicated. They are easy to find and at or before the point of collection. They are linked from the Web site homepage and from each and all information collection pages (e.g. site-wide navigation component, or header/footer), from pop-up or pop-under windows that contain web forms and in e-mail messages that originate from the Web site.

Policy Links – Links to the Institute or OD office privacy policy shall be clearly labeled and easy to access by all visitors to the Web site. If the privacy policy is combined with another mandated or recommended Web site statement, the link should be visibly labeled accordingly, e.g., "Privacy Policy/Disclaimer."

Plain Language – Web privacy policies shall conform to the *Plain Writing Act of 2010* which defines "plain writing" as writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience. Web privacy policies shall clearly and concisely inform visitors to the site of:

a. Specific purpose of the agency use of the Web site;
b. How the agency will use PII that becomes available through the use of the Web site;
c. Who at the agency will have access to PII;
d. With whom PII will be shared outside the agency;
e. Whether and how the agency will maintain PII, and for how long;
f. How the agency will secure PII that it uses or maintains; and,
g. What other privacy risks exist and how the agency will mitigate those risks.

NIH staff shall also comply with the following NIH policy:

NIH Manual Chapter 1825, *Information Collection from the Public*
NIH Manual Chapter 2804, *NIH Public-Facing Web Management*
NIH Manual Chapter 2809, *Social and New Media*

Machine-Readable Format – Web privacy policies and statements shall be represented in a machine-readable format (e.g. XML-based standard). A Platform for Privacy Preferences (P3P) is a way to translate a privacy policy into machine-readable format that a browser decodes in order to figure out what the policy says. P3P is designed to provide Internet users with a clear understanding of how PII will be used by a particular Web site. It allows Web site operators to explain their privacy practices to visitors and allows users to configure their browsers and other software tools to provide notifications about whether Web site privacy policies match their preferences.

2. **Privacy Act Requirements**

   a. **Privacy Notice or Notification Statement:** Any NIH Web site or property that collects and/or maintains PII that will, in practice, be retrieved by a personal identifier, shall include a privacy notice or notification statement. The notice shall be on or directly linked to the information collection page and contain the following information:

      (1) Authority (whether granted by statute, regulation, or executive order) which authorizes the solicitation and/or collection of the information;
      (2) Purpose of the information collection;
      (3) Routine uses for information disclosure (likely or known disclosures of the data made outside of the Department of Health and Human Services (HHS), without the consent of the subject individual, for a purpose which is compatible with the purpose for which the record was collected);
      (4) Whether disclosure of the information is mandatory or voluntary; and,
      (5) What effect, if any, there will be on the individual if they choose to not provide all or part of the requested information.

      OMB Memorandum M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information (PII)*, directs agencies to eliminate the unnecessary collection and use of Social Security Numbers (SSNs). SSNs may only be required when their collection is authorized by statute and individuals are informed whether provision of the SSN is optional or required.

b. **System of Records Notice (SORN):** Any NIH Web site, Web page or property designed to retrieve information about an individual by a personal identifier linked to them shall have a valid Privacy Act System Notice published in the Federal Register which covers the record system.

A SORN refers to the notice which describes the purpose of the system, the legal authority to collect information, the categories of information collected, maintained, retrieved, and used within a set of records, the categories of individuals for whom the information is collected, and to whom the information can be disclosed, and safeguards for protecting the information. The SORNs are written broadly to cover information collections designed to retrieve information about an individual by a name or personal identifier linked to the individual. If a collection of records that includes Privacy Act information is proposed for operation and is NOT covered under an existing SORN, one shall be developed and posted in the Federal Register 40 days prior to collection of the data. If no existing SORN covers the proposed data collection, the IC or OD office System Owner/Manager shall work with the IC Privacy Coordinator or NIH Privacy Act Officer to put one in place. Otherwise, the system of records is unauthorized and shall not be operated.

c. **Privacy Impact Assessment:** A Privacy Impact Assessment (PIA) shall be conducted on all IT systems (i.e., Web sites, databases associated with a Web site, etc.) owned, operated or controlled by the NIH or contractor acting on its behalf. A PIA is a living document that shall be updated when a major change occurs within an IT system as defined in OMB Memorandum M-03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*. The PIA is an analysis tool designed to identify any privacy or security risk associated with information that is collected, processed, stored, and/or transmitted by an IT system. A PIA collects data on the information to be contained/collected by an IT system, how the information will be used, and what safeguards will be put into place to protect the collected information. The PIA process assists System Owners/Managers in thoroughly assessing all phases of

the system development life cycle (SDLC). PIAs should be performed before the development phase of an IT system; however, an initial PIA can be performed on an existing operational IT system if it is found that a PIA is not currently in place. Departmental policy requires that PIAs be conducted and maintained on all IT systems, whether the system is already in existence, in development, or undergoing modification, as defined by the E-Government Act of 2002, OMB guidance, HHS policy, and supporting guidance.

An adapted PIA is required on all NIH uses of a third-party Web site or application (TPWA). TPWA can be defined as Web based technologies not exclusively operated or controlled by a government entity, or web-based technologies that involve significant participation of a nongovernment entity. Often, these technologies are located on a ".com" Web site or other location that is not part of an official government domain. However, TPWAs can also be embedded or incorporated on an agency's official Web site (e.g. Web 2.0 applications and social media networks such as Facebook, Twitter, YouTube, MySpace, LinkedIn, Flickr, blogs, email subscription services, mobile applications, and mobile Web sites). Each adapted PIA shall be tailored to address the specific functions of the Web site or application. It should describe (1) the specific purpose of the agency's use of the TPWA, (2) any PII that is likely to become available to the agency through public use of the TPWA, (3) the agency's intended or expected use of PII, (4) with whom the agency will share the PII, (5) whether and how the agency will maintain PII, and for how long, (6) how the agency will secure PII that it uses or maintains, (7) what other privacy risks exist and how the agency will mitigate those risks, and (8) whether the agency's activities will create or modify a "system of records" under the Privacy Act.

IC and OD office staff shall work with their Privacy Coordinator and Information Systems Security Officer (ISSO) to determine if a PIA is needed, when updates are necessary, and to ensure full compliance with OMB, HHS and NIH policies.

3. **Human Subject Requirements**

Web sites used for the purpose of recruiting study subjects shall comply with the human subject protection regulations at 45 CFR Part 46 and 21 CFR Part 56. These regulations require that an Institutional Review Board (IRB) review and approve all research activities including the use of advertising and plans for protecting the confidentiality of actual and prospective subjects. See OHRP guidance at http://www.hhs.gov/ohrp/policy/clinicaltrials.html, FDA guidance at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm and NIH policy (Manual Chapter 2809, NIH Social and New Media, Appendix 1) at http://oma.od.nih.gov/manualchapters/management/2809.

4. **Children's Online Protection Requirements**

NIH Web sites that are set up for the intended use by children under the age of 13 or that knowingly collect personal information from them shall comply with the Children's Online Privacy Protection Act of 1998 (COPPA) which restricts the marketing of products and services online to children under 13. NIH "Kid's Pages" shall comply with the following standards set forth in the COPPA, specifically:

a. **Avoid Unnecessary Data Collection** - Web sites that collect personally identifiable information from children under age 13 should eliminate or reconsider using instruments that could collect data on "Kid's Pages" if the information is not essential to the IC or OD office program. Using age gate techniques makes it difficult for younger users to provide personal information.

b. **Privacy Notice** – Internal or external Web sites and Kid's Pages that are set up for the intended use by children or that knowingly collect personal information from children under the age of 13, shall contain a privacy notice of the information collection practices (i.e., whether or not the Web sites collect/store information).

The "Kid's Page" privacy notice shall include:

(1) A description of the specific types of personal information you collect directly from children (e.g., name, age, home address, e-mail address, hobbies,

personal characteristics, etc.), and if any additional information is collected passively (e.g., via cookies and other Web measurement and customization technologies);

(2) A description of how you will use the information (e.g., make the information available through a child's participation in a chat room) and, whether personal information is forwarded to a third-party social network Web site and/or application;

(3) How long your IC will maintain the information;

(4) Who will have access to the information; and,

(5) A contact name and information (address, telephone, e-mail address) for the site.

c. **Parental Consent** – ICs and OD offices shall ensure that a parent (or legal guardian) of the child receives notice of these information collection practices and consents to those practices before personal information is collected from a child. (Note: Disclosure of personal information is permitted only to the extent that it has also been included as a "purpose" or "routine use" in an active Privacy Act System of Records). Specifically,

(1) The IC or OD office shall obtain parental consent when it collects an e-mail address or other personal information and:

(a) Plans to change the kinds of information previously collected;

(b) Changes how the information is used;

(c) Offers the information to new or different third-party Web site and/or application;

(d) Uses the information in a way that is different than how it was specified when parental consent was originally obtained; or

(e) Gives a child access to a secondary site that was not originally specified in the Web site privacy notice.

(2) Parental consent is not necessary if the "Kid's Page" site collects an e-mail address to:

(a) Respond to a one-time request from the child and then the e-mail address from the child is deleted (e.g., research poster, response to a survey or inquiry, and similar requests). Repeated contact with the same child requires consent;

(b) Contact the parent;

(c) Ensure the safety of the child or the site;

(d) Fulfill an NIH newsletter subscription request for one issue. (Note: Continuation of the subscription requires consent).

d. **Provide Instructions to Parents**

(1) Parents have the right to review, change or revoke their consent and ask that information about their children be deleted from the site's database at any time. When a parent revokes consent, the Web site shall immediately stop collecting, using or disclosing information from that child.

(2) It is also advisable that an exit page be placed between the IC or OD office "Kid's Page" and any external links. This provides clear notification to the child and parent that they are exiting NIH controlled Web space and that NIH can no longer guarantee their privacy or the security of information belonging to them.

5. **E-mail Requirements**

E-mail messages have similar privacy issues as Web sites. They not only convey information in text or HTML formats, but they may also involve hyperlinks, forms, cookies, Web beacons and active content.

Commercial e-mail includes promotional or marketing messages that recipients have indicated they wish to receive. Common privacy principles include no false or misleading header information, no deceptive subject lines, opt-out mechanisms in each message, notification to the recipient that the message contains an advertisement or promotional information, and information about the sending organization.

IC and OD offices shall include in their privacy notice, a statement to users about how the site handles unsolicited e-mail, and a notice that the sender should not expect privacy.

The following is a sample statement:

"E-mail sent to NIH may be seen by a number of people who are responsible for answering questions. If you send us an e-mail, you are advised that e-mail is not necessarily secure against interception. If your communication includes sensitive information like your Social Security Number or personal health information, it is advisable that you contact us by postal mail or telephone rather than e-mail."

6. **Web Measurement and Customization Technology Requirements**

These technologies are used to remember a user's online interactions with a Web site or online application in order to conduct measurement and analysis of usage or to customize the user's experience. Single-session technologies remember a user's online interactions within a single session or visit. Any identifier correlated to a particular user is used only within that session, is not later reused, and is deleted immediately after the session ends. Multi-session technologies remember a user's online interactions through multiple sessions. This approach requires the use of a persistent identifier for each user, which lasts across multiple sessions or visits. Refer to OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies*.

   a. **Appropriate Use and Prohibitions**

   Subject to the limitations described below, Web measurement and customization technologies (e.g. Web server logs, cookies, Web beacons, proxies, etc.) may be used for the purpose of improving IC and OD office services online through conducting measurement and analysis of usage or through customization of the user's experience. Where information is gathered automatically as the user navigates from page to page on a Web site or across Web sites, under no circumstances may such technologies be used:

   (1) To track user individual-level activity on the Internet outside of the Web site or application from which the technology originates;

   (2) To share the data obtained through such technologies, without the user's

explicit consent, with other departments or agencies;

(3) To cross-reference, without the user's explicit consent, any data gathered from Web measurement and customization technologies against PII to determine individual-level online activity;

(4) To collect PII without the user's explicit consent in any fashion; and,

(5) For any like usages so designated by the Office of Management and Budget (OMB).

b. **Usage Tiers**

Below are the defined tiers for authorized use of Web measurement and customization technologies.

(1) Tier 1 – Single Session. This tier encompasses any use of single session Web measurement and customization technologies.

(2) Tier 2 – Multi-Session without PII. This tier encompasses any use of multi-session Web measurement and customization technologies when no PII is collected (including when the IC and OD office is unable to identify an individual as a result of its use of such technologies).

(3) Tier 3 – Multi-Session with PII. This tier encompasses any use of multi-session Web measurement and customization technologies when PII is collected (including when the IC or OD office is able to identify an individual as a result of its use of such technologies).

c. **Clear Notice and Personal Choice**

ICs and OD offices shall not use Web measurement and customization technologies from which it is not easy for the public to opt-out. Opt-in/opt-out mechanisms shall be designed to be easily accessible and understandable and be implemented uniformly across all Web sites.

ICs and OD offices shall explain in their Privacy Policy the decision to enable Web measurement and customization technologies by default or not, thus requiring users to make an opt-out or opt-in decision. ICs and OD offices shall

provide users who decline to opt-in or decide to opt-out with access to comparable information or services.

(1) NIH side opt-out. ICs and OD offices are encouraged and authorized, where appropriate, to use Web tracking and measurement technologies in order to remember that a user has opted out of all other uses of such technologies on the relevant domain or application. Such uses are considered Tier 2.

(2) Client side opt-out. If IC and OD office opt-out mechanisms are not appropriate or available, instructions on how to enable client side opt-out mechanisms may be used. Client side opt-out mechanisms allow the user to opt out of Web measurement and customization technologies by changing the settings of a specific application or program on the user's local computer. For example, users may be able to disable persistent cookies by changing the settings on commonly used Web browsers. ICs and OD offices should refer to http://www.usa.gov/optout_instructions.shtml which contains general instructions on how the public can opt out of some of the most commonly used Web measurement and customization technologies.

(3) Tier 3 restrictions. ICs and OD offices employing Tier 3 uses shall use opt-in functionality. Opt-in functionality shall allow the client complete control over the collection and dissemination of their personal information. An opt-in functionality requires a client to self-select the services they wish to subscribe to, and how any information they provide may be used.

(4) Privacy Policy. The following items shall be included in the IC and OD office online Privacy Policy, in any instance when Web measurement and customization technologies are used:

(a) Purpose of the Web measurement and/or customization technology;

(b) Usage Tier, session type, and technology used;

(c) Nature of the information collected;

(d) Purpose and use of the information;

(e) Whether and to whom the information will be disclosed;

(f) Privacy safeguards applied to the information;

(g) Data retention policy for the information;

(h) Whether the technology is enabled by default or not and why;

(i) How to opt-out of the Web measurement and/or customization technology;

(j) Statement that opting-out still permits users to access comparable information or services; and,

(k) Identities of all third-party vendors involved in the measurement and customization process.

d. **Data Safeguarding and Privacy**

All uses of Web measurement and customization technologies shall comply with existing policies with respect to privacy and data safeguarding standards. If applicable, ICs and OD offices shall cite the PIA and/or SORN in their online Privacy Policy.

e. **Comparable Information and Services**

If ICs and OD offices are using a Web site or application hosted on a third-party site using Web measurement and customization technologies to which federal privacy and data safeguarding standards do not apply, they should provide the public with alternatives for acquiring comparable information and services. For example, members of the public should be able to learn about NIH activities or communicate with the IC and OD offices without having to join a third-party social media Web site. If the third-party service is used to solicit feedback, ICs and OD offices shall provide an alternative government e-mail address where users can also send feedback.

Additional guidance on the use of social media Web sites is addressed in NIH Manual Chapter 2809, *Social and New Media* and OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Web Sites and Applications*.

f. **Data Retention and Access Limits**

IC and OD offices shall retain data collected from web measurement and

customization technologies for only as long as necessary to achieve the specific objective for which it was collected. Moreover, only staff that needs to have access to the data shall be allowed to do so.

(1) **Retention Time**. The time frame for retention of data shall be both limited and correlated to a specific objective. If not required by law, policy, or a specific need for the web measurement or customization objective, IC and OD offices should limit the retention of such data to one year or less.

(2) **Records Disposition Schedule**. Information collected from web measurement and customization technologies that are determined to be a federal record must comply with Federal Records Act regulations. The General Records Schedule 20 (GRS 20) pertains to Electronic Records; specifically, the disposition authority cited in General Record Schedule 20 Item 1C, "Electronic Records" ("*Files/Records Relating to the Creation, Use, and Maintenance of Computer Systems, Applications, or Electronic Records - Electronic files ...created to monitor system usage...*") is applicable to information collected from web measurement and customization technologies. Use of GRS 20 is mandatory for those categories of electronic records described in the schedule unless the IC and OD office have requested an alternative disposition authority from the National Archives and Records Administration (NARA).

g. **Enforcement**

To the extent feasible, technical enforcement mechanisms should be put in place to implement stated retention times and to limit access to authorized personnel. Where technical enforcement mechanisms are not feasible, policy or contractual enforcement mechanisms shall be present.

h. **Verification**

IC and OD offices using web measurement and customization technology must annually review their systems and procedures to demonstrate that they are in

compliance with this policy. The results of this review shall be posted on http://www.hhs.gov/open/.

i. **Approval**

IC and OD offices are authorized to use Tier 1 or Tier 2 technologies as long as they are in compliance with this policy, and provide clear and conspicuous notice in their online Privacy Policy citing the use of such technologies. Any proposed use by an IC or OD office to engage in Tier 3 measurement and customization technology usage shall be reviewed by the NIH Chief Information Officer (CIO). (See Appendix 1)

(1) The NIH CIO will review the form and forward it to the NIH Senior Official for Privacy (SOP) for review. Following SOP review and CIO approval, the SOP will send the form to the Department. Following HHS review, HHS will post the notice for public comment on the Department's Open Government Web page at http://www.hhs.gov/open/ for 30 days. After the notice and comment period have passed, and approval by the HHS Senior Agency Official for Privacy (SAOP) has been granted, the NIH CIO will notify the IC or OD office to cite the Departmental approval in their online Privacy Policy prior to using the Tier 3 Web measurement and customization technology.

(2) If a contractor develops, operates or manages the Web site on behalf of NIH, a copy of the HHS SAOP approval should be kept in the contract file.

(3) If an IC or OD office is found to be using Web measurement and customization technologies outside of the process or parameters specified by this policy, the office shall immediately cease use of such technologies and inform the NIH CIO of the extent of such unauthorized use.

7. **Third-Party Web sites and/or Applications**
   a. **Privacy Policy**

   Before an IC or OD office uses any third-party Web site or application to engage with the public, it should examine the third-party's privacy policy to evaluate the

risks and determine whether the Web site or application is appropriate for NIH use. In addition, the IC or OD office shall monitor any changes to the third-party's privacy policy and periodically reassess the risks.

b. **External Links**

ICs and OD offices may post a link to external, government and non-government sites that are not part of the official NIH.gov domain, such as a third-party social network site. NIH IC and OD office Web pages containing links to external Web pages not located on the NIH network shall provide a statement adjacent to the link or a "pop-up" disclaimer that explains that visitors are being directed to an external, government or non-government Web site that may have different privacy policies from those of the NIH official Web site. The visitor should understand they are exiting the NIH domain and that NIH is not responsible for the material found on, or data collection activities of, external Web pages. Sample disclaimers provided at: https://ocio.nih.gov/aboutus/Pages/disclaimer.aspx

c. **Embedded Applications**

If an IC or OD office incorporates or embeds a third-party application on its Web site or any other official NIH domain, it shall take the necessary steps to disclose the third-party's involvement and describe the NIH activities in its privacy policy.

d. **Agency Branding**

When an IC or OD office uses a third-party Web site or application that is not part of the official NIH domain, it shall apply appropriate branding to distinguish NIH activities from those of non-government actors. For example, to the extent practicable, NIH should add its seal or emblem to its profile page on a social media Web site to indicate that it is an official agency presence.

e. **Information Collection**

If information is collected through the IC or OD office use of a third-party Web site or application, NIH shall collect only the information "necessary" for the proper performance of agency functions and which has practical utility. Where a user actively provides PII via an online form, profile, account setting or other technique, the NIH shall collect only the minimum necessary to accomplish its purpose and all applicable policies and regulations governing PII must be followed.

f. **Web Form Requirements**

A Web form is a portion of a Web page that contains fields that users can fill in with data (including personal information). When the user submits the form, it is sent to a Web server that processes the information where it can be stored in a database.

Web forms shall be designed to only require what is really needed (and make clear what, if anything is optional). They shall be accompanied by a link to the privacy notice or statement at the point of collection. They shall:

(1) Use the post method of form submission (the alternative Get method can inadvertently spill PII to third-parties via the referrer URL);
(2) Place limitations on one-line text boxes to help ensure they are only used as intended (e.g. maximum of 14 characters for first name);
(3) Be cautious in using free text fields where users may make PII available where none is requested;
(4) Use secure transmission (e.g., https//) for the collection of sensitive personal information; and
(5) Turn off Auto complete for all confidential information (e.g., passwords, credit card numbers, PINs, SSNs, etc.)

g. **Web Sites Developed, Maintained and Operated Under Contract**

"Contract" covers any contract subject to the Federal Acquisition Regulations (FAR). When an agency contracts for the design, development, or operation of a

Web site or Web page necessary to accomplish an NIH function, the IC or OD office shall apply the requirements of this policy to the contract. Web sites or Web pages operated under a contract, which are designed, developed or operated to accomplish an NIH function, are, in effect, deemed to be maintained by the agency.

The Contracting Officer is the official who oversees the development of the documentation and discussions of assigned contracts for award and administration, performs the final review of contract actions, and provides final signature authority. Health and Human Services Acquisition Regulation (HHSAR) Section 324.103(a) states that all requests for contract shall be reviewed by the Contracting Officer to determine whether the Privacy Act requirements are applicable.

Solicitations and contracts (both prime and sub) that require the contractor to maintain a system of records covered by the Privacy Act (i.e., when the records will contain personal information that is retrieved by an individual identifier), shall state that the Privacy Act applies and include appropriate FAR citations listed below:

(1) FAR Clause 52.224-1, Privacy Act Notification
(2) FAR Clause 52.224-2, Privacy Act
(3) FAR Clause 52.239-1, Privacy or Security Safeguards
(4) HHSAR Clause 324.102 – Applicability of the Privacy Act (please verify)
(5) HHSAR Clause 352.224-70 Confidentiality of Information
(6) HHSAR Clause 352.270-11 Privacy Act

Contracts for the development, maintenance, or management of NIH Web sites shall include certain language (See Appendix 2, Contract Sample Language).

When Federal Information Security Management Act (FISMA) security requirements relevant to the acquisition need to be included, the project Officer (PO), IC Information Systems Security Officer (ISSO), and the IC Privacy Officer

will assist the acquisitions staff in selecting the appropriate language.

NIH sample language for IT Security Acquisitions Provisions are available at: https://ocio.nih.gov/InfoSecurity/Policy/Pages/ContractingInformation.aspx

D. Additional Information/Requirements:

1. **Child and Children**: Unless the context otherwise provides, it means individuals under the age of 13. (*Children's Online Privacy Protection Act (COPPA) of 1998*)
2. **Contract**: A contract is a legal instrument used to reflect a relationship between the Federal Government and the recipient whenever the principle purpose of the transaction is to acquire goods or services for the direct benefit or use of the Government. (*A Guide to the NIH Acquisition Process 2007*)
3. **Cookies**: A piece of state information supplied by a Web server to a browser, in a response for a requested resource, for the browser to store temporarily and return to the server on any subsequent visits or requests. (NIST SP 800-28 Version 2, *Guidelines on Active Content and Mobile Code*)
   a. **Authentication Cookie** – A cookie that assists the visitor during the login process, by containing the user ID and possibly, password data. A login cookie is typically persistent but may be session-based, and may be linked to other personal information maintained by the Web site. Login cookies tied to a name, account number, or personal e-mail address are considered personally identifiable.
   b. **Personalization Cookie** – A cookie that is used to tailor a Web site based on the past behavior of the visitor. These cookies are not normally tied to a users stated preferences but based on analysis by the Web site on user activity. These cookies are normally persistent.
   c. **Tracking Cookie** – A cookie that is used for aggregate visitor tracking. It is non-personally identifiable and not linked to other logs or information about the visitors that are identifiable. A shopping cart cookie is used to maintain state and associate a visitor with a shopping cart or other transaction thread. These cookies may be linked to PII if the visitor has logged in, is in the check-out process, or is otherwise known. Otherwise, they are often non-personally

identifiable.

4. **Disclaimer**: NIH Web pages containing links to external Web pages not located on NIH servers should include a link to a statement that releases NIH from responsibility for the material included in the external Web pages. It is important to avoid giving a user the impression that NIH is endorsing information, or a commercial product described in an external site. Notice regarding inclusion of information which may be copyrighted and disclaimers on endorsement (general and external links), liability, and medical information should be used, as appropriate, for individual IC or OD office Web sites. In determining appropriate statements, careful consideration should be given to the nature of the specific site and its potential risk. (NIH Guidance, *World Wide Web*)

5. **External Links**: If an agency posts a link that leads to a third-party Web site or any other location that is not part of an official government domain, the agency should provide an alert to the visitor, such as a statement adjacent to the link or a "pop-up," explaining that visitors are being directed to a nongovernment Web site that may have different privacy policies from those of the agency's official Web site. (OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Websites and Applications*)

6. **Kid's Pages**: NIH Web sites directed to children under the age of 13. (*Children's Online Privacy Protection Act (COPPA) of 1998*)

7. **Machine-Readable Policy File**: A privacy policy file that can be read automatically by a Web browser or other software agent to enable an end-user to quickly determine a Website's privacy practices, and whether that site's privacy practices are in accordance with the end-user's privacy preferences, without the end-user having to read the entire privacy policy. (HHS-OCIO, *Policy for Machine-Readable Privacy Policies*)

8. **Make PII Available**: Includes any agency action that causes PII to become available or accessible to the agency, whether or not the agency solicits or collects it. In general, an individual can make PII available to an agency when he or she provides, submits, communicates, links, posts, or associates PII while using the Web site or application. "Associate" can include activities commonly referred to as "friend-ing," "following," "liking," joining a "group," becoming a "fan," and comparable functions. (OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Websites and Applications*)

9. **Platform for Privacy Preferences (P3P)**: A specification created by the World Wide Web Consortium. P3P allows allow users' Web browsers to automatically understand Websites' privacy practices. (HHS-OCIO, *Policy for Machine-Readable Privacy Policies*)

10. **Personal Identifier**: A name, or the identifying number, symbol, or other unique identifier, such as social security number or User ID Number assigned to an individual.

11. **Personally Identifiable Information (PII)**: Information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc. (OMB M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*)

12. **Privacy Act of 1974, as amended**: Protects the privacy of individuals by establishing "Fair Information Practices" for the collection, maintenance, use, and dissemination of information by federal agencies. The Privacy Act is the most significant milestone in the history of the protection of the privacy of personal information held by the Federal Government. Many subsequent laws, regulations, and guidance build upon the principles first articulated in the Privacy Act. (*Privacy Act of 1974*, as amended, 5 U.S.C. 552a)

13. **Privacy Act System of Records**: A group of any records under the control of any agency where information is retrieved by the name of the individual, by some identifying number or symbol, or other identifiers assigned to the individual. The key to this definition is that the records shall be "retrieved by", not "retrievable by" an individual's name and/or personal identifier. (*Privacy Act*, as amended, 5 U.S.C. Section 552a(a)(5))

14. **Privacy Impact Assessment (PIA)**: An analysis of how information is handled: (i) to ensure handling conforms to applicable legal, regulatory, and policy requirements regarding privacy, (ii) to determine the risks and effects of collecting, maintaining and disseminating information in identifiable form in an electronic information system, and (iii) to examine and evaluate protections and alternative processes for handling information to mitigate potential privacy risks. (OMB Memorandum M-03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*)

15. **Privacy Policy**: A consolidated explanation of the agency's general privacy-related practices that pertain to its official Web site and its other online activities. Federal agencies shall protect an individual's right to privacy when they collect personal information. This is required by the Privacy Act and OMB Circular No. A-130, *Management of Federal Information Resources*. Posting a privacy policy helps ensure that individuals have notice and choice about, and thus confidence in, how their personal information is handled when they use the Internet. Privacy policy in standardized machine-readable format means a statement about site privacy practices written in a standard computer language (not English text) that can be read automatically by a Web browser. (OMB Memorandum M-99-18, *Privacy Policies on Federal Web Sites* and OMB Memorandum M-03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*)

16. **Privacy Notice**: A brief description of how the agency's Privacy Policy will apply in a specific situation. Because the Privacy Notice should serve to notify individuals before they engage with an agency, a Privacy Notice should be provided on the specific Web page or application where individuals have the opportunity to make PII available to the agency. (OMB Memorandum M-99-18, *Privacy Policies on Federal Web Sites* and OMB Memorandum M-03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*)

17. **Senior Agency Official for Privacy (SAOP)**: A title extended by OMB to HHS to effectively meet the reporting requirements outlined in OMB M-06-20, *Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management*. (OMB Memorandum M-05-08, *Designation of Senior Agency Officials for Privacy*)

18. **System of Records**: A group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. (*Privacy Act of 1974*, as amended)

19. **Systems of Records Notice (SORN)**: All systems with Privacy Act information contained within them are required to publish a "Records Notice" in the Federal Register that informs the public what information is contained in the system, how it is used, how individuals may gain access to information about themselves, and other

specific aspects of the system. SORNs can be internal, such as those which cover NIH records. Central agency SOR notices are those that belong to OPM. Government-wide SOR notices are those that belong to the EEOC, FEMA, GSA, DOL, OGE, etc. and which are also referred to as "umbrella" systems of record notices. Before data can be collected, a SORN shall be published and maintained in the Federal Register for 40 days. (*Privacy Act of 1974*, as amended, 5 U.S.C. § 552a(e)(4) and HHS Cybersecurity Program, *Standard Operating Procedures for Completing a Privacy Impact Assessment*)

20. **Third-Party Websites or Applications (TPWA)**: Web-based technologies that are not exclusively operated or controlled by a government entity, or Web-based technologies that involve significant participation of a nongovernment entity. Often these technologies are located on a ".com" Web site or other location that is not part of an official government domain. However, third-party applications can also be embedded or incorporated on an agency's official Web site. (OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Websites and Applications*)

21. **Usage Tiers**: Below are the defined tiers for authorized use of Web measurement and customization technologies (OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies*):

    a. **Tier 1 – Single Session**. This tier encompasses any use of single session Web measurement and customization technologies.

    b. **Tier 2 – Multi-Session without PII**. This tier encompasses any use of multi-session Web measurement and customization technologies when no PII is collected (including when the agency is unable to identify an individual as a result of its use of such technologies)

    c. **Tier 3 – Multi-Session with PII**. This tier encompasses any use of multi-session Web measurement and customization technologies when PII is collected (including when the agency is able to identify an individual as a result of its use of such technologies)

22. **Verifiable Parental Consent**: Verifiable parental consent means any reasonable effort (taking into consideration available technology), including a request for authorization for future collection, use, and disclosure described in the notice, to ensure that a parent of a child receives notice of the operator's personal information collection, use, and

disclosure practices, and authorizes the collection, use, and disclosure, as applicable, of personal information and the subsequent use of that information before that information is collected from that child. (*Children's Online Privacy Protection Act (COPPA) of 1998*)

23. **Web 2.0/Social Media Technology**: Web 2.0 technologies refer to a second generation of the World Wide Web as an enabling platform for Web-based communities of interest, collaboration, and interactive services. These technologies include those that exist today (listed below) as well as emerging new media technologies that will be developed in the future.

    a. **Blogs**: Web sites where regular entries are made (such as in a journal or diary) and presented in reverse chronological order. Provides the ability to disseminate a message or information to a worldwide audience.

    b. **Cloud Computing**: Uses Internet hosted applications rather than locally installed applications.

    c. **Social Networking Sites**: Web sites that connect people through online communities. Users can establish pages with their profiles and find other people they know or look for other members with similar interests or affiliations. Examples include Facebook and Twitter.

    d. **Video and Multimedia Sharing**: Web sites that use videos, images, and audio libraries to share information. YouTube is an example.

    e. **Wikis**: Collections of Web pages that encourage users to contribute or directly modify the content.

    f. **Podcasting/Vodcasting**: Publishing digital media files on the Web so they can be downloaded onto computers or portable listening devices. Users can subscribe to a "feed" of new media files and download them automatically as they are posted.

    g. **RSS Feed**: Really Simple Syndication and Rich Site Summary used to publish frequently updated (syndicated) works to multiple venues.

    h. **Mashups**: Web sites that combine content from multiple sources for an integrated experience.

    i. **Mobile Applications**: Software designed to run on handheld computers, personal digital assistants (PDAs), enterprise digital assistants (EDAs), smart

phones and cell phones.

24. **Web Measurement and Customization Technologies**: These technologies are used to remember a user's online interactions with a Web site or online application in order to conduct measurement and analysis of usage or to customize the user's experience. (Ex. persistent cookies, Web bugs, Web beacons, etc.) (OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies*)

    a. **Single-session technologies** – These technologies remember a user's online interactions within a single session or visit. Any identifier correlated to a particular user is used only within that session, is not later reused, and is deleted immediately after the session ends.

    b. **Multi-session technologies** – These technologies remember a user's online interactions through multiple sessions. This approach requires the use of a persistent identifier for each user, which lasts across multiple sessions or visits.

25. **Web Site**: A collection of interlinked Web pages (on either Internet or intranet sites) with a related topic, usually under a single domain name, which includes an intended starting file called a "home page." From the home page, access is gained to all the other pages on the Web site. (HHS Cybersecurity Program, *Standard Operating Procedures for Completing a Privacy Impact Assessment (PIA) Guide*)

E. Responsibilities:

IC and OD office staff shall comply with the privacy policies in this chapter prior to posting new or revised Web pages. For example, if an IC or OD office Web site states that the information collected will not be available to any other entity, it is the responsibility of the IC or OD office to assure that no such sharing takes place. To ensure adherence to this policy, each IC and OD office shall review all new Web sites and Web page information to be posted or altered for compliance with the NIH privacy and security policy.

The following are officials with responsibilities associated with this policy:

1. **NIH Chief Information Officer (CIO)** - The NIH CIO is responsible for the management and oversight of information technology at NIH. Specific to this policy, the NIH CIO is responsible for reviewing and approving or disapproving IC and OD office

proposals to use Tier 3 measurement and customization technology as described in section C. Policy, subsection 6 (i) (1).

2. **NIH Senior Official for Privacy (SOP)** - The OPDIV official responsible for the NIH Privacy Program. Specific to this policy, the NIH SOP is responsible for reviewing IC and OD office proposals to use Tier 3 measurement and customization technology as described in section C. Policy, subsection 6 (i) (1).

3. **NIH Chief Information Security Officer (CISO)** – The OPDIV official responsible for the NIH Information Security Program.

4. **NIH Records Officer** – The OPDIV official responsible for the NIH Records Program.

5. **Chief, NIH Project Clearance Branch** – The OPDIV official responsible for clearance of information collections under the Paperwork Reduction Act.

6. **NIH Freedom of Information Act Officer** – The OPDIV official responsible for the NIH FOIA Program.

7. **NIH Forms Officer** – The OPDIV official responsible for establishing new, or revising existing NIH forms used on Web sites to collect data.

8. **IC Privacy Coordinator** – The IC or OD office official who serves as the liaison between IC and OD staff and the NIH Senior Official for Privacy on privacy issues.

9. **IC Privacy Act System Owner/Manager** – The IC or OD office official responsible for a group of records under the control of the agency where information is retrieved by the name of the individual, by some identifying number or symbol, or by other identifiers assigned to the individual.

10. **IC Information Technology (IT) System Owner/Manager** – The IC or OD office official responsible for the development, operation and/or maintenance of an information technology system defined as an organized assembly of IT resources and procedures integrated and regulated by interaction or interdependence to accomplish a set of specified functions.

11. **IC FOIA Officer** – The IC or OD office official who serves as the liaison between staff and the FOIA Officer on issues concerning the Freedom of Information Act.

12. **IC Information Systems Security Officer (ISSO)** – The IC or OD office official who serves as the principal contact for coordination, implementation, and enforcement of information-security policies with the NIH Senior ISSO and the NIH CISO.

13. **IC Records Liaison** – The IC or OD office official who serves as the liaison between

IC staff and the NIH Records Officer in overseeing the records management program within IC or OD Office.

14. **IC Project Clearance Liaison** – The IC or OD office official who serves as the liaison between IC staff and the Office of Management and Budget for clearance functions concerning public information collection activities such as regulations, survey interviews, customer satisfaction surveys, Web site questionnaires and epidemiology research.

15. **IC Web Site Owner/Manager** – The IC or OD office official who serves as the principal contact responsible for IC Web product development and project management.

16. **IC Contracting/Project Officer** – The IC or OD office official who oversees the development of the documentation and discussions of assigned contracts for award and administration, performs the final review of contract actions, and provides final signature authority.

F. Procedures:

Online Web activities shall follow appropriate procedures and clearances. In most cases, the procedures to be followed for print publication apply unless one is posting content that has already been cleared for public use.

For other types of less formal content, such as blogs, micro blogging, and replies to comments in public online space, coordinate your activities through your supervisory channels.

At a minimum, contact the IC or OD office (1) Communications Office for approval to communicate outgoing messages on behalf of the IC or OD office and to ensure that content procedures are followed, (2) CIO Office or ISSO to learn of security procedures that shall be followed and, (3) FOIA, PRA, Records and Privacy liaisons to learn about requirements under the Freedom of Information Act, Paperwork Reduction Act, Records Act and Privacy Act.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter shall be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records", Appendix 1, NIH

Records Control Schedule, in accordance with the specific schedule item as applied to the kind of records.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered federal records. These records shall be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information. All e-mail messages are considered government property, and, if requested for a legitimate government purpose, shall be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of the Inspector General who may request access to or copies of the e-mail messages. E-mail messages shall also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

Web 2.0 Information: A challenge associated with the use of Web 2.0 technologies, including government blogs and wikis and Web pages hosted by commercial providers, is the question of whether information exchanged through these technologies constitute federal records pursuant to the Federal Records Act. According to the guidance, records generated when a user interacts with an agency Web site may form part of a set of official agency records. National Archives and Records Administration (NARA) guidance indicates that content created with interactive software on government Web sites is owned by the government, not the individuals who created it, and is likely to constitute agency records and should be managed as such. NARA issued "Guidance on Managing Web Records" to help agencies make decisions on what records generated by these technologies should be considered agency records: http://www.archives.gov/records-mgmt/pdf/managing-web-records-index.pdf

H. Internal Controls:

This policy directs ICs and OD offices to meet requirements related to privacy and the protection of personal information on NIH Web pages.

1. **Office Responsible for Reviewing Internal Controls Relative to this policy:**

Oversight shall be carried out through a coordinated effort between the Office of Management Assessment (OMA), Office of the Chief Information Officer (OCIO), and Office of Communications and Public Liaison (OCPL).

2. **Frequency of Review:**

Reviews shall be ongoing. Appropriate internal controls shall be in place before a Web page may be utilized. Web masters, content managers, developers and programmers responsible for the design, development and management of NIH Web pages are responsible for ensuring compliance with NIH policy.

3. **Method of Review:**

Each year, a workgroup of members from OMA, OCIO and OCPL shall survey a sample of NIH Web sites for compliance with NIH policy. External reviews conducted by the OIG/GAO may be used as an alternative internal control review for this purpose. Additionally, the issuing office may decide to initiate an internal Risk Assessment (RA) at the IC or OD level.

4. **Review Reports:**

Reports shall be sent to the NIH Deputy Director for Management (DDM), and circulated to NIH privacy, security and Web stakeholders, as deemed appropriate by OMA, OCIO and OCPL. Reports should indicate that controls are in place and working well, or indicate any internal control issues that require the attention of the report recipient(s).

I. References:

Laws

1. Children's Online Privacy Protection Act (COPPA) of 1998, (15 U.S.C. Section 6501 et seq., 16 CFR, Part 312): http://www.coppa.org/coppa.htm and http://www.coppa.org/comply.htm
2. Computer Matching and Privacy Protection Act of 1988, (5 U.S.C. 552a(o)):

http://www.whitehouse.gov/sites/default/files/omb/inforeg/final_guidance_pl100-503.pdf

3. Computer Security Act of 1987, (15 U.S.C. Chapter 7, 40 U.S.C. Section 1441):

   http://www.nist.gov/cfo/legislation/Public%20Law%20100-235.pdf

4. E-Government Act of 2002 (E-GOV) Section 208, (44 U.S.C. Chapter 36):

   http://frwebgate.access.gpo.gov/cgi-
   bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ347.107.pdf

5. Federal Records Act of 1950, (44 U.S.C 2108 and 31, as amended):

   http://frwebgate.access.gpo.gov/cgi-
   bin/usc.cgi?ACTION=BROWSE&TITLE=44USCC31&PDFS=YES

6. Freedom of Information Act (FOIA) of 1966, (5 U.S.C 552):

   http://www.nih.gov/icd/od/foia/efoia.htm

7. Information Technology Management Reform Act of 1996, (40 U.S.C. 1401 et seq.):

   http://www.cio.gov/Documents/it_management_reform_act_Feb_1996.html

8. Paperwork Reduction Act (PRA) of 1995, (44 U.S.C. 3501):

   http://frwebgate.access.gpo.gov/cgi-
   bin/getdoc.cgi?dbname=104_cong_public_laws&docid=f:publ13.104.pdf

9. Plain Writing Act of 2010 (5 USC 301): http://www.gpo.gov/fdsys/pkg/PLAW-
   111publ274/pdf/PLAW-111publ274.pdf

10. Privacy Act of 1974, (5 U.S.C. 552a, as amended):

    http://www.justice.gov/opcl/privstat.htm

11. Rehabilitation Act of 1998 Section 508, (29 U.S.C. Section 794d):

    http://www.section508.gov/index.cfm?fuseAction=1998Amend

OMB Circulars and Memorandum

1. OMB Circular A-130, *Management of Federal Information Resources* (November 28, 2000): http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html

2. OMB Memorandum M-99-18, *Privacy Policies on Federal Web Sites* (June 2, 1999): http://www.whitehouse.gov/omb/memoranda/m99-18.html

3. OMB Memorandum M-03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002* (Sep. 26, 2003): http://www.whitehouse.gov/omb/memoranda_m03-22/

4. OMB Memorandum M-05-04, *Policies for Federal Agency Public Web Sites* (Dec. 17, 2004): http://www.whitehouse.gov/OMB/memoranda/fy2005/m05-04.pdf

5. OMB Memorandum M-05-08, *Designation of Senior Agency Officials for Privacy* (Feb. 11, 2005): http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-08.pdf

6. OMB Memorandum M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information* (May 22, 2007): http://www.whitehouse.gov/OMB/memoranda/fy2007/m07-16.pdf

7. OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies* (June 25, 2010): http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-22.pdf

8. OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Websites and Applications* (June 25, 2010): http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-23.pdf

9. OMB, Office of Information and Regulatory Affairs, Memorandum, *Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act* (April 7, 2010): http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/SocialMediaGuidance_04072010.pdf

Federal Acquisition Regulations (FAR)

1. FAR Part 52.224-1, Privacy Act Notification: http://www.acquisition.gov/FAR/current/html/52_223_226.html#wp1168976

2. FAR Part 52.224-2, Privacy Act: http://www.acquisition.gov/FAR/current/html/52_223_226.html#wp1168981

3. FAR Part 52.239-1, Privacy or Security Safeguards: http://www.acquisition.gov/FAR/current/html/52_233_240.html#wp1113650

HHS Policy

1. HHS-OCIO Policy for Machine Readable Privacy Policies: http://www.hhs.gov/ocio/policy/hhs-ocio-2010_0001_policy_for_machine-

readable_privacy_policies.html

2. HHS-OCIO Policy for Social Media Technologies:

   http://www.hhs.gov/ocio/policy/policy_2010-0003_-_ocio.html

3. HHS-OCIO Policy for Information Systems Security and Privacy:

   http://www.hhs.gov/ocio/policy/policy-hhs-ocio-2010-0006-html.html

4. HHS-OCIO Policy for Information Systems Security and Privacy Handbook:

   http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP/pol_for_info_sys_sec_and_priv_hndbk_9-22-2010.pdf

5. HHS-OCIO Memo for the Implementation of OMB M-10-22 and 23:

   http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PC/memo_implementation_of_omb_m_10_22_and_m_10_23_pdf.pdf

6. HHS-OCIO Guide for Using Web Measurement and Customization Technologies:

   http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/guide_for_using_web_measurement_and_customization_technologies_20110720.pdf

7. HHS Policy for Internet Domain Names:

   http://www.hhs.gov/policies/webpolicies/200501.html

8. HHS Policy for Section 508 Compliance:

   http://www.hhs.gov/od/508policy/508_policy.html

NIH Policy

1. NIH Manual Chapter 1186, *Use of NIH Names and Logos*:

   http://oma.od.nih.gov/manualchapters/management/1186

2. NIH Manual Chapter 1743, *Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule*: http://oma.od.nih.gov/manualchapters/management/1743/

3. NIH Manual Chapter 1745, *NIH Information Technology (IT) Privacy Program*:

   http://oma.od.nih.gov/manualchapters/management/1745/

4. NIH Manual Chapter 1745-1, *NIH Privacy Impact Assessments*:

   http://oma.od.nih.gov/manualchapters/management/1745-1/

5. NIH Manual Chapter 1825, *Information Collection from the Public*:

   http://oma.od.nih.gov/manualchapters/management/1825

6. NIH Manual Chapter 2804, *NIH Public-Facing Web Management*:

http://oma.od.nih.gov/manualchapters/management/2804

7. NIH Manual Chapter 2809, *NIH Social and New Media*:
http://oma.od.nih.gov/manualchapters/management/2809

NIH Guidance

1. NIH Web Authors Group Policy & Guidance on Web Site Development, Management, and Evaluation: http://www.nih.gov/icd/od/ocpl/resources/wag/index.htm
2. NIH, OCPL Guidance on Developing Web Sites at NIH:
http://www.nih.gov/icd/od/ocpl/resources/wag/documents/Developing_Issues.htm

National Archives and Records Administration (NARA)

1. National Archives and Records Administration, Guidance on Managing Web Records:
http://www.archives.gov/records-mgmt/pdf/managing-web-records-index.pdf
2. NARA Bulletin 2011-02, Guidance on Managing Records in Web 2.0/Social Media Platforms: http://www.archives.gov/records-mgmt/bulletins/2011/2011-02.html

Appendix 1 – Form To Request HHS Approval Of Tier 3 Technology:

FORM TO REQUEST HHS APPROVAL OF TIER 3 TECHNOLOGY

of a Multi-Session Web Measurement and Customization Technology that Collects Perso

ormation Form

anagement and Budget (OMB) instructions found in Memorandum 10-22 *Guidance for Online U*

nd Customization Technologies (June 25, 2010), the following information serves as public noti

y the United States Department of Health & Human Services of a Tier 3 a multi-session Web m

on technology that collects personally identifiable information (PII).

r Agency Official for Privacy (SAOP) will post this notice for public comment on the Department

eb page (www.hhs.gov/open) for 30 days from the date of the posting.

ut the proposed use can be submitted electronically or in writing. Electronic comments should b

. Written comments should be directed to: **HHS Senior Agency Official for Privacy, 200** **ependence Ave. S.W., Room 555-G, Washington, D.C. 20201**

DIV	
DIV Chief Information Officer (CIO)	
DIV CIO Approval Date	MM/DD/YYYY
S Senior Agency Official for Privacy	
e posted for public comment	MM/DD/YYYY
purpose of the Web measurement and/or tomization technology	
usage tier (i.e., Tier 1, 2, or 3)	
sion Type (multi-session or single session)	
rmation about the technology used	
cribe the nature of the information collected	
cribe the purpose and use of the information	
cribe whether and to whom the information will disclosed	
cribe the privacy safeguards applied to the rmation	
cribe the data retention policy for the rmation	
ne of the Privacy Impact Assessment associated the Web site or application using the Web asurement and/or customization technology	
ne of the System of Records Notice associated the Web site or application using the Web asurement and/or customization technology (if licable)	
cribe whether or not the technology is enabled	

default; and if so, why	
scribe how to opt-out or opt-in to the Web asurement and/or customization technology	
scribe how a member of the public can access nparable information or services if they choose to out of the Web measurement /or customization technology	
ntities of all third-party vendors involved in the asurement and/or customization process	

Appendix 2 – Contract Sample Language:

CONTRACT SAMPLE LANGUAGE

A. When FISMA security requirements relevant to the acquisition need to be included, the project Officer (PO), IC Information Systems Security Officer (ISSO), and the IC Privacy Officer will assist the acquisition staff in selecting the appropriate language. NIH sample language for IT Security Acquisitions Provisions are available at: https://ocio.nih.gov/InfoSecurity/Policy/Pages/ContractingInformation.aspx

B. Solicitations and contracts (prime and sub) to design, develop, operate or manage a Web site or Web page on behalf of the government which requires the contractor to maintain a system of records covered by the Privacy Act, shall state that the Privacy Act applies and include the appropriate FAR clauses:

Privacy Act Notification

FAR, Sec. 52.224-1

The Contractor will be required to design, develop, or operate a system of records on individuals, to accomplish an agency function subject to the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 U.S.C. 552a) and applicable agency regulations. Violation of

the Act may involve the imposition of criminal penalties.

Privacy Act FAR, Sec. 52.224-2

(a) The Contractor agrees to--

(1) Comply with the Privacy Act of 1974 (the Act) and the agency rules and regulations issued under the Act in the design, development, or operation of any system of records on individuals to accomplish an agency function when the contract specifically identifies--

(i) The systems of records; and
(ii) The design, development, or operation work that the contractor is to perform;

(2) Include the Privacy Act notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation, when the work statement in the proposed subcontract requires the design, development, or operation of a system of records on individuals that is subject to the Act; and

(3) Include this clause, including this subparagraph (3), in all subcontracts awarded under this contract which requires the design, development, or operation of such a system of records.

(b) In the event of violations of the Act, a civil action may be brought against the agency involved when the violation concerns the design, development, or operation of a system of records on individuals to accomplish an agency function, and criminal penalties may be imposed upon the officers or employees of the agency when the violation concerns the operation of a system of records on individuals to accomplish an agency function. For purposes of the Act, when the contract is for the operation of a system of records on individuals to accomplish an agency function, the Contractor and any employee of the Contractor is considered to be an employee of the agency.

(c)

(1) Operation of a system of records, as used in this clause, means performance of any of the activities associated with maintaining the system of records, including the collection, use, and dissemination of records.

(2) Record, as used in this clause, means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and that contains the person's name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint or voiceprint or a photograph.

(3) System of records on individuals, as used in this clause means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

<div align="center">

Privacy or Security Safeguards
FAR Sec. 52.239-1

</div>

(a) The Contractor shall not publish or disclose in any manner, without the Contracting Officer's written consent, the details of any safeguards either designed or developed by the Contractor under this contract or otherwise provided by the Government.

(b) To the extent required to carry out a program of inspection to safeguard against threats and hazards to the security, integrity, and confidentiality of Government data, the Contractor shall afford the Government access to the Contractor's facilities, installations, technical capabilities, operations, documentation, records, and databases.

(c) If new or unanticipated threats or hazards are discovered by either the Government or the Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately bring the situation to the attention of the other party.

<div align="center">

Applicability of the Privacy Act
HHSAR Sec. 324.102

</div>

(f) Whenever the contracting officer is informed that the Privacy Act is not applicable, but the resultant contract will involve the collection of individually identifiable personal data by the contractor, the contracting officer shall include provisions to protect the confidentiality of the records and the privacy of individuals identified in the records.

Confidentiality of Information HHSAR Sec. 352.224-70

(a) Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

(c) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(d) Confidential information, as defined in paragraph (a) of this clause, shall not be disclosed without the prior written consent of the individual, institution, or organization.

(e) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(f) Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

(g) The provisions of paragraph (d) of this clause shall not apply to conflicting or overlapping provisions in other Federal, State, or local laws.

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term ``system of records'' means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a (i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a (m) (1)).

The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

Additional Contract Language:

1. Under Federal Information Technology policy, Web sites owned or operated by or for the government shall post clear privacy policies on top-level/principal Web sites, including NIH and Institute/Center-level sites, major on-line public resource sites and any other known major entry points. Web sites that are owned or operated by a contractor on behalf of the NIH that implement and use mechanisms that collect and maintain personally identifiable information from individuals who visit the Web site, e.g., cookies, Web server logs, surveys, and similar mechanisms, may not use that information to identify specific individuals without a valid Privacy Act System Notice published in the Federal Register, which covers the identifiable records.

2. NIH IC and OD office Web pages containing links to external Web pages not located on

NIH servers should include a link to an Exit statement that disclaims NIH responsibility for the protection of privacy and material included in the external Web pages. Sample Disclaimers are available at: https://ocio.nih.gov/aboutus/Pages/disclaimer.aspx

3. Web pages that are directed to children under the age of 13 have additional requirements as provided in the Children's Online Privacy Protection Act of 1998 (15 U.S.C. 6501 et seq.), and implementing regulations (16 CFR 312) available at: http://www.coppa.org/coppa.htm

NIH POLICY MANUAL

2806 – Limited Authorized Personal Use of NIH Information Technology (IT) Resources

Issuing Office: CIT/ODCIO 402-4463

Release Date: 02/08/02

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1. **Explanation of Material Transmitted:**

   This policy provides for expanded personal use of NIH-owned information technology (IT) resources by NIH staff as authorized in DHHS policy HHS-IRM-2000-0003, "Personal Use of Information Technology Resources." The August 14, 1996, NIH policy on appropriate use of NIH email and Internet is also superseded by this issuance. This policy is intended to allow the maximum flexibility possible for using NIH IT resources without compromising the integrity of NIH and/or its IT resources. NIH Institutes and Centers (IC) may use this policy to develop their own internal policies and may apply additional or more stringent controls on the use of IC IT resources by their respective IC staff, as appropriate. IC-developed policies and procedures should not be implemented until the labor unions, if applicable, have been provided notice of the proposed changes and given the opportunity to fully exercise their representational rights.

2. **Filing Instructions:**

   Remove: None.

   Insert: NIH Manual Chapter 2806 dated 02/08/02.

PLEASE NOTE: To sign up for email notification of future changes, please go

to the [NIH Manual Chapters LISTSERV](#) Web page.

A. Purpose:

The purpose of this issuance is to establish the policy for limited authorized personal use of NIH-owned information technology (IT) resources by NIH staff. This policy applies to the use of NIH IT resources regardless of location (e.g., office, home, on travel, field locations, telecommuting sites, etc.).

This policy shall be in effect for all NIH staff (defined in section E.) and is intended to allow the maximum flexibility possible for using NIH IT resources without compromising the integrity of NIH and/or its IT resources. NIH Institutes and Centers (IC) may use this policy to develop their own internal policies and may apply additional or more stringent controls on the use of IC IT resources by their respective IC staff, as appropriate. IC-developed policies and procedures should not be implemented until the labor unions, if applicable, have been provided notice of the proposed changes and given the opportunity to fully exercise their representational rights.

This policy replaces the August 14, 1996, NIH policy on use of NIH email and Internet previously located on the CIT Management Policy webpage. However, this policy does not impact the utilization of the Internet to acquire information for official NIH or IC business, nor does it supersede existing policies or agreements concerning the use of voice communications devices. Further, this policy does not supersede any other applicable law or higher-level agency directive, policy guidance, or existing labor management agreement in effect as of the effective date of this policy.

B. Background:

The mission of NIH requires its staff to have access to certain NIH-provided IT resources to support official programmatic and administrative duties. NIH IT

resources are intended for official use; however, NIH staff are authorized to use NIH-owned IT resources, such as workstations, printers, electronic mail, and other IT resources listed in section E.3. for limited personal use as authorized in this policy.

C. Policy:

1. **General**

For the purposes of this chapter, the term 'staff' is inclusive of all persons working for NIH in a non-contract position (See listing of "NIH staff" types in section E.5.). Contractors may be permitted the same limited use of government IT resources with written approval of the responsible contract project officer (COR/COTR). Authorization and scope of use, and disciplinary action for misuse, shall be specifically addressed in the contracting document(s).

In summary, NIH staff are permitted limited personal use of authorized IT resources if the use (1) is incidental and involves minimal additional expense to the government, (2) does not interfere with staff productivity, the NIH mission or operations, (3) is not used to misrepresent oneself or NIH, (4) does not have the potential to cause public embarrassment to NIH, (5) does not compromise the integrity of any NIH system or system security safeguards, and (6) does not violate federal laws or policies or any provisions of this policy or other NIH policies. (See section C.3. for specific examples of prohibited uses.)

Limited or incidental personal use of NIH IT resources by staff during non-work time is considered to be "authorized use" of government property as that term is used in the Standards of Ethical Conduct for Employees of the Executive Branch. Limited personal use is a privilege and staff are expected to use professional judgment, follow rules and regulations and to be responsible for their own personal and professional conduct while using these IT resources.

NIH managers are responsible for ensuring that they and their staff are

aware of this policy with respect to the unauthorized use of IT resources, and for taking appropriate and immediate action–as described in section C.5. of this chapter–when unauthorized or inappropriate use of IT resources is suspected or known.

2. **Federally Prohibited Uses**

Use of NIH IT resources are subject to federal laws and regulations including, but not limited to:

- Anti-Lobbying Statutes, e.g., Lobbying Congress on behalf of causes, individuals, or organizations; promoting or conducting political activities;
- Copyright Act, e.g., violating copyrights or software licensing agreements by installing, downloading, or copying (in whole or in part) copyrighted materials in any format;
- Privacy and Freedom of Information Acts, e.g., accessing or using information inappropriately which is protected by the Privacy Act, or other federally mandated confidentiality provisions including the release of trade secrets, confidential business information, and other government information that is not available to the public;
- Standards of Ethical Conduct for Employees of the Executive Branch, e.g., making use of NIH IT resources for commercial purposes or in support of **for profit** activities, e.g., running a private business. See the detailed listing of "Principles of Ethical Conduct" available on the [NIH Office of Government Ethics web site](); and,
- Other illegal activities or activities otherwise prohibited by federal regulations, including creating, downloading, intentionally viewing, storing, copying or transmitting materials that exhibit or imply involvement with gambling, illegal weapons or drugs, child pornography, terrorism, and related activities.

3. **Other Prohibited Uses**

NIH staff shall not use NIH IT resources and systems in any manner that is prohibited by policy, causes unnecessary costs, congestion, disruption, or damage to government IT services, systems or equipment, or in a manner that demeans other staff, groups, individuals, and organizations, including:

- Using large amounts of bandwidth (data transmission exchange) for activities that are not related to NIH business, professional development, or is needed to accommodate staff with disabilities in accordance legislative mandates. Such prohibited activities that use large amounts of bandwidth include: sending chain letters, e-mailing or downloading large files, e.g., music, graphics, games, videos, etc., using continuous on-line connections for data or video streaming, interactive/on-line games, music, or other similar activities;
- Intentionally or unintentionally permitting the use of NIH IT resources by unauthorized persons, e.g., friends, family or others;
- Overriding or avoiding NIH security and system integrity procedures and devices or using NIH systems as staging ground to compromise the security of NIH and non-NIH systems;
- Intentionally accessing, viewing, disseminating, or storing offensive or disparaging information or graphical depictions, including hate, sexually explicit, violent, or racist materials;
- Installing and using hardware and/or software that is not in accordance with NIH or IC internal guidance. ICs should develop approval policies/processes that allow staff who need to add software and hardware as a part of their jobs to do so. Blanket authority can be granted, where/when appropriate, so that approval would not be required for each action.
- Conducting or participating in fund drives or monetary charitable events. The Combined Federal Campaign is the only authorized

solicitation of federal employees for money.

- Creating, receiving, transmitting, or storing any information that is considered 'classified' which could potentially compromise national security and/or cause public alarm (e.g., unconfirmed health epidemic);
- Establishing personal and/or non-work-related web sites or bulletin board systems;
- Using NIH logos or titles to misrepresent personal materials or intentionally misrepresenting, either implicitly or explicitly, personal views or comments in electronic forums or e-mail as official NIH or IC policy or position.

Also, see "[NIH Information Technology General Rules of Behavior](#)" for more detailed information on the appropriate use of NIH IT resources plus useful guidance on effectively safeguarding NIH IT resources on- and off-site.

4. **Privacy Expectations**

Staff cannot expect a right to privacy while using government-provided IT resources or equipment at any time, including during authorized personal use time.

NIH system administrators, agency officials, and supervisors and other authorized individuals, may access information, files, materials and messages which reside in hardware or software used by staff if there is reasonable suspicion that an individual is using NIH IT resources in an unauthorized or illegal manner.

Further, in the legitimate performance of their duties, e.g., technical, administrative, or legal reasons, authorized persons may access files, etc., for business purposes.

5. **Disciplinary Action for Misuse**

Individuals who abuse these resources, knowingly interfere with the operation of federal IT systems, or otherwise fail to comply with the provisions of this policy are subject to loss of associated privileges, may be held financially liable for any costs associated with the improper use, and/or may be subjected to disciplinary action, and/or criminal penalties.

Incidents of inappropriate, unauthorized, or risky use will be reported to the immediate staff supervisor, who will report the incident to the IC Executive Officer (EO), as appropriate. The EO will make the initial assessment of the reported action and determine the appropriate course of action. The EO may involve the IC CIO (or equivalent), IC Information Systems Security Officer (ISSO), and the NIH Incident Response Team (IRT), as appropriate, if matter involves risk to NIH IT resources. Matters involving inappropriate staff conduct on NIH IT resources should be reported to the IC Human Resource Management Officer for guidance on further disciplinary action, depending on the nature or seriousness of the misuse conduct.

Incidents involving the violation of laws or regulations or matters that pose potential public embarrassment to the NIH shall also be reported by the EO to the NIH Chief Information Officer, and the NIH Deputy Director for Management (DDM).

If management determines that disciplinary action is warranted against an individual, action shall be pursued through the established adverse action/progressive disciplinary process prescribed in NIH human resources policy. Proposing/Deciding Officials should refer to the information provided at the OHR website and consult with their respective HR Office. The following table describes the suggested penalties that may be imposed on staff for cases of misuse of NIH IT resources.

Suggested Penalties for Misuse of Electronic Resources [1]

Nature of Misconduct: using or allowing the use of government property or

government leased property of any kind (including equipment, supplies, services, information technology resources (including the internet, etc.) for other than authorized activities

First Action: reprimand to 14-day suspension
Second Action: 7-day suspension to removal
Third Action: removal

Nature of Misconduct: using NIH information removal technology resources for downloading or storage of child pornography purposes will result in an immediate proposal of removal and referral for prosecution.

First Action: removal

[1] Excerpted from NIH Table of *Suggested* Penalties. For more information on appropriate action/penalties for misuse, contact your respective human resources office.

D. References:

1. [HHS IRM Policy for Personal Use Of Information Technology Resources](#)
2. [Principles of Ethical Conduct for Government Officers and Employees](#)
3. [NIH Information Technology General Rules of Behavior](#)
4. [NIH Policy Manual 2810, NIH Remote Access Policy](#)
5. [NIH Policy Manual 26101-25-2-2, Personal Property Management Guide: Authorities and Responsibilities in Personal Property](#)
6. [NIH Policy Manual 2204, Reasonable Accommodations](#)
7. [Section 508 of the Rehabilitation Act, as amended by the Workforce Investment Act of 1998](#)
8. 5 CFR 2635 Section 101: Basic Obligation of Public Service; Section 704, Use of Government Property; Section 705, Use of Official Time
9. 17 USC, Copyrights, Sections 106-110, Exclusive Rights and Limitations
10. 18 USC 1913, Lobbying With Appropriated Moneys
11. 45 CFR 5, Freedom of Information Regulations

12. 45 CFR 5b, Privacy Act Regulations
13. 41 CFR 101-35.201, Telecommunications Management Policy, Authorized Use of Long Distance Telephone Services
14. OMB Circular A 130, Appendix III, Security Of Federal Automated Information Resources

E. Definitions:

1. **Authorized use:** Use of government/NIH-provided IT resources as permitted in this policy, IC-internal policies or as specifically authorized by management.
2. **Bandwidth:** The capacity of a networked connection to send data along the networked wires.
3. **IT resources:**
   a. **may include:** personal workstations and related peripherals and software, personal digital assistants (PDAs), telephones, facsimile machines, photocopiers, connectivity for access to Internet services and electronic mail and needed supplies for IT equipment. See [NIH Manual 2810](#), NIH Remote Access Policy, for special requirements for acquiring and managing remote access to the NIHnet.
   b. **may not include unless specifically authorized:** medical, laboratory, and other valuable equipment, e.g., videoconferencing equipment, supercomputers, and desktop publishing equipment.
4. **Minimal additional expense:** Use is limited to those situations where the government is already providing equipment or services and the staff's use of such equipment or services will not result in loss of employee productivity, interfere with official duties or other than "minimal additional expense." Examples include: limited communications costs for voice (telephones), data, or video image transmission, use of paper, ink, toner or other consumables in limited amounts, general wear and tear on equipment, data storage on storage devices; and transmission impacts

with moderate e-mail message sizes, such as e-mails with small attachments.

5. **NIH staff:** For the purposes of this chapter, includes: personnel employed by the Federal Government under a career or career-conditional appointment, guest researchers, adjunct investigators (volunteers), individuals on temporary appointments (including student appointments), Fogarty International Center scholars, Special Experts, Visiting Fellows, Intramural Research Training Award fellows, IC fellowship award recipients, research fellows, research fellows (VP) and clinical fellows, clinical fellows (VP), volunteers and special volunteers, and Commissioned Corps personnel.

6. **Personal or non-work time:** times when the staff are not otherwise expected to be conducting official business. Staff may, for example, use government office equipment during their own off-duty hours such as before or after a workday, lunch periods, authorized breaks, or weekends or holidays.

7. **Personal use:** authorized activity that is conducted for purposes other than accomplishing official or government business. **Sexually explicit material:** obscene or pornographic in nature; depiction of human nudity and other provocative material that could be viewed as offensive to other staff or could be perceived as sexual harassment. Note: Any activity involving child pornography is a criminal offense and will be referred to the Office of Inspector General, as appropriate.

8. **Religious Expression:** May be restricted under the following conditions: a. when/where it interferes with employee's work performance or creates a hostile work environment or could be viewed as harassing by other employees; b. when work time is used to pursue religious or ideological agendas; c. when/where it creates the impression that government is endorsing or sponsoring a particular religion or religious ideology.

9. **IC system manager:** Individual within the IC who is the primary contact with oversight responsibility for an automated information system (AIS)

facility or operation and any related issues. This usually includes an organizationally defined set of personnel, hardware, software, communications, and physical facilities ' a primary function of which is the operation of an AIS and an application system(s). As applicable, a system manager is responsible for the management of a major IC application system, workstations, and distributed computing applications, including local and wide-area networks. System managers are also involved with security considerations in applications systems development, implementation, and operation and maintenance activities.

F. Responsibilities:

1. Supervisors shall:
   - ensure that employees have a copy of this NIH policy and, if available, their IC personal use policy, and for advising employees to be familiar with the information.
   - ensure that staff using IT resources off-site have been issued, and keep current, necessary government property passes and are aware of all relevant property regulations for the property.
   - include information regarding the appropriate use of NIH IT resources in relevant orientation materials.
   - restrict a staff's right to use government equipment for personal use if his/her use conflicts with any federal policies, is excessive, or interferes with official government business.
   - report to IC EO, incidents of misuse that are of a serious nature or are unlawful.
2. NIH staff shall:
   - be familiar with the provisions of this policy and, if applicable, their respective IC personal use policy.
   - use IT resources for authorized purposes as set forth in this policy and other related NIH policies, including any IC-developed internal policies.

- refrain from using the equipment that in any way compromises federal or agency policy on privacy, Standards of Conducts, copyright laws, etc.
- protect all government IT resources made available to them from unauthorized use or access by other persons, and from damage or theft (see NIH Information Technology General Rules of Behavior).
- request approval from IC system manager to make changes to equipment configurations, including the loading of software or downloading free software from outside sources and connecting other peripherals, e.g., scanners, digital cameras, etc., to government equipment.
- obtain necessary approvals and property passes for equipment that is to be used off-site.
- consult with their supervisor on any questions relating to appropriate use practices of their respective office.

3. IC System Managers shall:
- remind NIH users of their responsibilities for appropriate personal use with system log-on messages on a regular frequency.
- approve or disapprove staff requests to install or download software or connect other equipment to government equipment that is outside the standard system configuration. IC System Managers need to assess the potential impact on the system before approval and/or to assist the individual in identifying an alternative means to accomplish the intended goal or to adjust the system to accommodate his/her needs prior to actions being taken that may interfere with the work of many individuals.
- ensure the security of the computer systems which staff use and as well as those computer systems which he/she operates or administers.
- take the necessary actions(s) for assuring that user access is

rescinded when it is no longer needed, e.g., when a user's employment with the IC ends or when otherwise advised by management.

- report suspected misuse of IT resources to IC EO (and the IC CIO (or equivalent) as needed, who can advise on the technical aspects of the situation) and take appropriate action to respond to incidents as advised by IC senior management.

- provide guidance or clarification to IC managers and staff, as requested, on technical issues or questions related to the use of NIH IT resources.

4. IC Executive Officers shall:

- make an initial assessment of the any reported incidents of inappropriate, unauthorized, or risky use and determine the appropriate course of action as described in section C. 5. above.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records, Appendix 1, "NIH Records Control Schedule," Section 1100-M-1 – General Administrative Files at IC and Lower Levels.

NIH e-mail messages. NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks, that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages

must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

H. Internal Controls:

The purpose of this manual issuance is to establish policy for appropriate personal use of NIH IT resources by staff.

1. **Offices Responsible for Reviewing Management Controls Relative to this Chapter*:**
   The CIT Office of the Deputy Chief Information Officer (ODCIO) will be responsible for communicating to IC senior management the policy on appropriate use of IT resources and for the review (and correction and reporting, as needed) of issues that are raised to the NIH level in accordance with section C. 5. of this chapter.

   The NIH ICs will be responsible for ensuring that management controls are implemented in accordance with this policy and for the review of (and correction, as needed) issues that do not warrant NIH-level review or action.

2. **Frequency of Review:** Ongoing.
3. **Method of Review:**

   IC supervisors are responsible for reviewing and maintaining information they receive related to inappropriate use of IT resources by staff, and for taking appropriate action that includes reporting incidents, when appropriate, to the IC EO.

   Incidents involving serious risk to NIH IT resources through improper

staff use will be reported by the IC to the NIH Incident Response Team (IRT). Reports of findings and recommendations resulting from IRT reviews will be issued to the IC EO. The EO will consult with the IC CIO (or equivalent) and IC ISSO, as necessary, to determine appropriate action.

The IRT, through the NIH ISSO, will prepare and submit reports of activities that are allegedly illegal, or have the potential to cause embarrassment to the NIH, to the NIH CIO and the NIH DDM for review and approval of any actions required.

Recurring issues that indicate a possible policy or material weakness in the management of staff personal use of IT resources will be brought to the attention of the NIH Chief Information Officer (CIO) and, if necessary, the NIH Information Technology Management Committee (ITMC) for discussion and corrective action at the NIH level. Corrective actions may include: (1) a request for IC system managers to conduct a review of computer activity to identify the magnitude of a frequently identified problem and/or (2) revisions to this policy.

4. **Review Reports are sent to:** DDM

*Also see Internal Control Review information contained in NIH Manual Chapters covering the use of specific NIH IT Resources, e.g., Cellular Telephone Services And Equipment, Remote Access to the NIH Network, etc.

NIH POLICY MANUAL

2807 – NIH Wireless Network Policy

Issuing Office: CIT/ODCIO 301-402-4457

Release Date: 01/24/03

1. **Explanation of Material Transmitted:** This document establishes the policy for the deployment and use of wireless network technology at the NIH. This policy implements procedures to protect NIH resources and data from security threats, improve incident response for wireless issues, and mitigate interference among wireless technologies.

   This policy applies to all NIH personnel, contractors and visitors that have access to NIH facilities or NIH information. Further, it applies to all wireless network access devices and technologies that provide a bridge between wireless and wired networks or any device that is designed to communicate with such a device via the wireless network.

2. **Filing Instructions:**

   Remove: None.
   Insert: NIH Manual Chapter 2807 dated 01/24/03.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-4606, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This document establishes the policy for the deployment and use of wireless network technology at the NIH. It is intended to provide procedures to protect NIH resources and data from security threats, improve incident response for wireless issues, and mitigate interference among wireless technologies.

This document establishes policies for wireless network access services implemented within the NIH. It applies to all NIH personnel, contractors and visitors that have access to NIH facilities or NIH information. It applies to all wireless network access devices and technologies that provide a bridge between wireless and wired networks (hereafter "access points"), or any device that is designed to communicate with such a device via the wireless network (hereafter "access clients").

B. Background:

Wireless network devices offer a simple, convenient, and inexpensive solution to extend network accessibility by reducing the requirements of physical infrastructure. Wireless networking removes the encumbrance of wire connections on portable devices, and can also enable laptop and handheld users the ability to travel beyond traditional network boundaries (e.g. between buildings) without losing network connectivity.

In addition to the inherent risks associated with any wired network, wireless technology introduces several unique vulnerabilities. Since wireless signals are radio transmissions, they can be intercepted by suitable radio receiving devices, sometimes even devices operating outside the intended service area. If data transmissions are not encrypted or are inadequately encrypted, the intercepted data can be read and understood in a matter of seconds. Any data transmission sent through the wireless network is at risk, including research correspondence, usernames and passwords, financial data, and other sensitive information. Because wireless transmissions circumvent traditional perimeter firewalls, those existing protections established to prevent unauthorized access are ineffective. Advances in wireless signaling technology may increase transmission distances, further exacerbating the problem of unauthorized

reception.

Exposure of sensitive data is not the only concern for the NIH. If improperly implemented, a wireless network allows an unauthenticated user an NIH IP address with all the benefits offered to any authenticated user. Using one of these trusted IP addresses, attacks could be launched against the NIH or any outside network accessible through NIHnet. Web sites devoted to open access points throughout the country are expanding and may eventually include open access points ("hot spots") within the NIH.

Since wireless network devices operate using radio signals, their proliferation at the NIH can lead to Radio Frequency Interference (RFI) among these devices and other radio devices using the same frequency bands.

This policy serves as the foundation for a comprehensive risk mitigation strategy; enhanced by published security standards, best practice documents and, where applicable, more granular IC-specific policy.

C. Policy:

1. **Registration of Wireless Devices**
   - Registration of access clients is not required unless the same device is configured as an access point.
   - All wireless network access points must be registered with a Central Wireless Device Database managed by CIT at the time of deployment in the NIH environment. CIT will provide a secure web interface for the IC Information System Security Officer (ISSO) or designated IC personnel to add, change and remove wireless devices on any NIHnet-connected network (including contractor sites).
   - CIT, in cooperation with the IC ISSO, will establish general risk mitigation strategies for access points, users and client devices such as virus protection, password standards, and other preventative measures.
   - Prior to deployment, access points must meet the standards of current security audits established by the CIT and the IC ISSOs and published in the "NIH

Wireless Network Security Standards" document.

- Only approved and registered access points will be deployed within the NIH. Unapproved (rogue) devices may be removed from service by CIT in coordination with the IC's ISSO.

2. **Management and Security of Access Points**

- *Physical Security*: Access points should be properly secured within a safe, adequately monitored area to prevent unauthorized access and physical tampering. Devices should not be placed in easily accessible public locations.

- *Configuration Management*: All wireless access points must be secured using an administrative password per the password requirements in the NIH Account Lifecycle Policy (see https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Account_Lifecycle_Policy.doc.) Administrators must ensure all vendor default usernames and passwords are removed from the device. Administration of the device should be prohibited from the wireless network.

3. **Broadcast Security and Encryption**

- CIT, in coordination with the IC ISSOs, will provide an updated standards list that will include approved wireless technologies, current minimum encryption standards, and best practices for secure installations.

4. **Access to NIH Facilities and Data**

- Once authenticated to an access point, users must either be routed outside the NIH firewall(s), or authenticated to an NIH network. Just as with a wired network, NIH network authentication--whether NIH-wide or IC-specific-- must satisfy prescribed login/password combinations prior to using NIH or IC-specific resources that are not normally accessible by nodes outside the NIH firewall(s).

- Access control mechanisms such as firewalls should be deployed to separate the wireless network from the internal wired network.

- As the technology permits, wireless networks should employ a combination of layered authentication methods to protect sensitive, proprietary, and patient information.

5. **Naming Conventions**

- Final device names are assigned during the registration process to avoid conflicts and confusion, and to aid the Incident Response Team (IRT) and IC ISSOs in identifying and locating wireless devices.
- If technology allows for the broadcast of a device name, standardized names shall appear in the broadcast description, along with any unique identifiers assigned to the unit.

6. **Disruption and Interference**
- All newly deployed wireless technologies must satisfy all existing and future standards as required by law or established by the NIH Spectrum Management Team (see section F. RESPONSIBILITIES of this policy).
- The NIH CIO, in coordination with the NIH Information Technology Management Committee (ITMC), will resolve any conflicts between wireless devices. Priority is granted to fully supported and registered installations, except in the case of medical, safety, or emergency devices, as appropriate.

D. References:

1. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P) Policy and Handbook - http://www.hhs.gov/ocio/policy/hhs-ocio-2011-0003.html and http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP /pol_for_info_sys_sec_and_priv_hndbk_20110707.pdf

2. NIH Information Technology General Rules of Behavior – https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx

3. NIH Limited Authorized Personal Use of NIH Information Technology Resources – http://oma.od.nih.gov/manualchapters/management/2806/

4. DHHS Policy for IT Security for Remote Access – http://www.hhs.gov/ocio/policy/2000-0005.html

5. NIH Remote Access to the NIH Network – http://oma.od.nih.gov/manualchapters/acquisitions/26101-26-08/

6. NIH Remote Access Standards – https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FI

[NAL.doc](NAL.doc)

7. NIH Account Lifecycle Policy –

   https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Account_Lifecycle_Policy.doc

8. NIH Warning Banner Policy –

   https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Warning_Banner_Policy-FINAL.doc

9. Privacy Act – The Privacy Act of 1974, 5 U.S.C. § 552a (as amended)

E. Definitions:

1. **NIH Firewall** – A network device used to block unauthorized network traffic from entering NIHnet.

2. **NIHnet** – The name used to designate the NIH backbone computer network and all subnetworks attached to the NIH backbone.

3. **Service Set Identifiers (SSID)** – A unique identifier attached to the header of packets sent over a LAWN (Local Area Wireless Network). It is primarily intended to differentiate LAWNs, but also acts as a rudimentary password.

4. **Wireless** – A technology that permits the transfer of information (active or passive) between separate points using electromagnetic waves rather than a physical connection.

F. Responsibilities:

1. **NIH Chief Information Officer (CIO)**
   a. develops and implements NIH-wide policy for wireless devices and is ultimately responsible for the safety and security of the NIH Enterprise Network.
   b. (or designee) must approve all exceptions to this policy.

2. **NIH Information Technology Management Committee (ITMC)**
   a. provides broad level oversight and guidance on this policy and wireless operations.
   b. serves as the review and advisory body for the development and implementation of the actions required by this policy.

3. **NIH Senior Information Security Officer (ISSO), CIT**

a. ensures the technical security of the NIH Enterprise Network.

    b. implements this policy by providing detailed monitoring of this policy, enforcement tools, and procedures.

4. **IC CIOs** are responsible for the overall control and supervision of each IC-specific wireless implementation, and for IC compliance with this policy.

5. **IC ISSOs**

    a. serve as IC's point of contact for receiving alerts and other notifications that result from the enforcement of this policy.

    b. enforce compliance of this policy within their respective ICs. ICs are encouraged to designate a specific e-mail address and phone number for 24 x 7 notification.

6. **Incident Response Team (IRT)**

    a. in cooperation with the IC ISSOs, will regularly scan the RF spectrum for vulnerable and/or unregistered wireless devices.

    b. will coordinate with IC ISSOs in the event of a possible system compromise.

7. **NIH Spectrum Management Team**

    a. will maintain the list of acceptable RF frequencies and wireless technologies.

    b. will conduct periodic spectrum analysis to assess the potential impact of electromagnetic interference (EMI) from transmitters and the impact of electromagnetic emissions from wireless devices.

8. **Technical Assistance Support Center (TASC), CIT**, will provide educational resources and instructional materials to support the deployment of wireless technology within the NIH.

G. Procedures:

Registration process

At the time of deployment, all wireless devices will be registered with the Central Wireless Device Database. Registration information will include, but is not limited to, the following information:

- Contact information for owner and responsible parties
- Location of devices

- Intended use and coverage area
- Type of wireless technology deployed
- Manufacturer name and model number
- Device description
- SSID/ESSID (or equivalent)
- Hopping sequence (if applicable)
- Security checklist responses

Security Auditing and Intrusion Detection

Device installers must ensure the wireless device is properly secured prior to deployment. Once deployed, the responsible ISSO shall perform a security analysis using current wireless security methods. All wireless devices must meet the minimum security requirements dictated by NIH policies.

Incident Handling Process

Coordination between the IRT, IC ISSOs, and other designated parties will follow existing and future guidelines available through the IRT Web site.
https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/index.aspx

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records", Appendix 1, "NIH Records Control Schedule," Section 2800 which covers all aspects of Data Processing.

NIH e-mail messages. NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks, that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate

Government purpose, must be provided to the requester. NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Internal Controls:

The purpose of this manual issuance is to establish policy for appropriate personal use of NIH IT resources by staff.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter (Issuing Office):** Office of the Deputy Chief Information Officer, CIT
2. **Frequency of Review (in years):**

   A wireless management plan is in place to address wireless security at NIH.

   - *Internal review of controls* relevant to wireless security will be performed on an *ongoing basis* as new technologies emerge and new areas of concern present themselves, and the existing management plan will be updated.
   - *Security controls* applied to wireless technologies at NIH will be reviewed *annually* as part of the Government Information Security Reform Act (GISRA) review of the entire NIH security program.
3. **Method of Review:**

   In accordance with section **G. PROCEDURES** of this policy, the following controls are implemented. Further, NIH reviews of wireless technology security will be conducted in accordance with the NIH Wireless Network Security Standards located at http://irm.cit.nih.gov/policy/wirelessStand.pdf

4. **Review Reports are sent to:** NIH Chief Information Officer

NIH POLICY MANUAL

2808 – NIH Enterprise Architecture Policy

Issuing Office: OD/OCIO (301) 402-1044

Release Date: 03/25/05

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1. **Explanation of Material Transmitted:** This policy establishes an Enterprise Architecture (EA) practice for the National Institutes of Health (NIH). This document provides information, policy, guidance, and links to other NIH IT resources for developing a practical and integrated EA across the NIH.

2. **Filing Instructions:**

   Remove: None.
   Insert: NIH Manual Chapter 2808 dated 03/25/05.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL: http://oma.od.nih.gov/manualchapters/

- To sign up for email notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This policy establishes an Enterprise Architecture (EA) practice for the National Institutes of Health (NIH). Facilitated by the Office of the Chief IT Architect

(OCITA), within the Office of the Chief Information Officer, NIH, this document provides information, policy, guidance, and links to other NIH IT resources for developing a practical and integrated EA across the NIH.

The NIH EA aligns NIH's Information Technology (IT) assets and initiatives with its mission, and enables computer systems, networks, software, and data/information systems that support government functions and services to more effectively and efficiently communicate, interoperate, and share resources. The NIH EA facilitates the application of IT to business initiatives and objectives in an orderly, efficient, and cost-effective manner by describing a direction for technology activities supported by guiding principles, standards, and best practices.

This policy focuses on NIH EA integration to achieve the following benefits for NIH:

- Improved interoperability between systems;
- More reliable and accurate information that is available whenever and wherever needed;
- Improved consistency, accuracy, timeliness, integrity, quality, availability, and access to IT-managed information sharing across the enterprise;
- Elimination of multiple, disparate and duplicate systems;
- Economies of scale by providing mechanisms for sharing services across the enterprise;
- Improved communication among the business organizations and IT organizations within the enterprise; and
- Stability of systems operations.

There are other benefits of having an effective EA such as business innovation and faster system development timelines.

B. Background:

The Clinger-Cohen Act of 1996 mandates the implementation of an effective EA

policy and an associated EA practice. This act requires Federal Agency Chief Information Officers to develop, maintain, and facilitate "a sound and integrated information technology architecture for the executive agency". Subsequently, the Office of Management and Budget (OMB), in its Circular A-130, issued explicit guidance that requires agency information system investments to be consistent with the Agency's EA. Further legislative guidance has been provided in the e-Government Act of 2002. The scope of NIH's EA includes a description of the baseline environment (i.e., current or "as is" state) and target environment (i.e., future or "to be" state) for the business, technical, security, and information/data environments. This description of "as is" and "to be" is required by the legislation referenced in Section D.

The OCITA was created within the Office of the Chief Information Officer, NIH, to plan, coordinate, develop, implement, and provide ongoing oversight for all EA policy issues at NIH. The OCITA has developed an NIH EA framework that promotes an integrated design for IT systems and its supporting technology implementation at NIH. The NIH EA was created and implemented to:

- Further the NIH mission through automated processes that expand and enhance the productivity of NIH staff.
- Facilitate a greater relationship between NIH and its customers, stakeholders, and suppliers in the United States and abroad.
- Establish standard system engineering approaches that have worked for complex systems and design issues for the benefit of the NIH mission.

This EA policy has been established based on the governing laws, regulations and guidance set forth in the Reference section (Section D) of this policy.

C. Policy:

1. This policy applies to all NIH Institutes and Centers (ICs).
2. The NIH EA, as defined by OCITA through the publication of standards, applies to all aspects of information technology (IT) at the NIH, including

systems, infrastructure, products, and designs, developed internally and by outside contractors.

3. All NIH ICs shall use the NIH EA framework, methodologies, current ("as is") and target ("to be") technologies (i.e., architectural patterns and bricks), and best practices to develop, implement, and/or acquire computer hardware systems, software systems, application systems, operating systems, security systems, and networking systems. The NIH CIO with the concurrence of the ARB will establish clearance and approval procedures to ensure compliance with the EA.

4. Architecture exceptions may be granted on a case-by-case basis by either the Office of the Chief IT Architect (OCITA) or the NIH Architecture Review Board (ARB) as appropriate https://enterprisearchitecture.nih.gov/Pages/file.aspx.

5. The maintenance of the content of the EA is the responsibility of the Chief IT Architect and the location of this information will be made accessible through the OCITA.

6. This policy excludes stand alone IT systems that directly support Intramural scientific research.

D. References:

1. HHS-OCIO Policy for Enterprise Architecture, dated August 7, 2008. http://www.hhs.gov/ocio/policy/2008-0003.001.html

2. Clinger-Cohen Act, 1996 http://www.fismacenter.com/Clinger%20Cohen.pdf

3. E-Government Act, 2002 http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR02458:|TOM:/bss/d107query.html

4. OMB Circular, A-130, Management of Federal Information Resources, http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html

5. OMB Circular A-11, Preparation and Submission of Budget Estimates, http://www.whitehouse.gov/omb/circulars_a11_current_year_a11_toc

6. OMB Memorandum, Implementation Guidance for the E-Government Act of 2002, dated August 1, 2003
   http://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf

7. OMB, Federal Enterprise Architecture
   http://www.whitehouse.gov/omb/e-gov/fea/

8. GAO, A Framework for Assessing and Improving Enterprise Architecture Management, Version 1.1, dated April 2003
   http://www.gao.gov/new.items/d03584g.pdf

9. NIH Enterprise Architecture
   http://enterprisearchitecture.nih.gov/

E. Definitions:

1. **Enterprise Architecture** – is both a model and a set of guidelines. As a model it documents the NIH and its universe of relationships, operations, processes, and underlying systems. It represents the NIH and how it executes its mission. As a set of guidelines, it defines the technical environment, standards, and policy within which technical solutions will be established. An 'architecture' is a set of guidelines and standards that brings order into the world of information systems. It explains where data resides, how systems interface, and what type of "building materials" will be used to develop information systems.

2. **Current Architecture** – is a dynamically updated representation of the "'as-is" business, data, technical and security IT environment.

3. **Target Architecture** – is a dynamically updated representation of the "to-be" business, data, technical and security IT environment achieved at a future time.

4. **Domain Team** – IC representatives assembled to apply their collective knowledge and experience of its individual members, industry best practice, and other knowledge sources to define and document a specific component of the NIH EA.

5. **Information Technology (IT)** – is the hardware, software, and services operated by an organization that processes information to accomplish a business function, regardless of the technology involved, whether computers, telecommunications, or others.

F. Responsibilities:

1. **NIH staff** (to include any contractor support staff) that are involved with IT activities that are described in this policy are responsible for complying with the NIH EA.
2. **NIH CIO** is responsible for developing, and managing IT policies and procedures in compliance with Federal law and HHS regulations.
3. **NIH Chief IT Architect** is responsible for researching and organizing information to define and develop the NIH EA. Additionally, the NIH Chief IT Architect is an advisor to the NIH CIO on issues relating to EA.
4. **The Office of the Chief IT Architect (OCITA)** is responsible for:
   - developing, executing and managing NIH's EA policy and program;
   - ensuring that EA policy directly supports NIH's IT Strategic Plan;
   - developing and maintaining EA management processes to include oversight and control, and EA review, validation, and refinement;
   - providing EA input to NIH's Capital Planning and Investment Control (CPIC) process;
   - establishing teams and task forces (e.g., Domain Teams) as needed or required to develop components of the EA;
   - developing and supporting a process for requesting exceptions to the architecture; and
   - maintaining and distributing EA artifacts.
5. **Architecture Review Board**, chaired by the NIH Chief IT Architect, is the architecture oversight steering committee with ultimate NIH EA decision authority.

G. Procedures:

Enterprise Architecture procedures are documented and available on the [NIH EA website](#). The standards development process is described in [NRFC0001](#).

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this policy must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records'", Appendix 1, 'NIH Records Control Schedule,' Section 2800-A., ADP Management and Research.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information. All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Internal Controls:

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** CIT

2. **Frequency of Review:** This policy shall be reviewed for applicability on a yearly basis by the IT Policy and Planning Group.
3. **Method of Review:** OCITA evaluates input from users based on e-mail, telephone calls, meetings and memoranda, and makes appropriate changes as needed.
4. **Review Reports are sent to:** The NIH Chief Information Officer.

NIH POLICY MANUAL

2809 – NIH Social and New Media Policy

Issuing Office: OCPL 301-496-5787; OMA 301-496-2832; and OCIO 301-496-1168

Release Date: 11/04/11

1. **Explanation of Material Transmitted:** This chapter provides policy and guidance on the use of social and new media at NIH, including, but not limited to, NIH hosted and/or funded social media sites, Web applications and mobile Web sites.

2. **Filing Instructions:**

   Remove: None.
   Insert: Manual Issuance 2809, dated 11/04/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing offices listed above.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-4606, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

The policy and guidance set forth in this manual chapter provide parameters to ensure NIH use of social media, also known as "new" media, presents reliable information consistent with applicable law, regulations, policy, and guidance and that personal opinions are not misrepresented as official NIH, Department of Health and Human Services (HHS) or Federal

Government positions.

As NIH increasingly relies on the use of new technologies such as social media networks (also known as Web 2.0 and/or new media) for promoting the goals of transparency, public participation and collaboration, it is essential that the NIH implement a social and new media policy that defines appropriate use of these tools by NIH employees and its contractors (or non-federal employees including students, fellows, and volunteers) for communications between NIH and members of the public, while protecting privacy and minimizing risk to NIH systems and data, whenever Web-based technologies are used.

B. Scope:

This policy applies to the use of Web 2.0 tools and technologies that allow a person to share information, inclusive of, but not limited to blogs, social networks, forums, micro blogs (i.e. Twitter), automated data feeds (e.g., image/video sharing sites, social bookmarking services, as well as future and emerging technologies and environments. Such tools offer important opportunities for promoting the goals of transparency, public participation and collaboration. However, end users may share information about themselves without always realizing the potential consequences. With respect to personally identifiable information, the presumption shall be in favor of openness (to the extent permitted by law and subject to valid privacy, confidentiality, security, or other restrictions).

This policy applies to all NIH staff, contractors and other personnel working on behalf of the government when on official work duty or when they are using NIH IT resources for authorized personal use in accordance with the NIH Policy on Limited Authorized Personal Use of NIH Information Technology (IT) Resources.

C. Background:

Social media, social networking and Web 2.0 technologies represent new ways for NIH Institutes and Centers (ICs) and the Office of the Director (OD) to communicate and engage audiences; they also present the potential for mismanagement and misuse. Such risks include damage to NIH's credibility or reputation due to a loss of public trust resulting from failure to

comply with Federal, Department and NIH requirements for online communications.

NIH staff, contractors, and other personnel working for or on behalf of the government use social and new media to connect with the public and address their interests. NIH staff and others who work in the intramural community and are involved in patient research may, under appropriate circumstances and in compliance with applicable laws, regulations and policies, use social media tools to recruit or interact with potential or actual participants in clinical research.

Third-party Web site and application tools are Web-based technologies that are not exclusively owned, operated or controlled by the government, and usually involve significant participation by nongovernment entities. While the use of third-party tools represents a significant opportunity, it also presents some risks. For example,

- Some participants in social media environments may not understand the degree to which information may be shared or how long the data might be retained and that it cannot be changed.
- Some participants may think shared information is protected from public view when it is not.
- Some participants may want to retract or revise something that was posted only to learn it cannot be edited.

Staff who plan on using these tools need to understand how social media platforms work and how any and all data is managed by the site to ensure it complies with this policy and applicable laws, regulations, HHS and Government-wide policies and guidance.

It is important that users are familiar with the information security practices, user agreements, and privacy policies of the sites they are using and implications to the user and to NIH. More specifically, care must be exercised when using social and new media tools to ensure that users fully understand (1) how any shared data is managed by the social media platform and (2) the implications of their participation. For example, the data shared on third-party sites rests in the hands of the firm that hosts the service, not NIH. To that degree, NIH cannot

guarantee how that data might be used by the host corporation. Therefore, NIH personnel:

- Need to exercise care when engaging the public in online spaces dedicated to specific topics and user interests.
- Respect various codes of behavior of the online spaces they employ.
- Exercise courtesy and respect the norms of any groups in online spaces.
- Should not share personal details about themselves to avoid personal attacks and minimize the chance of information being harvested for the purpose of social hacking and impersonation of NIH staff.
- Should not encourage users to share personal information or details for the same reason above.

This policy also provides employees, contractors, and other personnel with guidance to ensure limited authorized personal use of social and new media complies with Office of Management and Budget (OMB), HHS, NIH policies and minimizes information security risks to NIH systems and resources.

D. Policy:

OFFICIAL AND PERSONAL USE OF NIH SOCIAL MEDIA ACCOUNTS

NIH staff are permitted to establish social and new media accounts to further the IC or NIH mission; however, staff that establish accounts for both official purposes and for their own personal/private use must be cognizant of the important distinctions that exist between the use of their official and their personal accounts as described below.

Accounts for Authorized Official Use

NIH encourages the use of appropriate social media (Web 2.0) technologies by NIH staff while in their official work capacity to enable communication, collaboration, and engagement with the public in support of NIH's mission. ICs may establish a presence on a non-government third-party site, such as Facebook, GovLoop or LinkedIn for the purpose of furthering their mission when appropriately managed and monitored.

While NIH recognizes the potential value of social media, there is also potential risk of mismanagement and misuse of social media tools that could result in a loss of credibility or otherwise cause damage to the NIH. Examples of misuse include misrepresentation of NIH policy or its official position on issues or the collection or release of confidential or personally identifiable information (PII). Therefore, each NIH IC and OD office shall:

1. Determine how to communicate the provisions of this policy to their staff regarding the use of social media tools as part of their overall strategic communication plan.
2. Develop internal guidelines and commit resources to effectively govern, create and maintain official social media sites and accounts.
3. Determine and communicate their internal policy to their IC on the use of social media tools based on the provisions of this policy and on its strategic communications plan and should commit its own resources to govern, create and maintain official social media accounts.
4. Consider the implications and risks when using 'widgets,' or embedded third-party applications on an NIH Web page (e.g., including YouTube videos on NIH Web sites).
5. Comply with the following guidelines when using social media tools for official communications to ensure compliance with Federal, HHS and NIH policy and ensure public trust:
    a. **Terms of Service (TOS) Agreements:** Many third-party social and new media sites have standard user terms of agreement that are unacceptable for the Federal Government. To mitigate risk, ICs shall use the pre-negotiated terms of service agreements provided by HHS (http://newmedia.hhs.gov/standards/tos.html) whenever possible and applicable. In addition, the Web Content Managers Forum, led by the General Services Administration (GSA), provides agencies with access to information about government-friendly business applications, productivity applications, cloud IT services and social media applications (http://www.apps.gov).

    These new media technologies are still subject to current standards and policies that govern Web communications (http://newmedia.hhs.gov/standards/tos.html). A signed TOS does not indicate that a tool meets these requirements and

additional contractual agreements may be necessary to address any issues not covered in the TOS. Before using/purchasing the products and services, IC and OD offices shall carefully evaluate the TOS agreements to ensure that the product or service can be purchased and used in accordance with all NIH policies and procedures pertaining to procurement, information technology, cyber security, privacy, accessibility, social media, paperwork reduction and any other applicable Federal mandates.

A list of government agency points of contact for the TOS agreements is available at (http://www.howto.gov/web-content/resources/tools/terms-of-service-agreements/agency-points-of-contact). To effectively mitigate risk, IC and OD office staff should coordinate as needed with contracts staff and the Office of the General Counsel (OGC) to ensure the IC or OD office can agree to the provisions of each agreement as well as the IC Privacy Coordinator and Information Systems Security Officer to make sure applicable privacy and system security requirements are met.

b. **NIH Logo Use:** NIH ICs and OD offices shall ensure that any use of the names, symbols, logos or identifying marks of NIH, its ICs, offices or programs be reviewed and approved consistent with the provisions of the requirements of the NIH Manual Chapter 1186, *Use of NIH Names and Logos* (http://oma.od.nih.gov/manualchapters/management/1186/). NIH ICs and OD offices are required to submit a request to the NIH Office of Communications and Public Liaison for review and approval before the NIH logo or name may be used on a social media site.

Use of agency branding on social media tools must also be compliant with *OMB Guidance for Agency Use of Third-Party Web sites and Applications* (http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-23.pdf).

c. **Records Management:** NIH ICs and OD offices shall ensure that NIH policy is extended to records associated with and/or shared via social media. IC Records

Liaison shall be responsible for maintaining records in accordance with the NIH Manual Chapter 1743, *Keeping and Destroying Records* (http://oma.od.nih.gov/manualchapters/management/1743/).

d. **Freedom of Information Act (FOIA):** NIH ICs and OD offices shall ensure their social media communications are in compliance with FOIA requirements issued by the NIH FOIA Office.

e. **Privacy:** ICs shall ensure official social media accounts are compliant with NIH Manual Chapter 2805, *NIH Web Privacy Policy* (http://oma.od.nih.gov/manualchapters/management/2805/). Maintaining privacy is critical for ensuring public trust in NIH. Many third-party social media sites enable submission of user-generated content, which may include personally identifiable information (PII). ICs should evaluate the collection and security of PII on social media sites with the IC Privacy Coordinator to ensure they are compliant with Department and NIH privacy policy. The IC Privacy System Owner/Manager shall complete a Privacy Impact Assessment (PIA) on the use of a third-party Web site and application and/or Web technology for which they are responsible and ensure privacy policies and notices are posted as appropriate. Social media sites that are used to collect PII must provide users with clear notice and utilize opt-in functionality, in compliance with OMB guidance. Furthermore, ICs shall provide the public with alternatives for acquiring comparable information and services.

ICs shall post a disclaimer about privacy and the use of cookies and tracking devices, including third-party social media sites, on their Privacy page on the external IC Web site.

f. **Web Measurement and Customization Technologies:** Use of Web measurement and customization technologies must be compliant with OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies* located at http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-22.pdf and NIH

Manual Chapter 2805, *NIH Web Privacy Policy*.

"Persistent" Web cookies are defined as Web cookies that can track the activities of users over time and across different Web sites. "Persistent" Web cookies may be used on an NIH-branded social media site or application "widget" if there is a compelling need to gather the data on the site, appropriate and publicly disclosed privacy safeguards exist for handling any information derived from the cookie and the site gives clear and conspicuous notice.

g. **Accessibility:** NIH ICs and OD offices shall ensure that their social and new media applications are set up and managed in accordance with Section 508 of the Rehabilitation Act of 1973. Specifically, each IC shall ensure that (1) individuals with disabilities who are Federal employees have access to and use of information and data that is comparable to the access to and use of information and data by Federal employees who are not individuals with disabilities; and (2) individuals with disabilities who are members of the public seeking information or service from NIH have access to and use of information and data that is comparable to the access to and use of the information and data by such members of the public who are not individuals with disabilities. This includes, but is not limited to all social and new media services purchased under a contract as well as third-party Web sites and embedded application widgets.

NIH ICs and OD offices shall give preference to third party social and new media sites that are Section 508-compliant and/or accessible to persons with disabilities. Alternatively, an exception or accommodation may be requested in accordance with NIH Section 508 Accommodations Process; the respective [IC Section 508 Coordinator](#) should be contacted for current information. All requests must be documented with an appropriate justification and approved by the NIH Section 508 Coordinator in advance of use.

h. **Plain Language:** NIH ICs shall comply with the Plain Writing Act of 2010 (Public Law 111-274) which was signed into law on October 13, 2010. The Act requires

the Federal Government to write in simple easy-to-understand language. Specifically the Act defines "plain writing" as writing that the intended audience can readily understand because the writing is clear, concise, well-organized and follows best practices for plain writing. Furthermore, the Act specifies that plain writing must be used in any writing that is relevant to obtaining Federal benefits or services or complies with Federal requirements.

i. **Moderated Commenting:** Some Third-Party Web sites and Applications (TPWAs) allow individuals to leave comments that other users/individuals may see. The realities of TPWA engagement are that individuals will leave comments that are off-topic, misleading, contain offensive or personal attack language or provide inaccurate information, etc. Moderated Commenting Policies describe acceptable uses of the commenting feature, including a clear description of material that is allowed and what types of information will be removed. Per HHS, public interaction is encouraged with the following caveats:

      1) All comments must be reviewed and cleared (moderated) before they are posted whenever possible.

      2) A comment policy must be clearly stated or linked.

      3) Comments must not be cleared for posting if they contain:

a) Blatantly partisan political views

b) Explicit commercial endorsements

c) Discriminatory, racist, offensive, obscene, inflammatory, unlawful or otherwise objectionable statements, language or content.

j. **Recruiting Study Subjects:** ICs who plan to use social and new media applications to recruit study subjects shall adhere to the human subject protection regulations at 45 CFR Part 46 and 21 CFR Part 56, which require that an Institutional Review Board (IRB) review and approve all research activities, including the use of advertising and plans for protecting the confidentiality of actual and prospective subjects. See Office for Human Research Protections (OHRP) guidance at http://www.hhs.gov/ohrp/policy/clinicaltrials.html and Food

and Drug Administration (FDA) guidance at
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.

>*See Appendix 1 for detailed guidance and discussion on the subject of using social and new media to inform the public about the recruitment of subjects to clinical trials.*

k. **Security or Privacy Breach:** If a security or privacy breach occurs or is suspected, the IC ISSO must be immediately notified per NIH policies and procedures regarding the reporting of breaches. Further information is available at http://ocio.nih.gov/security/sec_policy.html.

l. **Paperwork Reduction Act (PRA):** Do not include surveys, polls, questionnaires, etc., unless the questions have received clearance from the Office of Management and Budget. IC Project Clearance Liaison will coordinate OMB clearance with IC or OD office.

Accounts for Personal Use

NIH Federal employees, contractors and other personnel working for or on behalf of the NIH shall comply with provisions of the NIH Manual Chapter 2806, *NIH Policy on Limited Authorized Personal Use of NIH Information Technology (IT) Resources* that includes policies and laws governing the behavior of staff when using NIH owned information technology resources

NIH e-mail addresses should not be used to establish personal accounts or as an identifier during participation in personal or otherwise, unofficial social and new media activities. NIH staff who choose to disclose their affiliation with NIH, HHS or the Federal Government shall ensure that they do not post material or statements that could give the impression that they are representing NIH, HHS or the Federal Government. If there is a chance that the materials or statements could be misconstrued as NIH or Federal Government business, the user shall post a disclaimer stating that the opinions expressed are those of the individual alone and do not reflect those of the NIH, HHS or

Federal Government.

E. References:

Laws and Regulations:

1. Code of Federal Regulations (CFR) Title 45, part 5, *Freedom of Information Regulations*:
    http://www.nih.gov/icd/od/foia/cfr45.htm
2. Executive Order 12674, *Principles of Ethical Conduct for Government Officers and Employees*:
    http://ethics.od.nih.gov/lawreg/EO12674.htm
3. Freedom of Information Act (FOIA) of 1966, (5 U.S.C 552):
    http://www.nih.gov/icd/od/foia/efoia.htm
4. Privacy Act of 1974, (5 U.S.C. 552a, as amended):
    http://www.justice.gov/opcl/privstat.htm
5. Plain Writing Act of 2010 (Public Law 111-274) (October 13, 2010):
    http://www.gpo.gov/fdsys/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf
6. Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635):
    http://www.usoge.gov/ethics_docs/publications/reference_publications/rfsoc.pdf
7. Paperwork Reduction Act (44 USC 33501 et seq.)

OMB Memorandums:

1. OMB Memorandum M-05-04, *Policies for Federal Agency Public Web Sites* (December 17, 2004):
    http://www.whitehouse.gov/OMB/memoranda/fy2005/m05-04.pdf
2. OMB Memorandum M-10-06, *Open Government Directive* (December 8, 2009):
    http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf
3. OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies* (June 25, 2010):

http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-22.pdf

4. OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Web sites and Applications* (June 25, 2010):

   http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-23.pdf

HHS Policy:

1. HHS Policy for Section 508 Electronic and Information Technology (EIT):

   http://www.hhs.gov/web/508/contracting/hhs508policy.html

2. HHS Implementation Guidance for OMB Memorandums M-10-22 and M-10-23:

   http://www.hhs.gov/ocio/policy/implementation_of_omb_m-10-22_and_m-10-23.html

3. HHS Web Records Management Policy:

   http://www.hhs.gov/ocio/policy/policydocs/2007-0004.001.doc ; and

   http://www.newmedia.hhs.gov/standards/.

4. HHS IRM Policy for Usage of Persistent Cookies:

   http://www.hhs.gov/ocio/policy/2000-0009.html

NIH Policy:

1. NIH Manual Chapter 1825, *Information Collection from the Public*:

   http://oma.od.nih.gov/manualchapters/management/1825/

2. NIH Manual Chapter 2400 Series, *NIH Ethics Manual*:

   http://ethics.od.nih.gov/lawreg/Manual.htm

3. NIH Manual Chapter 2804, *Public-Facing Web Management*:

   http://oma.od.nih.gov/manualchapters/management/2804/

4. NIH Manual Chapter 2805, *Web Privacy Policy*:

   http://oma.od.nih.gov/manualchapters/management/2805/

5. NIH Manual Chapter 2806, *Limited Authorized Personal Use of NIH Information Technology (IT) Resources*:

   http://oma.od.nih.gov/manualchapters/management/2806/

6. NIH Manual Chapter 1743, *Records Retention and Disposal*:

   http://oma.od.nih.gov/manualchapters/management/1743/

NIH Guidance:

1. NIH FOIA Office: http://www.nih.gov/icd/od/foia/index.htm
2. NIH Information Technology General Rules of Behavior:
   https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/NIH_IT_GeneralRulesofBehavior.aspx

National Archives and Records Administration (NARA)

1. NARA Bulletin 2011-02, *Guidance on Managing Records in Web 2.0/Social Media Platforms*:
   http://www.archives.gov/records-mgmt/bulletins/2011/2011-02.html

National Institute of Standards and Technology (NIST)

1. NIST Special Publication 800-122, *Guide to Protecting the Confidentiality of Personally Identifiable Information (PII)*:
   http://csrc.nist.gov/publications/nistpubs/800-122/sp800-122.pdf

U.S. Office of Special Counsel

1. U.S. Office of Special Counsel, *Frequently Asked Questions Regarding Social Media and the Hatch Act*:
   http://www.osc.gov/haFederalfaq.htm

Office of the Attorney General

1. Memorandum from the Office of the Attorney General, *The Freedom of Information Act* (March 19, 2009):
   www.usdoj.gov/ag/foia-memo-march2009.pdf

F. Definitions:

The following definitions are adapted from the GSA Social Media Handbook published July, 2009 (www.gsa.gov/graphics/staffoffices/socialmediahandbook.pdf)

1. **"Social media" or "Web 2.0" technologies** - Though many definitions of Web 2.0 exist, it is consistently characterized as the collection of Web tools that facilitate collaboration and information sharing. Web-based communities and hosted services include social-networking sites, video and photo sharing sites, wikis, blogs, virtual worlds, and other emerging technologies.

2. **Internal Web 2.0 technologies** - Web 2.0 systems running on agency-controlled servers (within NIH or via contract to NIH). This could include, for example, wiki and blogging software installed on the agency's own infrastructure or a Web site on an outside server under contract with NIH.

3. **External Web 2.0 technologies** - Web 2.0 systems hosted on servers over which the agency has little control. This includes proprietary social networking sites such as Facebook, and GovLoop, as well as collaboration services such as Wikipedia, Blogspot and Delicious.

4. **Blog** - a Web-based forum with regular entries of commentary, descriptions of events, or other materials where the blog host posts material on the Web site, and others may provide comments. Blogs may be moderated by the host or may allow any material to be posted.

5. **Micro-Blog** - extremely short blog posts in the vein of text messaging. The messages can either be viewed by anyone or by a restricted group that is chosen by the user. Twitter, a popular micro-blog client, allows for posts of up to 140 characters in length to be uploaded and read online or through instant messaging or mobile devices via text messaging.

6. **Cloud Computing** – The use of applications hosted across the Internet by an independent service provider. An example of cloud computing is a Google Doc, in which the word processing program is accessible through a Web browser, and the content in the document resides in Google's servers.

7. **Mashup** – a Web-based presentation of information that combines data and/or functionality from multiple sources. For example, a mashup would be a Google map showing average housing prices drawn from a city assessor's online database.

8. **Personally Identifiable Information (PII)** - Information which can be used to distinguish or trace an individual's identity, such as their name, social security number,

biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc. (OMB M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*)

9. **Photo Sharing** – Web sites which allow users to post and share digital photos. These sites typically allow commenting and meta-data to be attached to photos.

10. **Podcast** – a way of publishing MP3 audio files on the Web so they can be downloaded onto computers or portable listening devices. Podcasting allows users to subscribe to a feed of new audio files using software which automatically checks for and downloads new audio files.

11. **Privacy Impact Assessment (PIA)** - An analysis of how information is handled: (i) to ensure handling conforms to applicable legal, regulatory, and policy requirements regarding privacy, (ii) to determine the risks and effects of collecting, maintaining and disseminating information in identifiable form in an electronic information system, and (iii) to examine and evaluate protections and alternative processes for handling information to mitigate potential privacy risks. (OMB Memorandum M-03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*)

12. **RSS Feed (most commonly referred to as Really Simple Syndication)** - a Web content format or "web feed" which, when used with an RSS aggregator, alerts users to new or exciting content on a Web site. They enable users to avoid the conventional methods of browsing or searching for information on Web sites. Once users subscribe to an RSS feed, they can gather material from Web sites of their choosing. Examples of an RSS feed include: blog posts, news headlines, website changes, job vacancy announcements.

13. **Social Bookmarking** - a Web-based service where users create and store links. Although Web browsers have the ability to bookmark pages, those links are tied to that browser on that computer. Social bookmarking, in contrast, is tied to an online account, which can be made public. These bookmarks can be shared and discovered by others. Examples of social bookmarking sites include del.icio.us, Digg, and, Reddit.

14. **Third-Party Web sites or Applications (TPWA)** - Web-based technologies that are not exclusively operated or controlled by a government entity, or Web-based

technologies that involve significant participation of a nongovernment entity. Often these technologies are located on a ".com" Web site or other location that is not part of an official government domain. However, third-party applications can also be embedded or incorporated on an agency's official Web site. (OMB Memorandum M-10-23, *Guidance for Agency Use of Third-Party Web sites and Applications*)

15. **Video Sharing** – Web sites on which users post video they have taken for others to view and comment on. Such sites allow viewers to "embed," or display others' video on their own sites.

16. **Virtual worlds** – imagined places where users can socialize, connect and create using voice and text chat.

17. **Web Measurement and Customization Technologies** - These technologies are used to remember a user's online interactions with a Web site or online application in order to conduct measurement and analysis of usage or to customize the user's experience. (Ex. persistent cookies, Web bugs, Web beacons, etc.) (OMB Memorandum M-10-22, *Guidance for Online Use of Web Measurement and Customization Technologies*)

    a. **Single-session technologies** - These technologies remember a user's online interactions within a single session or visit. Any identifier correlated to a particular user is used only within that session, is not later reused, and is deleted immediately after the session ends.

    b. **Multi-session technologies** - These technologies remember a user's online interactions through multiple sessions. This approach requires the use of a persistent identifier for each user, which lasts across multiple sessions or visits.

18. **Widgets** - interactive tools with single-purpose services such as displaying the latest news and weather, a map program, or photos.

19. **Wiki** – a collection of Web pages that encourages users to contribute or modify the content. By using a simple Web interface, a community can collaborate.

G. Responsibilities:

NIH ICs and OD offices must review this chapter prior to using or creating social and new media sites to ensure compliance. The following are officials with responsibilities associated with this policy:

1. **NIH Senior Official for Privacy (SOP)** - The OPDIV official responsible for the NIH Privacy Program. Approves Privacy Impact Assessments (PIAs) conducted by IC and OD staff on NIH uses of third-party Web sites and applications as well as Web measurement and customization technologies. Provides advice to IC Privacy Coordinators.
2. **NIH Section 508 Coordinator** – Responsible for approving (or disapproving) Section 508 exception and accommodation requests.
3. **NIH Chief Information Security Officer (CISO)** – The OPDIV official responsible for the NIH Information Security Program. The CISO will ensure that all security and privacy policies and procedures are implemented if a suspected or known breach occurs.
4. **NIH Records Officer** - The OPDIV official responsible for the NIH Records Program. Responsible for ensuring adequate and proper documentation of all social and new media records. Provides advice to IC Record Liaisons.
5. **Chief, NIH Project Clearance Branch** – The OPDIV official responsible for clearance of information collections under the Paperwork Reduction Act. Ensures the quality and completeness of NIH requests for PRA approval. Provides advice to IC Project Clearance Liaisons.
6. **NIH Freedom of Information Act Officer (FOIA)** – The OPDIV official responsible for the NIH FOIA Program. This office is responsible for FOIA policy implementation and also responds directly on issues pertaining to the Office of the Director, trans-agency requests or in the case of a denial, those are to be forwarded to the NIH FOIA officer as described: http://www.nih.gov/icd/od/foia/. This office is located within OCPL.
7. **NIH Forms Officer** – The OPDIV official responsible for establishing new, or revising existing NIH forms used on Web sites to collect data from the public.
8. **NIH Office of Communications and Public Liaison (OCPL)** – Responsible for review and approval of IC requests for content clearances of materials, creation of new Web site, clearance of written materials, campaigns and multi-media productions as well as the use of the NIH logo or name on a social media site. OCPL is responsible, in collaboration with the ICs and OD offices, and with the Department of Health and Human Services, for the overall NIH strategic communication efforts.

9. **IC Privacy Coordinator** – The IC or OD office official who serves as the liaison between IC and OD staff and the NIH Senior Official for Privacy on privacy issues. The IC Privacy Coordinator shall ensure the IC's social media sites are compliant with NIH Manual Chapter 2805, *NIH Web Privacy Policy*.

10. **IC Privacy System Owner/Manager** – The IC or OD office official responsible for a group of records under the control of the agency where information is retrieved by the name of the individual, by some identifying number or symbol, or by other identifiers assigned to the individual. In coordination with other stakeholders, completes a Privacy Impact Assessment (PIA) on the use of a third-party Web site and application and/or Web technology for which s/he is responsible and ensures privacy policies and notices are posted as appropriate.

11. **IC Information Technology (IT) System Owner/Manager** – The IC or OD office official responsible for the development, operation and/or maintenance of an information technology system defined as an organized assembly of IT resources and procedures integrated and regulated by interaction or interdependence to accomplish a set of specified functions.

12. **IC FOIA Coordinator** – The IC or OD office official who serves as the liaison between staff and the FOIA Officer on issues concerning the Freedom of Information Act. On issues pertaining to the Office of the Director, trans-agency requests or in the case of a denial, those are to be forwarded to the NIH FOIA officer as described: http://www.nih.gov/icd/od/foia/.

13. **IC Information Systems Security Officer (ISSO)** – The IC or OD office official who serves as the principal contact for coordination, implementation, and enforcement of information-security policies with the Office of the CISO (OCISO). Any suspected or known security breach should be reported within the hour to the ISSO in the IC or OD.

14. **IC Records Liaison** – The IC or OD office official who serves as the liaison between IC staff and the NIH Records Officer in overseeing the records management program within their IC or Office. The IC Records Liaison shall be responsible for maintaining the IC's social media records in accordance with the NIH Manual Chapter 1743, *Keeping and Destroying Records*.

15. **IC Project Clearance Liaison** – The IC or OD office official who serves as the liaison

between IC staff and the Office of Management and Budget for clearance functions concerning public information collection activities such as regulations, survey interviews, customer satisfaction surveys, Web site questionnaires and epidemiology research.

16. **IC Web Site Owner/Manager** – The IC or OD office official who serves as the principal contact responsible for IC Web product development and project management.

H. Procedures:

Online social and new media activities shall follow appropriate IC or OD procedures and clearances. In most cases, the procedures to be followed for print publication apply unless one is posting content that has already been cleared for public use.

For other types of less formal content, such as blogs, micro blogging, tweets and replies to comments in public online space, coordinate your activities through your supervisory channels, as defined in the IC or OD procedures.

At a minimum, contact the IC or OD office (1) Communications Office for approval to communicate outgoing messages on behalf of the IC or OD office and to ensure that content procedures are followed, (2) CIO Office or ISSO to learn of security procedures that shall be followed and, (3) FOIA, PRA, Records and Privacy liaisons to learn of requirements under the Freedom of Information Act, Paperwork Reduction Act, Records Act and Privacy Act.

I. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual Chapter 1743, *Keeping and Destroying Records*, Appendix 1, *NIH Records Control Schedule*, in accordance with the specific schedule item as applied to the kind of records.

Web 2.0 Information: A challenge associated with the use of Web 2.0 technologies, including government blogs and wikis and Web pages hosted by commercial providers, is the question of whether information exchanged through these technologies constitute federal records pursuant to the Federal Records Act. According to the guidance, records generated when a

user interacts with an agency Web site may form part of a set of official agency records. National Archives and Records Administration (NARA) guidance indicates that content created with interactive software on government Web sites is owned by the government, not the individuals who created it, and is likely to constitute agency records and should be managed as such. NARA issued "Guidance on Managing Web Records" to help agencies make decisions on what records generated by these technologies should be considered agency records: http://www.archives.gov/records-mgmt/pdf/managing-web-records-index.pdf.

NIH e-mail messages: NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

J. Internal Controls:

The purpose of this manual issuance is to provide guidance to ICs and OD offices in meeting requirements related to privacy and the protection of personal information on NIH and Third-Party social and new media Web sites and applications.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** Oversight of this policy will be carried out through a coordinated effort between the Office of Management Assessment (OMA), Office of the Chief Information Officer (OCIO), and Office of Communications and Public Liaison (OCPL).
2. **Frequency of Review:**

Reviews will be ongoing. Appropriate internal controls must be in place before a social and new media Web site or application may be activated. Webmasters and programmers developing NIH social and new media Web pages are responsible for ensuring compliance with NIH policy.

3. **Method of Review:**

Each year, a workgroup of members from OMA, OCIO and OCPL will survey a sample of NIH social and new media sites for compliance with NIH policy. External reviews may be used as alternative reviews for this purpose.

4. **Review Reports:**

Reports will be sent to the NIH Deputy Director for Management (DDM), and circulated to NIH stakeholders, as deemed appropriate by OMA, OCIO and OCPL. Reports should indicate that controls are in place and working well, or indicate any internal management control issues that require the attention of the report recipient(s).

Appendix 1: NIH OIR Guidance for Use of Social Media for Recruitment of Subjects to Clinical Trials :

All of the items below are to be considered additional guidance and do not change the HHS regulations at 21 CFR Part 56 and 45 CFR Part 46 and implementing guidance at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm and http://www.hhs.gov/ohrp/policy/clinicaltrials.html

Background

NIH Institutes and Centers with intramural programs increasingly rely on the use of new technologies such as social media networks (also known as Web 2.0) for informing potential participants about or recruiting them to clinical trials. Therefore, guidance is needed to define appropriate use of these tools by NIH employees, contractors, or partners who are engaged in OIR recruitment of patients to clinical trials.

Scope

This guidance is focused on social media tools and technologies that allow people to exchange information in real (or delayed time) on platforms that are public--including but not

limited to--social networks (such as Facebook), micro blogs (such as Twitter), automated feeds (such as RSS), image/video sharing sites (such as YouTube), social bookmarking services, blogs, forums and other emerging technologies with the purpose of social interaction.

These media are inherently different from the print environments that have controlled messages in text where potential subjects come to the announcements of clinical research opportunities by reading papers, magazines, posters, or hearing/seeing radio and television ads that are pre—produced. (When a trial recruiter purchases an ad space or ad time for a recruitment, the information is contained and is placed where one expects it to appear and in the pre-determined form. Outlets are selected to reach appropriate populations.)

In the social media environment the movement and placement, context and content of information, may all be manipulated. Also, audiences may be highly-targeted without individuals in those audiences self-selecting to be reached (as in the purchase of a magazine, responding to a poster, or seeing an ad and calling an 800 number.)

Our Responsibility to Protect Potential (or Actual) Study Volunteers

To fulfill our responsibilities in using new and social media for recruiting research participants, the Investigators should consider the following questions.

1. Have I considered the full implications of privacy in this new and less-controlled environment?

   The Principal Investigator (PI) and Institutional Review Boards (IRB) should assure the procedures followed adequately protect the rights and welfare of the prospective subjects as well as the accuracy of information for decision making. The PI should assure the IRB that the information provided by individuals will be appropriately handled. [As with current policy: A simple statement such as "confidentiality will be maintained" is not sufficient to inform the IRB about the procedures that will be used]. When using social media, PIs need to be familiar with and should describe to the IRB the privacy/confidential/information practices of any platform being used to collect and

store information that is not owned or operated by the U.S. Government. For example, some Web services maintain copies of all information submitted through their sites, including answers to investigator-posted surveys or screening instruments. In this scenario, an individual is no longer providing information solely to the government, but also to a third-party who is not necessarily bound by the same laws and regulations and who can analyze and search the data for its own purposes, monitor it at will, lawfully or unlawfully, or sell it.

When considering whether a Third-Party Web site or Application (TPWA) is appropriate for NIH use, you must ensure all uses of Third-Party Web sites and Applications comply with existing OMB Guidance, HHS and NIH policies with respect to privacy, system security and data safeguarding standards.

http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-23.pdf

2. I need to carefully consider how my materials will be used.

Although there has been a historic division between ads that are "purely informational" and "recruitment" ads, in the social media environment, this is much harder to distinguish and monitor. The outreach itself to groups or individuals with disease-specific interest may already allow for intrusion into personal privacy and result in disclosure of personal medical information not only to the PI but others.

Investigators need to consider the possible venues of presentation of recruitment materials, including the ability of recruitment services to place ads on Web sites that the Investigators do not choose in advance. Might some of those Web sites be inappropriate for presentation of an NIH recruitment notice?

3. Have I controlled my informational data in a locked format?

OHRP guidance provides that IRB review and approval is required for any information provided to potential participants beyond a directory listing that includes this basic

descriptive information:

> -Study Title
>
> -Purpose of the study (in plain language)
>
> -protocol summary
>
> -basic eligibility criteria
>
> -study site location(s), and
>
> -how to contact the study site for further information

With interactive media, the location of the information is not static—(as it is in printed posters, flyers, Web sites), so it is recommended that this information be provided in a controlled, pdf or other locked format, for distribution. If a locked format is not going to be used, the PI should make the IRB aware of how the information will be presented.

4. Have I made the contact for further information site protected for the privacy of interested individuals?

   Any contact information (such as a Web mailbox) should bring the interested person behind a security wall for any further information exchange. Until accepted in the study, individuals working on the study may not use intake and inquiry procedures for prior decision-making about potential subjects (e.g. using Google and commercial databases) to determine if someone appears to be an appropriate subject) until the individual has been fully consented.

5. Do I clearly understand that the interactive nature of social media escalates the speed of interaction, allowing for greater opportunities for errors in protecting private information? Have I planned to obviate those errors?

6. Have I accounted for problems related to the portability and secure handling of information, including the encryption of all government laptops, the encryption of sensitive information during transport, including but not limited to transport across the network or on portable media, and the reporting of unintended breaches of sensitive personal information in the government's possession?
   http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-16.pdf

7. Have I included my complete strategy for use of the social media and my strategies for protection of privacy and strategies for informed consent explicitly in my proposal to the IRB?

8. Have my team and I clearly understood the invasive nature of joining groups (i.e., support groups, disease groups, advocacy groups, etc.) for the purpose of recruitment? This can undermine the trust of government research and your IC.

Appendix 2: NIH Social and New Media Checklist:

This checklist is also available as a PDF file for you to download and fill-in or print by clicking here: MC2809_Appendix2.pdf

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1. **Approval:**
   - Contact the IC or OD Communications Director for your office or program to determine the appropriate strategy and tools for your audience and mission and to obtain any required IC approval(s) to use social and new media.
   - Notify the NIH IT Service Desk to request local access to the social or new media account for the individual(s) in the IC or OD office that is/are to be granted permission to create, maintain, and monitor the account.
   - Notify the NIH Online Information Branch to have your account added to the NIH List of Subscriptions.

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2. **IT Security:**
   - Read NIH IT Rules of Behavior to be aware of how users of NIH IT are responsible for information security and are held accountable for their actions.
   - Read NIH Manual Chapter 2806, Limited Authorized Personal Use of NIH Information Technology (IT) Resources for policy and other information on how NIH IT resources may or may not be be used.
   - Contact your IC or OD Information Systems Security Officer (ISSO) to determine appropriate IT security practices and whether the technology meets applicable

security standards.

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3. **Licensing:**
   - o Check the list of [HHS Terms of Service (TOS) agreements](#) to determine if the General Services Administration (GSA) has negotiated a federally-friendly TOS agreement with the third-party vendor.
   - o Contact the HHS Center for New Media at newmedia@hhs.gov if you are interested in a tool that is not on the list and that you would recommend they should pursue.
   - o Contact the NIH Office of General Counsel (OGC) to determine if your IC or OD office can agree to the terms and conditions of the Third-Party Web site or Application (TPWA) and/or the licensing agreement supplied by the vendor.

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4. **Official Agency Sources of Information, Branding, and Copyrighted Content:**
   - o Contact the NIH Office of Communications and Public Liaison (OCPL) to obtain permission to use trademarked images and logos.
   - o Read [NIH Manual Chapter 1186, Use of NIH Names and Logos](#).
   - o Link to [NIH's official Web site](#).
   - o Use NIH branding that clearly identifies your program's ownership or sponsorship as a government entity.

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5. **Accessibility:**
   - o Ensure content posted or produced through the use of new technologies is accessible to people with disabilities and in compliance with Section 508 of the Rehabilitation Act of 1973; see http://www.hhs.gov/web/508/index.html for current Section 508 policy and standards, guidance and other information.
   - o Contact your [IC Section 508 Coordinator](#) or the NIH OCIO Section 508 Team (section508help@nih.gov) with questions or assistance on compliance.

6. **Information Collection from the Public:**
   - Read [OMB Guidance on Information Collection under the Paperwork Reduction Act (PRA)](#) to determine if the uses of social media and Web-based interactive technologies are information collections subject to the PRA and require approval from the Office of Management and Budget.
   - Read [NIH Manual Chapter 1825, Information Collection from the Public](#) for a description of NIH policies and procedures governing the collection of information from the public.
   - Contact your [IC or OD Project Clearance Liaison](#) to determine appropriate clearance functions concerning public information activities (i.e., regulations, survey interviews, customer satisfaction surveys, Web site questionnaires and epidemiology research).

7. **Soliciting Official Public Comment:**
   - Do not solicit formal or informal consensus advice from the public using Web technologies.

8. **Protecting the Public's Privacy:**
   - Contact your [IC or OD Privacy Coordinator](#) to determine the specific steps to protect privacy. For assistance, contact the Office of the NIH Senior Official for Privacy at privacy@mail.nih.gov or call (301) 451-3426.
   - In accordance with [NIH Manual Chapter 1745-1, NIH Privacy Impact Assessments](#), complete an adapted PIA for your IC or OD office use of a TPWA.
   - Review your IC or OD office Privacy Notice to ensure it reflects the use of the TPWA.
   - Prominently post a [Privacy Notice](#) on the TPWA itself, to the extent feasible. It should be conspicuous, salient, clearly labeled, written in plain language, and prominently displayed at all locations where the public might make PII available

to NIH.

- o Read [OMB Memorandum 10-23, Guidance for Agency Use of Third-Party Web sites and Applications](#) to determine the steps necessary to protect individual privacy when using TPWAs to engage with the public.
- o Read [NIH Manual Chapter 2805, NIH Web Privacy Policy](#) for additional guidance to determine the policy and procedures for ensuring the privacy and protection of personal information maintained and disseminated via NIH Web sites.

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9. **Use of Tier 3 Web Technologies:**
   - o Contact the NIH Senior Official for Privacy at 301-451-3426 or email privacy@mail.nih.gov if using Web measurement and customization technologies (i.e., persistent cookies, Web beacons and bugs) that collect Personally Identifiable Information (PII).
   - o Read [OMB Memorandum 10-22, Guidance for Online Use of Web Measurement and Customization Technologies](#) to determine the requirements for agency use of Web measurement and customization technologies.

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10. **Record Keeping:**
    - o Contact your [IC or OD Records Liaison](#) to determine appropriate records schedule and records management practices.

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11. **Comment Moderation:**
    - o Determine and document a process to moderate (review and clear) comments.
    - o Clearly link to a comment policy if you will allow the public to make PII available to the agency (e.g., "friend-ing," "following," "liking," joining a "group," becoming a "fan," and comparable functions).

12. **Linking, Liking, Following and Endorsement:**
    - o Ensure Web pages containing links to external Web pages not located on the NIH network provide a statement adjacent to the link or a "pop-up" disclaimer that explains that visitors are being directed to an external, government or non-government Web site that may have different privacy policies from those of the NIH official Web site.
    - o Determine what entities are appropriate to link/like/follow/endorse from your account.

NIH POLICY MANUAL

2810 - NIH Remote Access Policy

Issuing Office: CIT 301-402-4445

Release Date: 1/3/06

1. **Explanation of Material Transmitted:** This policy, and the corresponding NIH Remote Access Security Standards and Procedures at https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc, have been revised by the NIH Information Technology and Management Committee (ITMC) Security and Privacy Subcommittee. Changes reflect the addition of a new requirement (for remote access users to complete specific training), updated URLs, and the newly assigned policy number within the IT management series (the policy was previously located in the 2600 Property and Logistics series).

    The implementation of this policy is an important part of the NIH IT Security Consolidation project. The policy, developed and approved by the ITMC Security and Privacy Subcommittee, states that remote access to the NIHnet must be routed through secure, approved services provided by CIT (NIH Virtual Private Network (VPN) or PARACHUTE) or an IC-provided service that has been approved as an exception by the NIH CIO. The policy requires all remote access users, including NIH employees, contractors, and other authorized users, to take the Securing Remote Computers course (available at https://ocio.nih.gov/InfoSecurity/training/Pages/default.aspx) and to sign the NIH Remote Access User Certification Agreement available at http://cims.cit.nih.gov/nihforms.cfm?form=remote.access.

2. **Filing Instructions:**

    Remove: NIH Manual 26101-26-8, dated 9/10/03.

Insert: NIH Manual 2810, dated 1/3/06.

PLEASE NOTE: To sign up for e-mail notification of future changes, please go to the [NIH Manual Chapters LISTSERV](#) Web page.

A. Purpose:

This document provides the policy and procedures for acquiring and managing resources used for remote access to the NIH Network (NIHnet). The NIHnet, which is managed by the NIH Center for Information Technology (CIT), encompasses the collection of Institute and Center (IC) local area networks (LANs) and the wide area network (WAN) used to interconnect them, Internet Services, and access to central network computing services.

This policy specifically addresses connectivity to the NIHnet by individuals that NIH management has determined require remote access to the NIHnet to perform work duties. This document also establishes the policies that are to be followed to assure that NIH's information technology (IT) resources are appropriately protected when authorized users remotely access NIH automated information and systems.

B. Background:

Technology advancements in telecommunications and IT have increased the demand for remote access to NIH information systems. These enhanced telecommunications resources allow employees to work off-site, have access to data for authorized use, and maintain contact with co-workers and managers while away from their official NIH worksite.

While network technology advancements have increased efficiency by allowing authorized users to remotely access NIH resources, if not managed properly, remote access connections can result in vulnerabilities that can be exploited to cause unacceptable security risks. Therefore, all systems and connections used to remotely access NIHnet must have a level of security that ensures confidentiality, integrity, and availability commensurate with the risk and magnitude of the harm that could result from the loss, misuse, disclosure, or

modification of the information contained in the system.

C. Scope:

This policy applies to all NIH IT resources, whether maintained by NIH or by a contractor on behalf of NIH. This policy applies to methods used to remotely access NIHnet, and covers the security of remote access gateways both attached to the NIH and at remote endpoints, as well as information transiting remote access connections. This policy is mandatory for all employees, contractors, and other authorized users who remotely access NIH resources. This policy applies to all existing automated systems and to any new systems technology acquired after the effective date of this policy.

This policy is in compliance with the DHHS IRM Policy for IT Security for Remote Access at http://ocio.nih.gov/itmra/HHS-IRM-2000-0005.html, other DHHS and NIH policies, and applicable federal IT legislation and regulations (See Section E, References).

This policy also applies to wireless remote access to NIHnet, which must meet the requirements in the NIH Wireless Network Policy at NIH Manual 2807.

D. Policy:

1. Remote access to the NIHnet must be routed through secure, approved services provided by CIT or an IC-provided service that has been approved as an exception by the NIH CIO and complies with DHHS security requirements and the NIH Remote Access Security Standards and Procedures at

    https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc.

2. Remote access privileges will be granted only to an individual who management has determined has a job-related need to access the NIHnet. Contractors are permitted remote access to the NIHnet if such an arrangement is determined necessary by the project officer and adequate safeguards are implemented and monitored.

3. NIH staff are permitted limited personal use of authorized NIH IT resources in accordance with the Limited Authorized Personal Use of NIH Information Technology Resources Policy at NIH Manual 2806, "Limited Authorized Personal Use of NIH Information Technology (IT) Resources"

4. When remotely accessing sensitive NIH IT resources (except for publicly available web sites), all electronic communications over the Internet between authorized users and NIH must be encrypted using federally approved encryption mechanisms listed in the NIH Remote Access Security Standards and Procedures at https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc.

5. NIH ICs are responsible for managing IC remote access resources and may acquire any additional resources that are needed by individuals for remote access to the NIHnet. CIT is responsible for managing NIHnet and overseeing the NIH remote access program.

6. Remote access accounts shall be reviewed and re-evaluated on (at least) an annual basis to ensure that there is a continuing need for the remote access resources and privileges.

7. Authorized individuals may access the NIHnet from their residence or other approved worksite by using their own home computer and connectivity resources, or third party resources (e.g., motel, or other private facility or private residence). ICs may use appropriated funds to pay for remote access connections in non-NIH worksite locations if these resources/services are (a) necessary to carry out the purpose of the appropriation, and (b) effectively safeguarded.

8. If remote access users provide their own equipment, they are responsible for service and maintenance unless otherwise determined by the IC. Users should utilize, maintain, and store sensitive information on NIHnet servers when feasible in accordance with https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc.

9. All remote access must be accomplished directly between end user systems and NIH secure remote access gateways.

E. References:

DHHS IT Policies and Guidelines

1. HHS IRM Policy for IT Security for Remote Access at http://www.hhs.gov/ocio/policy/2000-0005.html

2. DHHS IRM Policy for Personal Use of Information Technology Resources - http://www.hhs.gov/read/irmpolicy/0003.html

3. DHHS Telecommuting Program Policy - http://www.hhs.gov/asa/ohr/manual/files/990-1.pdf

NIH IT Policies and Guidelines

1. NIH IT General Rules of Behavior - https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx

2. NIH Manual 2806 - Limited Authorized Personal Use of NIH Information Technology Resources - http://oma.od.nih.gov/manualchapters/management/2806/

3. NIH Manual 2300-600-1 - Telework Policy - http://oma.od.nih.gov/manualchapters/person/2300-600-1/

4. NIH Manual 2807 - Wireless Network Policy - http://oma.od.nih.gov/manualchapters/management/2807/

5. NIH Wireless Security Policy - https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_WRSPol.doc

6. NIH Network Firewall Policy - https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIHFWPol.doc

7. NIH Account Lifecycle Policy - https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Account_Lifecycle_Policy.doc

8. NIH Warning Banner Policy - https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Warning_Banner_Policy-FINAL.doc

9. NIH Sensitivity Level Designations - https://ocio.nih.gov/InfoSecurity/Policy/Documents/NH2866.doc

10. NIH Remote Access Solutions - http://cit.nih.gov/ServiceCatalog/Services.htm?Service=NIHnet+Remote+Access+Service

11. NIH Manual 2300-940 - Clearance of Personnel for Separation or Transfer - http://oma.od.nih.gov/manualchapters/person/2300-940/

12. NIH Manual 2204 - Reasonable Accommodations - http://oma.od.nih.gov/manualchapters/management/2204/

Applicable Laws and Regulations

1. 31 USC 1301(a), as amended

2. 31 USC 1348, as amended

3. Office of Personnel Management Guidelines, Attachment to FPM letter 368-1

4. Principles of Ethical Conduct for Government Officers and Employees - http://ethics.od.nih.gov/principl.htm

5. Privacy Act of 1974 (P.L. 93-579) - http://www.nih.gov/icd/od/foia/privact74.htm

6. Clinger-Cohen Act (formerly the Information Technology Management Reform Act of 1996 - Division E of P.L. 104-106) - https://ocio.nih.gov/ITGovPolicy/Documents/DIVISION_D-E_Public_Law_104-106.pdf

7. Office of Management and Budget (OMB) Circular No. A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources - http://www.whitehouse.gov/omb/circulars/a130/a130.html

8. Health Insurance Portability and Accountability Act (HIPAA, P.L. 104-191); August 21, 1996 - http://aspe.hhs.gov/admnsimp/pl104191.htm

9. Presidential Decision Directive 63 (PDD-63), Critical Infrastructure Protection, May 22, 1998 - http://www.fas.org/irp/offdocs/paper598.htm

10. Section 508 of the Rehabilitation Act, as amended by the Workforce Investment Act of 1998 - http://www.section508.gov/

11. HIPAA Privacy Rule: Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164); October 10, 2002 - http://www.hhs.gov/ocr/hipaa/finalreg.html

12. Federal Information Security Management Act (FISMA, P.L. 107-347, Title III); December 17, 2002 - http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ347.107.pdf

F. Definitions:

Bandwidth – The capacity of a connection. High bandwidth usually results in high

performance, or speed.

Broadband – High bandwidth transmissions that carry several data channels over a common wire. Cable modems, Digital Subscriber Line (DSL) services, and satellite modems are examples of broadband technologies.

Cable Modems – Modems that provide high-speed data access from a broadband cable television network.

Digital Subscriber Lines (DSL) – Digital Lines that use the existing telephone network to deliver broadband (high-bandwidth/speed) data communications.

Encryption – A process used to convert plaintext into scrambled, or unreadable ciphertext in order to prevent anyone but the intended recipient from reading that data.

Highly Sensitive Information – Data containing the most sensitive unclassified information (e.g., payroll records, proprietary information); Information subject to the Privacy Act that meets the qualifications of Exemption 6 of the Freedom of Information Act (i.e., unauthorized disclosure would constitute a clearly unwarranted invasion of personal privacy likely to lead to specific detrimental consequences for the individual). Highly sensitive information requires the greatest number and most stringent security safeguards at the user level.

NIH Network (NIHnet) – The NIHnet, which is managed by CIT, encompasses the collection of Institute and Center (IC) local area networks (LANs) and the wide area network (WAN) used to interconnect them, Internet Services, and access to central network computing services. In addition to connections on the main NIH campus, NIHnet connections extend to LANs in off-campus NIH buildings.

Remote Access – Electronic access to the NIHnet by authorized users not located at their normal worksite, e.g., traveling with a laptop computer or working at home.

Remote Access Connections – 'Components' required to establish a remote connection to the NIHnet, e.g., hardware, software, service, link/signal, etc. Requirements will vary depending on the remote access location and work to be performed. ICs should refer to the

NIH Remote Access web site at

http://cit.nih.gov/ServiceCatalog/Services.htm?Service=NIHnet+Remote+Access+Service for

further information on high remote access connections – availability, cost, and supported
platforms.

Sensitive Information – Agency information of which the loss, misuse, or unauthorized
access to or modification of, could adversely affect the national interest or the conduct of
Federal programs, or the privacy to which individuals are entitled under the Privacy Act, but
which has not been specifically authorized under criteria established by an Executive Order or
an Act of Congress to be kept secret in the interest of national defense or foreign policy.
(Computer Security Act of 1987)

G. Responsibilities:

1. **Institutes and Centers (ICs)**

   The ICs (Executive Officers (EOs) or their designee(s), in conjunction with IC CIOs) are
   responsible for developing and implementing an IC remote access program for the
   management of resources (and related acquisitions, as needed) used for remote
   access to the NIHnet. Specific program responsibilities of the IC EOs, or their
   designee(s) in conjunction with IC CIOs include:

   - Approving requests for remote access to the NIHnet.

   - Certifying that a government-furnished remote access connection is necessary for an
     individual.

   - Certifying that adequate safeguards are in place to minimize security risks of
     government-furnished remote access connections in accordance with the NIH Remote
     Access Security Standards and Procedures at
     https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.do
     c.

   - Implementing more rigorous remote access policies for systems with highly sensitive
     information such as patient records. See NIH Sensitivity Level Designations at

https://ocio.nih.gov/InfoSecurity/Policy/Documents/NH2866.doc. For example, stronger authentication through technologies such as biometrics or smart cards may be warranted in some instances (NIH Password Policy).

- Maintaining all approved remote access justifications.

- Requesting/arranging any needed residential connectivity with CIT.

- Conducting a comprehensive review of remote access accounts and resources on an (at least) annual basis through Web Sponsor to ensure that account and service information is correct and continued use is needed.

- Ensuring that all remote access services/accounts are terminated when the requirement ends, in accordance with the NIH Clearance of Personnel for Separation or Transfer Policy at http://oma.od.nih.gov/manualchapters/person/2300-940/.

- Ensuring that any remote access services/accounts that are not used in compliance with the Limited Authorized Personal Use of NIH Information Technology Resources Policy at http://oma.od.nih.gov/manualchapters/management/2806/ and the NIH Remote Access User Certification Agreement at http://cims.cit.nih.gov/nihforms.cfm?form=remote.access are terminated.

2. **Center for Information Technology (CIT)**

The CIT is responsible for managing the NIHnet and overseeing the NIH remote access program. Specific responsibilities include:

- Maintaining and providing access to the NIHnet.

- Providing security to protect the integrity of the NIHnet by allowing access only to authorized users.

- Developing NIH policy and guidance on remote access use and services, and making the information available to the NIH community.

- Processing registrations for all Centralized NIH Remote Access Services and providing notification of new CIT-provided or supported accounts to the IC account sponsor and approving official upon activating the account.

- Maintaining an inventory of remote access users who use Centralized NIH Remote Access Services through Web Sponsor and providing ICs access to the inventory on an as needed basis.

3. **Remote Access Users**

   Individuals who have been approved by their respective IC management to use the NIHnet and resources through remote access are responsible for ensuring that adequate safeguards are implemented to protect the integrity of the NIHnet and associated resources. All Remote Access Users must adhere to the NIH Remote Access Security Standards and Procedures which detail the appropriate operation and use of remote systems and the NIHnet by all parties involved in the remote access process:
   https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc.

H. Procedures:

Procedures and requirements for acquiring Centralized NIH Remote Access Services are described below. The IC EOs or designee(s) in conjunction with IC CIOs are responsible for approving the use of and managing remote access resources.

1. **Remote Access Approval**

   a. **Prepare Justification for IC Review**

      ICs must prepare justifications for individuals who IC management has determined require remote access to the NIHnet before action is taken to activate accounts.

   b. **Obtain IC Approval**

      The completed justification is to be submitted to the IC approving official (EO or designee(s)) for review and approval. The IC approving official shall notify the individual and IC account sponsor when he/she has granted approval so that the

application can be processed by the IC.

c. **Ensure User Submits Certification Agreement**

All remote access users including NIH employees, contractors, and other authorized users must certify that they have read and agreed to the rules on all remote access connections by signing the NIH Remote Access User Certification Agreement (see the NIH Remote Access Security Standards and Procedures at https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc for a copy of the agreement). ICs will maintain copies of signed agreements on file.

d. **Ensure User Submits Remote Access Training Certificate**

All remote users must take the *Securing Remote Computers* training course (available at https://ocio.nih.gov/InfoSecurity/Policy/Pages/Awareness_and_Training.aspx). The course provides a completion certificate which should be submitted with the NIH Remote Access User Certification Agreement when an individual applies for a remote access account. Users who have already signed the agreement must still take the course to maintain an active remote user status. Completion of this course can also be verified by ISSOs who have access to the training database.

2. **Remote Access Connectivity**

Individuals who have obtained management approval to use the NIHnet via the Centralized NIH Remote Access Services may obtain these services through their respective ICs. CIT will process the request through Web Sponsor, and assign and notify the individual of a user ID and password. The account sponsor will be advised that the individual's remote access service has been activated.

Individuals authorized for remote access from a private residence may already have all the necessary components in their residence to establish connectivity with the NIHnet

and may not require additional resources. Acquiring government-furnished remote access resources for residential connectivity will require justification and will be initiated only after remote access to the NIHnet has been approved.

a. **Prepare Justification for a Residential Connectivity**

Individuals participating in an approved telecommuting/FWP program may be provided residential connectivity without additional justification. For other individuals, the justification must include a detailed explanation of why the continuous availability of a government–furnished remote access connection to the NIHnet is necessary. Specifically, resources may be provided to individuals whose (a) need (not desire) for access to the NIHnet is frequent enough to justify the cost of installing and maintaining the connectivity or (b) work requires simultaneous voice and data communication capability.

b. **Determine Residential Connectivity Requirements**

CIT can provide a technical evaluation to assist ICs in determining the requirements and costs and in preparing the needed justification. For more information, see NIH Remote Access Solutions at http://cit.nih.gov/ServiceCatalog/Services.htm?Service=NIHnet+Remote+Access+Service.

c. **Obtain IC Approval**

The completed justification must be submitted to the IC approving official for review and approval. The IC approving official must state that the employee is working off-site as part of a telecommuting/FWP program or certify that a remote access connection is necessary for authorized activities. The approving official is also responsible for ensuring that all necessary paperwork (e.g., telecommuting/FWP agreements, remote access justifications) is completed, approved and on file, and that safeguards are in place at the time of the service order to prevent misuse.

d. **Order Residential Connectivity Service**

(1) Data Line Connectivity

Application for government–furnished data line connectivity requires that the individual's respective IC Administrative Officer (AO) submit a request to CIT for review. CIT will then contact the IC AO, who will authorize use of the IC CAN number. CIT will provide the AO with vendor information and the AO will coordinate with the authorized end user and vendor to arrange the installation. CIT personnel will be available to provide assistance in ordering the service and troubleshooting technical problems.

(2) Broadband Connectivity

Application for broadband connectivity requires the IC AO to coordinate with the authorized vendor to set up an account and make the necessary arrangements for installation and payment. Technical support for broadband service will be provided by the vendor and IC.

3. **General Information and Technical Assistance on Remote Access Services:**

For additional information on remote access connectivity and services, see the NIH Remote Access web site at http://cit.nih.gov/ServiceCatalog/Services.htm?Service=NIHnet+Remote+Access+Service or call GO-CIT (301-594-6248).

4. **Remote Access Program Review**

a. **CIT Responsibilities**

CIT will provide the ICs a listing of all CIT-supported remote access accounts and reports listing personnel with government-furnished residential connections and related services.

b. **IC Responsibilities**

ICs will review CIT–provided user reports through Web Sponsor, and other

account reports provided directly by remote access service vendors. When an individual's work status changes and remote access is no longer required, ICs will, as applicable, terminate the account, disconnect government-furnished residential connections and services, and ensure that all government-provided residential computing resources are returned to the IC.

All residential connectivity service and remote access accounts must be reviewed (at least) annually to ensure that there is a continuing need for the remote access resources and privileges. The IC must demonstrate that reviews are being conducted.

I. Incident Handling Process:

Coordination between the IRT, IC ISSOs, and other designated parties will follow existing and future guidelines available through the NIH IT Security web site at https://ocio.nih.gov/InfoSecurity/Policy/Pages/default.aspx.

J. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule," Item 1700-D, Communication Services.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information. All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. See for policy on e-mail back-up files.

K. Internal Controls:

The purpose of this manual issuance is to define policies and procedures for acquiring and managing resources used for remote access to the NIHnet.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** Center for Information Technology (CIT)
2. **Frequency of Review:** The ICs will be reviewed on a rotating basis depending on the resources available for the reviews. Each IC will be reviewed at least once every third year.
3. **Method of Review:** This review will be part of the periodic review of the IT Management Process of the ICs conducted by the CIT. This review will include:
   (a) total number of remote access accounts and individuals approved to use remote access resources and/or services;
   (b) number and type of government-furnished residential remote access connections/services (e.g., data lines and broadband connections) and the names of authorized users;
   (c) all required justifications.

   The IC should also be able to provide documentation that demonstrates how it reviews and monitors employee remote access.

4. **Internal Control Reports:** Management Control Reports are sent to the Deputy Director for Management (DDM), NIH.

NIH POLICY MANUAL

2811 – NIH Policy on Smart Card Authentication

Issuing Office- Phone: OD/OCIO – 301-496-2317; http://ocio.nih.gov
Release Date: 06/16/11

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1. **Explanation of Material Transmitted:** This chapter is revised to update the framework and timeline for NIH to implement the information technology (IT) smart card authentication requirements of Homeland Security Presidential Directive 12 (HSPD-12) and other related Federal requirements and directives.

2. **Filing Instructions:**

   Remove: NIH Manual Chapter 2811, dated 11/25/09.
   Insert: NIH Manual Chapter 2811, dated 06/16/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support, OMA on 301-496-2832 or enter this URL: http://oma.od.nih.gov/manualchapters/.

A. Purpose:

This chapter establishes a policy that provides a framework and timeline for NIH to implement the information technology (IT) smart card authentication requirements of Homeland Security Presidential Directive 12 (HSPD-12) and other related Federal requirements and directives.

B. Background:

A smart card is a trusted authentication token that uniquely identifies an individual to information technology (IT) systems. Smart card authentication is accomplished through the use of public key infrastructure (PKI) digital certificates located on the smart card. The use of smart cards as authentication tokens is governed by the standards and directives provided in section E of this policy.

C. Scope:

This policy covers the use of smart cards by NIH staff to authenticate to NIH IT systems. Smart card authentication, as required by this policy, may be performed with any smart card device, including PIV badges, which utilize digital certificates issued under the U.S. Federal PKI Common Policy Framework or issued by a Certification Authority cross certified with the Federal PKI Architecture at medium-hardware or high assurance.

This policy is focused solely on utilizing smart card PKI digital certificates and associated encryption keys to authenticate to IT systems. The use of biometric or other data contained in the PIV card is neither required by, nor within the scope of this policy.

This policy does not apply to authentication requirements associated with standalone IT systems, mobile devices/portable digital assistants (e.g., BlackBerrys), and external users of NIH IT systems. Remote access to the NIH Network, which is covered by the NIH Remote Access Policy, is outside the scope of this policy. The use of other smart card supported PKI functions, such as digital signatures and data encryption, are also outside the scope of this policy.

D. Policy:

To satisfy the requirements of the Federal Information Security Management

Act (44 U.S.C. § 3541), Homeland Security Presidential Directive 12, and other related Federal IT security regulations and Office of Management and Budget (OMB) memoranda, the following provisions regarding the acquisition, configuration, and use of smart cards (e.g., PIV cards) and smart card readers are provided. An approved waiver is required to deviate from the standards set forth below.

1. NIH servers, desktop computers, and laptops shall be equipped, to the maximum extent practicable, with a FIPS 201-certified transparent reader (i.e., smart card reader) and NIH-approved PIV middleware (i.e., smart card software) as follows:
   a. In accordance with HHS OCIO 2009-0001.01S, all newly purchased servers, desktop computers, and laptops shall be equipped with a smart card reader and software.
   b. NIH-networked desktop computers and laptops must be equipped with a smart card reader and software.
   c. NIH-networked servers, with a physically attached keyboard or console, must be equipped with a smart card reader and software.
2. NIH IT systems shall, to the maximum extent practicable, shall be configured to enable smart card authentication as follows:
   a. Applications that use the NIH Login authentication service must support the acceptance of smart cards by NIH Login as a means to authenticate NIH staff.
   b. NIH-networked servers, desktop computers, and laptop computers must support smart card-enabled login.
   c. Where smart card authentication is enabled, the removal of a smart card from the reader, in and of itself, will not result in a screen lock, forced logout, or any other system action.
3. Smart card authentication shall, to the maximum extent practicable, become mandatory for NIH staff as follows:
   a. 90 days following the HHS deployment of key smart card support services[1], smart cards must be required to log in to systems that

must use multifactor authentication to satisfy [NIST 800-53](#) Identification and Authentication (IA-2) security control requirements.

    b.   180 days following the HHS deployment of key smart card support services[1], smart cards must be required to log into NIH-networked desktop and laptop computers.

    c.   Where smart card authentication is mandatory, "backdoor" authentication mechanisms (e.g., user id/password) shall not be supported. If an individual does not have a smart card, he/she will not be granted access to the system.

    d.   Unless otherwise stated, this policy does not preclude the use of single factor authentication mechanisms where permitted by NIST 800-53 (e.g., user id/passwords to authenticate to FIPS 199 LOW impact systems other than NIH-networked desktop and laptop computers).

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[1] Key smart card support services are the capability to issue smart cards for use by system administrators and duplicate smart cards for staff on travel and other situations where a back-up smart card is needed. The HHS IAM@HHS program, responsible for issuing smart cards to NIH staff, expects this capability to be available by fall of 2011.

E. References:

1. [Federal Information Security Management Act of 2002](#) (44 U.S.C. § 3541) - requires agencies to provide information security protections commensurate with the risk and magnitude of the harm resulting from the unauthorized access to a Federal Information Technology (IT) system.

2. [Homeland Security Presidential Directive/HSPD-12](#): Policy for a Common Identification Standard for Federal Employees and Contractors - requires that Federal employees and contractors be issued smart card identification badges, known as personal identity verification (PIV) cards,

and requires that PIV cards shall be used to the maximum extent practicable for access to Federally controlled IT systems.

3. OMB M-11-11: Continued Implementation of Homeland Security Presidential Directive (HSPD) 12 - Policy for a Common Identification Standard for Federal Employees and Contractors - requires agencies to issue an implementation policy through which the agency will require the use of smart cards as the common means of authentication for access to networks and information systems. M-11-11 further mandates that beginning in FY2012, existing physical and logical access control systems must be upgraded to use PIV smart cards, in accordance with NIST guidelines, *prior* to the agency using development and technology refresh funds to complete other activities.

4. OMB M-06-18: Acquisition of Products and Services for Implementation of HSPD-12. - requires agencies to acquire FIPS 201 certified PIV products and services listed on the General Services Administration's (GSA) FIPS 201 Evaluation Program Approved Products List (APL).

5. OMB M-05-24: Implementation of Homeland Security Presidential Directive (HSPD) 12 - Policy for a Common Identification Standard for Federal Employees and Contractors.

6. National Institute of Standards and Technology (NIST), Federal Information Processing Standards Publication 201: Personal Identity Verification (PIV) of Federal Employees and Contractors.

7. NIST Federal Information Processing Standards Publication (FIPS) 199: Standards for Security Categorization of Federal Information and Information Systems.

8. NIST Special Publication 800-63-1: Electronic Authentication Guideline.

9. NIST Special Publication 800-53: Recommended Security Controls for Federal Information Systems and Organizations - identifies what authentication are required to gain access to Federal IT systems based upon those systems' risk categorizations, determined by FIPS 199. NIST 800-53 states that identification and authentication requirements are

satisfied by complying with HSPD-12, consistent with agencies' implementation plans provided to OMB.

10. Department of Health and Human Services (HHS), [HHS Standard 2009-0001.001s](), Standard Security Configurations Language in HHS Contracts.

11. [NIH Policy Manual 2810](), NIH Remote Access Policy.

12. [NIHRFC0030](): NIH Login to Support Single Sign-On Technologies for Web-Based Applications.

13. [NIH OCIO Website]()

14. [NIH Policy Manual 1743](), Keeping and Destroying Records.

15. National Archives, General Records Schedules, [Schedule 24]().

F. Definitions:

1. **Assurance** – the degree of confidence that the individual who uses a smart card or other token to gain access to an IT system is the individual to whom the credential was issued.

2. **Authentication** – the process of determining whether someone or something is, in fact, who or what they claim to be. Authentication is not authorization, which is the process of determining what rights or privileges are associated with a person or thing.

3. **Digital Certificate** – an electronic document, issued and digitally signed by a trusted third party, which binds an identity (e.g., person or organization) to their public key.

4. **FIPS 201 Certified** – indicates that the product has been successful evaluated by GSA as operating in compliance with the current version of the [FIPS 201 standard](). The GSA approved products list is located at [http://fips201ep.cio.gov/apl.php]().

5. **Multifactor Authentication** – using two or more factors to authenticate to an IT system. Factors include: (i) something you know (e.g., password/PIN); something you have (e.g., smart card); something you are (e.g., biometric).

6. **NIH Login** – a single sign–on (SSO) solution that manages user authentication processes on behalf of NIH web–based applications. Its use by NIH web–based applications is mandated by NIHRFC0030.

7. **NIH-networked** – a NIH IT system that has full or partial network connectivity to NIH-net and/or the Internet. Standalone IT systems are not considered NIH-networked.

8. **NIH Staff** – includes employees, contractors, students, guest researchers, visitors, and others who have an active record in the NIH Enterprise Directory (NED).

9. **Personal Identity Verification (PIV) Card** – a smart card Federal identification (ID) badge issued in accordance with the policies and procedures defined by [Federal Information Processing Standards Publication 201: Personal Identity Verification (PIV) of Federal Employees and Contractors](Federal_Information_Processing_Standards_Publication_201).

10. **PIV Interoperable Card (PIV-I)** – a smart card that meets PIV technical specifications and is issued in a manner that *allows Federal government relying parties to trust the card*. PIV-I cards do not require background investigations and other procedures mandated by [FIPS 201](FIPS_201).

11. **PIV Middleware** – computer software that provides the interface between the PIV smart card and applications utilizing the digital certificates stored on the card to perform cryptographic operations for authentication, encryption and digital signatures.

12. **Practicable** – a requirement that is capable of being put into practice or of being done or accomplished. Installation of smart card readers and/or PIV middleware on IT systems that cannot support their use, or where such an installation would seriously inhibit the system's functionality, is considered "not practicable".

13. **Public Key** – one of a set of two cryptographic keys used by PKI systems to support authentication, digital signatures and encrypted email. The public key is freely distributed in digital certificate, whereas the associated Private Key is

securely kept by the entity (e.g., in a smart card).

14. **Public Key Infrastructure (PKI)** – is the set of hardware, software, people, policies, and procedures needed to create, manage, store, distribute, and revoke digital certificates.

15. **Smart Card** – a PIN or password activated authentication device containing a microprocessor that enables the holder to perform cryptographic functions using PKI keys and digital certificates that are stored in the card's microprocessor.

16. **Smart Card Authentication** – a process that enables a user to login into an IT system using the identity is asserted by a digital certificate on the smart card which is cryptographically verified against the user's private key protected by the smart card.

17. **Smart Card Reader** – a device, connected to a computer, into which you insert a smart card thus enabling the computer to communicate with the smart card's microprocessor.

18. **Standalone IT System** – IT systems that are either not connected to a network or are connected to an isolated local area network that has no connections to NIH-net or the Internet.

G. Responsibilities:

1. **Institutes and Centers (ICs) Chief Information Officers (CIOs) and Executive Officers (EOs)**, or their designee(s), are responsible for implementing the smart card policies defined in section D. of this document. Specific responsibilities include:

   a. Providing NIH staff with FIPS 201-1 certified smart card readers and supporting software.

   b. Ensuring that IC IT systems and computers are configured to accept/require smart card authentication in accordance with the system's FIPS 199 security designation and the requirements of this

policy.

    c. Requesting waivers where adherence to the policies defined in section D. is not practicable.

2. **Division of Personnel Security and Access Control (DPSAC)** is responsible for issuing PIV cards and PIV-Interoperable smart cards to NIH staff.

3. **NIH Staff** are responsible for maintaining possession of their smart cards and protecting the confidentiality of the private PKI keys contained on the smart cards.

4. **NIH Chief Information Officer (CIO)** is responsible for developing and managing IT policies and procedures in compliance with Federal law and HHS regulations.

5. **NIH Chief IT Architect (CITA)** is responsible for researching and establishing smart card hardware and software standards as a component of the overall NIH Enterprise Architecture. The NIH CITA is responsible for specifying NIH approved PIV middleware.

6. **NIH Chief Information Security Officer (CISO)** is responsible for:

    a. Establishing NIH IT security policies and enforcing all Federal, HHS and NIH IT security policies and regulations.

    b. Reviewing and approving/disapproving HHS Information Security Policy/Standard Waivers, including waivers pertaining to the policies defined in section D. of this document.

7. **IC Information Systems Security Officers (ISSO)** are responsible for enforcing IT security policies, including the policies defined in section D of this document, within their IC.

8. **Center for Information Technology (CIT)** is responsible for distributing the NIH approved PIV middleware; providing technical assistance with the installation and configuration of smart card related hardware and software; enabling smart card login in the NIH Active Directory (AD) and in NIH Login; and assisting application owners in configuring their applications to accept

smart card credentials.

9. **IAM@HHS Program** is responsible for the operations of the smart card management system (SCMS) used to issue smart card credentials to NIH staff.

H. Procedures:

Procedures and requirements for enabling and performing smart card authentication and other smart card functions are as follows:

1. **Acquisition of Smart Card Readers**

   The acquisition of computing systems and smart card readers must be performed in accordance with [Federal Acquisition Regulation (FAR) Subpart 4.12](#) and [HHS-OCIO-2009-0001.001S - Standard Security Configurations Language in HHS Contracts](#).

   PIV middleware shall be pre-installed on all newly purchased servers, desktop computers and laptops. For existing systems, NIH staff should submit a request to the NIH IT Service Desk to have PIV middleware installed and configured on their desktop or laptop systems.

2. **Smart Card Authentication**

   The general procedures to be followed for using smart cards and digital certificates for authentication, digital signatures and secure email may be found at http://smartcard.nih.gov.

3. **Obtaining, Renewing and Replacing Smart Cards**

   The procedures to be followed to obtain, renew and replace smart cards may be found at http://idbadge.nih.gov/.

4. **Obtaining a Waiver**

   The procedure to obtain a waiver to the provisions of this policy is as

follows:

      a. The IC CIO, EO, or their designee, will fill out the NIH Information Security Policy/Standard Waiver. The waiver should indicate

          (1) If the waiver is for a single IT system or a blanket waiver covering a set of like systems and circumstances (e.g., Windows 98 systems used to support medical equipment at the Clinical Center);

          (2) The compensating authentication mechanisms that will be used to maintain the required level of security for the covered systems; and

          (3) If a deadline extension is being requested, by what date will the policy requirements be met.

      b. The completed waiver is submitted to the NIH CISO at IRT@mail.nih.gov.

      c. The CISO will review the information contained within the waiver form and determine if a waiver is justified.

      d. The CISO will notify the requester by email if the waiver is approved or disapproved.

I. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, Section 1100 – "General Administration," Item 1100-B-1, "Policy Files," Section 2600 – "Procurement Files," Item 2600-A-4, "Routine Procurement files and all sections that apply," and General Records Schedule 24, "Information Technology and Management Records," and all sections that apply.

NIH e-mail messages, including attachments that are created on NIH computer

systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

J. Internal Controls:

The purpose of this manual issuance is to establish the policy for using smart cards to authenticate to NIH IT systems at NIH.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter (Issuing Office):** NIH OCIO\ Information Technology and Security Awareness Office.

2. **Frequency of Review (in years):** Ongoing review that includes review of periodic reports to determine if changes are required.

3. **Method of Review:** Review of the controls associated with this chapter shall be part of the IT security certification and accreditation process that must be conducted for all IT systems and applications (see https://ocio.nih.gov/InfoSecurity/SystemAuth/Pages/default.aspx).

4. **Review Reports are sent to:** NIH CIO.

NIH POLICY MANUAL

2813 – NIH Information Security Awareness and Training Policy

Issuing Office: OD/OCIO – Phone: 301-496-1168; http://ocio.nih.gov
Release Date: 05/02/11

1. **Explanation of Material Transmitted:** This chapter contains information that sets forth information security awareness and training requirements for all personnel to ensure they understand the processes and procedures that are required to protect the confidentiality, integrity, and availability of agency information and information systems.

2. **Filing Instructions:**

    Remove: None.
    Insert: NIH Manual Chapter 2813, dated 5/2/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support, OMA on 301-496-2832 or enter this URL: http://oma.od.nih.gov/manualchapters.http://oma.od.nih.gov/manualchapters/

A. Purpose:

This policy sets forth information security awareness and training requirements for all personnel (including contractors and other users of information systems who support the operations and assets of NIH) to ensure they understand the processes and procedures that are required to protect the confidentiality, integrity, and availability of agency information and

information systems.

B. Background:

The Federal Information Security Management Act of 2002 (FISMA), P.L. 107-347, Tit. III, and the Office of Personnel Management (OPM) Regulation 5 Code of Federal Regulations 930.301 Information Systems Security Awareness Training Program require federal agencies to do the following:

1. Provide information security awareness training prior to granting a user access to information technology (IT) systems,
2. Provide refresher training annually,
3. Identify personnel with significant information system security responsibilities, and
4. Ensure that personnel with significant information system security responsibilities have completed information security training commensurate with their responsibilities in the form of role-based training.

The NIH Information Security Awareness and Training Policy is consistent with, and supplements, the Department of Health and Human Services (HHS) Office of the Chief Information Officer (OCIO) Policy for Information Systems Security and Privacy.

C. Scope:

This policy applies to all users of NIH information systems that have, or will receive an NIH Active Directory (AD) account.

D. Policy:

1. All users will take the mandated online NIH Information Security Awareness course, which is part of the NIH Information Security and Privacy Tracking System. The course must be completed prior to receiving their NIH AD account and password information. Thereafter, the NIH OCIO will notify users of their requirement to take an annual security awareness refresher course and provide the website information for taking the refresher training. The NIH OCIO will update the course content annually to ensure emerging and high priority security issues are addressed. Both courses require users

to read and agree to follow the NIH General Information Technology Rules of Behavior. (Staff may also receive additional rules of behavior relevant to specific systems they access.)

2. HHS requires that privileged users (for definition, see F.2) read and agree to follow Rules of Behavior for Privileged User Accounts. Therefore, privileged users will receive a modified version of the awareness course that includes additional privileged user training and the NIH Rules of Behavior for Privileged User Accounts.

3. Role-based Security Training is required for personnel with significant information security responsibilities to ensure they possess the knowledge and skills needed to protect information and information systems. The requirements for the Role-based Security Training are as follows:

    a. Security training must be tailored to each individual's information security role and responsibilities.

    b. Each year, using HHS guidance, Institutes and Centers (ICs) will update their list of staff considered to possess significant information security responsibilities and track their compliance with required training.

    c. Users with more than one significant role must complete role-based training associated with each role.

    d. Newly designated staff must complete appropriate role-based training within three months of their initial start date.

    e. Role-based training must be completed at least once every three years or more frequently, as needed, to address technology changes or patterns of vulnerabilities in information systems.

    f. Individuals who develop or manage sensitive systems must receive training relevant to their specific duties and the technologies they use.

4. Security Training Records:

    a. The NIH Information Security and Privacy Tracking System is used to monitor compliance with this policy. The system also has a function whereby individuals can record additional role-based training documentation.

    b. In addition to the electronic course record, only certificates of completion generated by the NIH Information Security and Privacy Tracking System are

considered valid proof of course completion.

   c. If a user provides a NIH Security Awareness or Refresher course certificate from the NIH Learning Management System (LMS), but there is no record in the NIH Information Security and Privacy Tracking System – no credit will be given for the course. The user must complete these courses in the Security and Privacy Tracking System as described in section D.4.a.

E. References:

1. Federal Information Security Management Act of 2002 (FISMA), P.L. 107-347, Title III, codified at 44 U.S.C. 3541 et seq.
2. U.S. Office of Personnel Management (OPM) Regulation, 5 CFR 930.301
3. HHS-OCIO Policy for Information Systems Security and Privacy http://www.hhs.gov/ocio/policy/policy-hhs-ocio-2010-0006-html.html
4. HHS Rules of Behavior, For Use of HHS Information Technology Resources http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/ROB/hhs_ocio_2010_0002.001s_hhs_rules_of_behavior_08262010.pdf
5. National Institute of Standards and Technology (NIST) Special Publication (SP) 800-16, Information Technology Security Training Requirements http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
6. NIST SP 800-53, Rev. 3, Recommended Security Controls for Federal Information Systems and Organizations http://csrc.nist.gov/publications/nistpubs/800-53-Rev3/sp800-53-rev3-final_updated-errata_05-01-2010.pdf
7. NIH OCIO Website http://ocio.nih.gov
8. NIH Manual Chapter 1743, "Keeping and Destroying Records": http://oma.od.nih.gov/manualchapters/management/1743/
9. National Archives, General Records Schedules, Schedule 24: http://www.archives.gov/records-mgmt/grs/grs24.html

F. Definitions:

1. **Significant responsibilities**: Responsibilities associated with a given role or position, which, upon execution, could have the potential to adversely impact the security

posture of one or more HHS systems.

2. **Privileged User**: A user that is authorized (and therefore, trusted) to perform security-relevant functions that ordinary users are not authorized to perform. A privileged user is also one whose account roles have elevated privileges above those in place for general user accounts regardless of account scope (e.g., including both local and domain administrator accounts). (NIST SP 800-53, Rev. 3, *Recommended Security Controls for Federal Information Systems and Organizations, HHS Rules of Behavior* (For Use of HHS Information Technology Resources))

The NIH Master Glossary of Information Security Terms which contains definitions of all information security terms is located at https://ocio.nih.gov/InfoSecurity/Policy/Pages/NIH-IT-Security-.aspx.

G. Responsibilities:

1. **NIH Chief Information Officer (CIO) or their designee(s) are responsible for:** Establishing and ensuring the implementation of this policy at NIH, consistent with all other Federal, HHS, and NIH rules and regulations.

2. **NIH Chief Information Security Officer (CISO) or their designee(s) are responsible for:**
   a. Implementing this policy within NIH, ensuring compliance, and approving all exceptions;
   b. Ensuring that this policy is updated to reflect changes in higher level directives or other issues that may impact the provisions of this policy.

3. **Institutes and Centers Chief Information Officer (IC CIO) or their designee(s) are responsible for:** Establishing and ensuring the implementation of this policy within their IC consistent with NIH rules and regulations.

4. **IC Information System Security Officers (IC ISSOs) or their designee(s) are responsible for:**
   a. Coordinating the implementation of this policy within their IC, monitoring and ensuring compliance, and submitting exception requests to the NIH CISO;
   b. Promoting awareness of information security issues among IC managers, technical support staff, and users;

c. Disseminating awareness information provided by the NIH CISO;

d. Coordinating and tracking staff security training;

e. Annually updating their list of IC staff that require role-based training and ensuring compliance.

H. Compliance & Oversight:

NIH users who do not comply with the prescribed Information Security Awareness and Training Policy are subject to penalties that can be imposed under existing policy and regulations, including: official written reprimands; suspension of system privileges; temporary suspension from duty; removal from current position; termination of employment; and even criminal prosecution.

At a minimum, ICs shall disable the active directory accounts of individuals who fail to complete their security awareness and required role-based training by the IC and/or NIH deadline. Accounts can only be reactivated after the individual has satisfied their relevant training requirements.

Requests for exceptions to this policy will be evaluated by the NIH CISO. A waiver request must include a business case for the request (how the enforcement of this policy would restrict the mission of NIH) and the specific compensating controls that will be implemented. IC ISSOs are responsible for submitting exception requests to the NIH CISO using the NIH Policy Waiver form.

I. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section 1100 – "General Administration," Item 1100-B-1, "Policy Files," Section 2300 – "Personnel," Item 2300-410-2-b, "Employee Training," and General Records Schedule 24, "Information Technology and Management Records," all items that apply.

NIH e-mail messages, including attachments that are created on NIH computer systems or

transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management Manual Chapter. Contact your IC Records Liaison or the NIH Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

J. Internal Controls:

The purpose is to set forth information security awareness and training requirements for all personnel (including contractors and other users of information systems who support the operations and assets of NIH)

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** NIH OCIO/ Information Technology and Security Awareness Office.
2. **Frequency of Review (in years):** Ongoing review occurring at least annually. Review will include a periodic assessment of IT security policies to determine if changes are required.
3. **Method of Review:** This review will be part of the periodic review and annual assessment of the IT Management Process of the ICs.
4. **Type of Review:** Review of the controls associated with this chapter shall be part of IT security certification and accreditation process.
5. **Review Reports are sent to:** NIH Chief Information Officer (CIO).

NIH POLICY MANUAL

2814 – NIH Policy on the Prohibited Use of Non-Government Furnished (Non-GFE) IT Equipment

Issuing Office – Phone: OD/OCIO – 301-496-1168;

http://ocio.nih.gov

Release Date: 06/23/11

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1. **Explanation of Material Transmitted:** The purpose of this policy is to restrict the use of non-government furnished information technology (IT) equipment (Non-GFE) at NIH and to provide a schedule for the implementation of this policy.

2. **Filing Instructions:**

   Remove: None.

   Insert: NIH Manual Chapter 2814, dated 6/23/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support, OMA on 301-496-2832 or enter this URL: http://oma.od.nih.gov/manualchapters/.

A. Purpose:

The purpose of this policy is to restrict the use of non-government furnished information technology (IT) equipment (Non-GFE) within the National Institutes of Health (NIH). This policy is written as part of an effort to ensure NIH compliance with Office of Management and Budget (OMB), Department of Health and Human Services (HHS), and other federal security

and property policies.

The use of Non-GFE poses a substantial risk to NIH IT systems when connected either directly to the NIH network (NIHnet) or via the Internet. This policy is intended to clarify the restriction on the use of Non-GFE, to provide guidance for the NIH community, and to provide a schedule for compliance.

B. Background:

The OMB and HHS recognize the dangers inherent in allowing the use of Non-GFE and have issued mandates prohibiting its use.

Computers and other electronic devices can harbor viruses and other software agents that can harm IT systems or enable the theft of data. Those harmful agents can be transferred from one system to another via the Internet or by connection to the NIHnet. NIH data is put at risk when it is stored on systems or storage devices that are not managed and configured by NIH.

Protecting the security of the unique and widely disbursed multi-platform computing environment of NIH plays a vital role in facilitating the NIH mission. NIH must provide the essential controls, including property management, encryption, access control, and other measures needed to protect information assets while facilitating the free flow of information.

C. Scope:

This policy applies to all types of IT systems and devices (servers, desktops, laptops, Blackberries, personal digital assistants (PDAs), smart phones, data storage devices, and all other information processing equipment) used to connect to NIH IT resources.

This policy applies to all NIH Staff, including employees, contractors, researchers, fellows, volunteers, interns, visitors, guests and all users of NIH IT resources (that are not designated systems for public use).

The use of Non-GFE connecting through guest access via the NIH Wireless Network is not included within the scope of this policy; as such, this type of access is governed by its own

policies, listed under 1.c. of the Policy section. NIH Institutes and Centers (ICs) may allow Verified Contractor Furnished IT Equipment (V-CFE) to connect to NIH IT resources; however, ICs must have an established policy and procedures in place to identify V-CFE if they allow the use of this IT equipment and the policies and procedures governing proper use of V-CFE must be addressed in the applicable contract.

This policy does not supersede any other applicable law or higher level agency directive or policy guidance. This policy shall be incorporated by reference, as necessary, into contracts or memoranda of agreement/understanding, and other acquisition mechanisms, such as purchase orders, as applicable.

D. Policy:

This policy implements changes to accessing NIH IT resources, with respect to Non-GFE, as follows [Note: the use of the term Government Furnished Equipment (GFE) in the subsequent paragraphs is inclusive of all IT equipment that is furnished by the government and Verified Contractor Furnished IT Equipment (V-CFE)]:

1. Local access requirements:
    a. Only GFE with government issued software can connect to NIH IT resources, excluding NIH public web sites and other identified public use systems. All NIH IT equipment used to connect to NIHnet or any internal NIH or IC IT resource must be purchased, configured, tracked, and managed by the government.
    b. NIH staff, contractors, or other non-government staff are not permitted to use any Non-GFE to connect to NIH IT resources or any other resources to do official government work.
    c. Non-GFE is only permitted to be used for connections via the NIH Wireless Guest Network as specified in the NIH Wireless Security Policy, the NIH Wireless Network Policy, and the NIH Wireless Network Security Standards documents. Information on this service can be found on the CIT Service Catalog's [NIHnet Wireless Network Service web page](#).
2. Remote Access requirements:
    a. Remote and direct logical access to NIH IT resources that include the use of

Non-GFE will be phased out and prohibited by the end of calendar year 2013. For more information, please see the [NIH Remote Access Standards](#).

b. By the end of 2013, remote desktop connections must be performed over approved NIH Virtual Private Network (VPN) services and can only be made from GFE. (Remote desktop connections using approved Citrix or terminal servers are allowed under the NIH Remote Access Standards, Appendix B.)

E. References:

1. NIH Delegations of Authority, Program: General; No 42 "National Institutes of Health Information Technology Security Program," http://www.delegations.nih.gov/DOADetails.aspx?id=3304

2. NIH Initial Security Configuration Policy, https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Initial_Security_Configuration_Policy.doc

3. NIH Remote Access Policy, http://oma.od.nih.gov/manualchapters/management/2810/

4. NIH Remote Access Standards, https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_Remote_Access_Standards_FINAL.doc

5. NIH Wireless Security Policy, https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_WRSPol.doc

6. NIH Wireless Network Policy, http://oma.od.nih.gov/manualchapters/management/2807/

7. NIH Records Management Policy, http://oma.od.nih.gov/manualchapters/management/1743/

8. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P) - Policy, http://www.hhs.gov/ocio/policy/policy-hhs-ocio-2010-0006-html.html

9. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P) - Handbook, http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP/pol_for_info_sys_sec_and_priv_hndbk_9-22-2010.pdf

10. National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53 Revision 2, *Recommended Security Controls for Federal Information Systems,* http://csrc.nist.gov/publications/nistpubs/800-53-Rev3/800-53-rev3_markup-rev2-to-rev3_updated-

[may-01-2010.pdf](may-01-2010.pdf)

11. NIST SP 800-46 Revision 1, *Guide to Enterprise Telework and Remote Access Security,*
    http://csrc.nist.gov/publications/nistpubs/800-46-rev1/sp800-46r1.pdf

12. OMB M-06-16, Protection of Sensitive Agency Information,
    http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2006/m06-16.pdf

13. OMB M-07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable
    Information,
    http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-16.pdf

F. Definitions:

The NIH Master Glossary of Information Security Terms which contains definitions of all
information security terms is located at https://ocio.nih.gov/InfoSecurity/Policy/Pages/NIH-IT-
Security-.aspx.

G. Responsibilities:

1. **NIH Chief Information Officer (CIO) or their designee(s) are responsible for:**

   Establishing this policy for NIH and ensuring that the provisions and implementation of
   this policy are consistent with all other Federal, HHS, and NIH policies, rules, and
   regulations.

2. **NIH Chief Information Security Officer (CISO) or their designee(s) are responsible
   for:**

   Implementing this policy within NIH, ensuring compliance, and approving all
   exceptions.

3. **IC CIOs or their designee(s) are responsible for:**
   a. Providing the resources necessary for policy implementation and training of IC
      employees, as appropriate;
   b. Implementing security controls required and reporting policy implementation

status to the CISO;

      c. Ensuring that IC specific policies and procedures are written and implemented consistent with this policy, as applicable.

4. **IC Information System Security Officers (IC ISSOs) or their designee(s) are responsible for:**

      a. Coordinating the implementation of this policy within their IC;

      b. Monitoring and ensuring compliance;

      c. Submitting exception requests to the NIH CISO.

5. **Management Officials, in their supervisory role, are responsible for:**

      a. Disseminating this policy to employees, contractors, interns, etc. and ensuring that they are aware of the requirements of this information security policy in a timely manner, as appropriate;

      b. Informing users (employees, contractors, interns, etc.) of their rights and responsibilities under this policy;

      c. Incorporating by reference, as necessary, into contracts or other agreements, and purchase orders this policy.

6. **NIH Staff (employees, contractors, fellows, volunteers, special volunteers, interns, tenants, and visitors) are responsible for:**

      a. Following this policy and not connecting equipment to NIH IT resources that is not conformant to the specifications herein;

      b. Seeking guidance from their supervisors or IC CISO when in doubt about the implementation of this policy.

H. Compliance and Oversight:

Compliance standards for systems used for remote access to NIH IT resources are specified in the [NIH Remote Access Standards](#) and as outlined in section D of this document.

For systems used for local access to NIH IT resources, NIH staff may only use government equipment, software, and applications for official government work.

Requests for exceptions to this policy will be evaluated by the NIH CISO. A waiver request must include a business case for the request (how the enforcement of this policy would

restrict the mission of NIH) and the specific compensating controls that will be implemented. IC ISSOs are responsible for submitting exception requests to the NIH CISO using the NIH Policy Waiver form.

I. Records Retention and Disposal:

Records Retention and Disposal: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the [NIH Manual Chapter 1743](#), "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section 1100 – "General Administration," Item 1100-B-1, "Policy Files," Section 2300 – "Personnel," Item 2300-410-2-b, "Employee Training," and General Records Schedule 24, "Information Technology and Management Records," all items that apply.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management Manual Chapter. Contact your IC Records Liaison for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same requests as the original messages.

J. Internal Controls:

The purpose of this manual issuance is to restrict the use of Non-GFE within the NIH.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** NIH Office of the Chief Information Officer/ Information Technology and Security Awareness Office.
2. **Frequency of Review (in years):** Ongoing review occurring at least annually. Review

will include a periodic assessment of IT security policies to determine if changes are required.

3. **Method of Review:** This review will be part of the periodic review and annual assessment of the IT Management Process of the ICs.

   Type of Review: Review of the controls associated with this chapter shall be part of IT security authorization process.

4. **Review Reports are sent to:** NIH Chief Information Officer (CIO).

NIH POLICY MANUAL

2815 - NIH Policy on the Use of Peer-to-Peer Software

Issuing Office - Phone: OD/OCIO - 301-496-1168; http://ocio.nih.gov/

Release Date: 11/29/11

1. **Explanation of Material Transmitted:** This policy is established to provide the requirements of using Peer-to-Peer (P2P) software applications on systems which access the National Institutes of Health (NIH) information technology (IT) resources.

2. **Filing Instructions:**

   Remove: None.
   Insert: NIH Manual Chapter 2815, dated 11/29/11.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-4606, or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This policy is established to provide the requirements of using Peer-to-Peer (P2P) software applications on systems which access the National Institutes of Health (NIH) information technology (IT) resources.

B. Background:

Peer-to-Peer (P2P) refers to any software or system that allows individual users of the Internet to connect to each other and share files. These systems are usually decentralized and are designed to facilitate connections between persons who are looking for certain types of files. While there are appropriate uses of this technology, a number of studies show the vast majority of files shared on P2P networks are copyrighted music files and pornography. Data also suggests P2P is a common avenue for the spread of computer viruses and other malware within IT systems.

The Office of Management and Budget (OMB) Memorandum M-04-26, *Personal Use Policies and "File Sharing" Technology* and the Department of Health and Human Services (HHS) IRM *Policy for Personal Use of Information Technology Resources*, prohibit the use of P2P software without the consent of the NIH Chief Information Officer (CIO) or designee. Specifically, these policies require NIH to implement security controls to prevent and detect improper file sharing and to establish waiver procedures for approved P2P software purchases and implementations. In addition, the NIH policy on *Limited Authorized Personal Use of NIH Information Technology (IT) Resources* prohibits the use of NIH IT resources in a manner that compromises the integrity of NIH computers and networks or results in a significant increase in the use of network bandwidth.

To address these requirements, NIH has instituted technical controls to supplement this policy. These technical controls include network security management tools, such as firewalls, intrusion detection systems (IDS), intrusion prevention systems (IPS), anomaly detection systems, web filtering, etc.

C. Scope:

This policy applies to IT systems and devices that process NIH information or access the NIH network (NIHnet) or NIH systems or resources. This includes, but is not limited to, desktops, servers, laptops, mobile devices or remote access systems connecting via virtual private network (VPN) or through other authorized remote access methods.

D. Policy:

To protect the security and privacy of NIH data and systems:

1. P2P software may not be installed on any device used to process NIH information or access NIH systems or other resources, regardless of the type of system (desktop, laptop, server, mobile device) or the owner of the system, e.g., Government Furnished Equipment (GFE) or Verified Contractor Furnished Equipment (V-CFE).
2. If a prohibited P2P application is detected, the associated source Internet Protocol (IP address) will be blocked and the accounts involved will be deactivated until those connections can be made secure again by removing the P2P software. Appendix A contains a list of some of the P2P applications that are prohibited and detected by the NIH intrusion detection system.
3. There are two general exceptions to this policy:
   a. The use of Instant Messaging (IM) applications via the NIH Instant Messaging Gateway, which meets the criteria of this and the NIH IM policy, is allowed.
   b. Skype implementations that are centrally and securely managed by the Institutes and Centers. IC CIOs are responsible for the safe and managed use of Skype in their IC.

E. References:

1. Federal Information Security Management Act of 2002 (FISMA)
   http://csrc.nist.gov/drivers/documents/FISMA-final.pdf
2. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P) - Policy
   http://www.hhs.gov/ocio/policy/policy-hhs-ocio-2010-0006-html.html
3. HHS-OCIO Policy for Information Systems Security and Privacy (IS2P) – Handbook
   http://intranet.hhs.gov/it/cybersecurity/docs/policies_guides/PISSP/pol_for_info_sys_sec_and_priv_hndbk_9-22-2010.pdf
4. HHS IRM Policy for Personal Use of Information Technology Resources
   http://www.hhs.gov/ocio/policy/2006-0001.html
5. NIH Delegations of Authority, Program: General; No. 42, National Institutes of Health Information Technology Security Program
   http://www.delegations.nih.gov/DOADetails.aspx?id=3304
6. Office of Management and Budget (OMB) Circular A-130, Appendix III, Security of Federal Automated Information Resources
   http://www.whitehouse.gov/omb/circulars_a130_a130appendix_iii

7. Office of Management and Budget (OMB) Memorandum M-04-26, Personal Use Policies and "File Sharing" Technology
   http://www.whitehouse.gov/omb/memoranda_fy04_m04-26

8. NIH Enterprise Information Security Plan
   https://ocio.nih.gov/InfoSecurity/Policy/Documents/EISP_FINAL.doc

9. NIH Manual Chapter 2806, Limited Authorized Personal Use of NIH Information Technology (IT) Resources
   http://oma.od.nih.gov/manualchapters/management/2806/

10. NIH Manual Chapter 1743, Keeping and Destroying Records
    http://oma.od.nih.gov/manualchapters/management/1743/

F. Definitions:

The NIH Master Glossary of Information Security Terms, which contains definitions of all information security terms, is located at https://ocio.nih.gov/InfoSecurity/Policy/Pages/NIH-IT-Security-.aspx.

G. Responsibilities:

1. **NIH CIO or their designee(s) are responsible for:**
   a. Establishing and ensuring the implementation of this policy at NIH consistent with all other Federal, HHS, and NIH policies, rules and regulations.

2. **NIH CISO or their designee(s) are responsible for:**
   a. Implementing this policy within NIH and ensuring compliance;
   b. Reviewing all requests for waivers and exceptions and rendering decisions regarding them.

3. **IC CIOs or their designee(s) are responsible for:**
   a. Providing the resources necessary for this policy implementation;
   b. Training IC employees, as appropriate;
   c. Implementing security controls required and reporting this policy implementation status to the NIH CISO;
   d. Ensuring that related IC specific policies, guidance, and standards are written and implemented, as applicable.

4. **IC Information System Security Officers (IC ISSOs) or their designee(s) are responsible for:**
   a. Coordinating the implementation of this policy within their ICs;
   b. Monitoring and ensuring compliance;
   c. Submitting exception requests to the NIH CISO;
   d. Coordinating with the IC Central IT System Support Staff to make sure that all mobile devices covered by this policy are registered and verified to be in compliance.
5. **IC Central System Support Staff are responsible for:**
   a. Ensuring that unauthorized P2P software is not installed on any government system or any system connected to NIH IT resources.
6. **Management Officials or their designee(s) are responsible for:**
   a. Ensuring that employees, contractors, interns, etc., participate in the development and the review of this information security policy in a timely manner;
   b. Informing users (employees, contractors, interns, etc.) of their rights and responsibilities, including the dissemination of the information in this policy.
7. **System Owners are responsible for:**
   a. Ensuring that systems under their control adhere to this policy or that a current and approved policy waiver is in place.

H. Compliance & Oversight:

NIH staff who do not comply with this policy are subject to penalties that can be imposed under existing policy and regulations, including: official written reprimands, suspension of system privileges, temporary suspension from duty, removal from current position, termination of employment, and possible criminal prosecution.

Requests for exceptions to this policy will be evaluated by the NIH CISO. A waiver request must include a business case for the request (how the enforcement of this policy would restrict the mission of NIH) and the specific compensating controls that will be implemented. IC ISSOs are responsible for submitting exception requests to the NIH CISO using the NIH Policy Waiver form.

I. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section 1100 – "General Administration," Item 1100-B-1, "Policy Files," Section 2300 – "Personnel," Item 2300-410-2-b, "Employee Training," and General Records Schedule 24, "Information Technology and Management Records," all items that apply.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management Manual Chapter. Contact your IC Records Liaison or the NIH Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester, employees' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same information requests as original messages and documents.

J. Internal Controls:

The purpose of this policy is to provide the requirements of using Peer-to-Peer (P2P) software applications on systems which access NIH Information Technology (IT) resources.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** NIH Office of the CIO/ Information Technology and Security Awareness Office.
2. **Frequency of Review (in years):** Ongoing review occurring at least annually. Review will include a periodic assessment of IT security policies to determine if changes are required.
3. **Method of Review:** This review will be part of the periodic review and annual

assessment of the IT Management Process of the ICs.

4. **Type of Review:** Review of the controls associated with this chapter shall be part of IT security certification and accreditation process.

5. **Review Reports are sent to:** NIH CIO.

Appendix A – Prohibited Peer-to-Peer Applications:

The following list provides some of the many P2P applications that are prohibited and detected by the NIH Intrusion Detection System (IDS). The list is not an exhaustive list and new P2P applications may be added on a daily basis. Accordingly, please check with your IC ISSO for updates. Other measures to block prohibited P2P traffic may be implemented without prior notice.

IRC	Pando
Ares/Warez-Gnutella	PPLive
Azureus	PPStream
BearShare	QQDownload
BitTorrent	QQLive
Direct Connect	Shareaza
eDonkey	Swapper Alive
GnutellaKaZaA	TeamViewer
Kugoo	Thunder KanKan
LimeWire	Torrent uTP
Manolito	WinMX
Morpheus Alive	Xunlei
Octoshape	

NIH POLICY MANUAL

4204-204A - Requirements for Maximum Competition under Assistance Programs

Issuing Office: OER/OEP 301-435-2768

Release Date: 6/15/2006

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1. **Explanation of Material Transmitted:** This NIH Grants Administration Manual (NIH GAM) sets forth the requirements for maximum competition under NIH grants and cooperative agreements (hereinafter referred to as "grants"). Further, it implements PHS regulations and those portions of HHS Grants Policy Directive (GPD) 2.04, "Awarding Grants," that apply to maximum competition, single-source awards, urgent awards and earmarks, and rescinds PHS Grants Administration Manuals (PHS GAMs) Part 119, "Applications for Projects with Time Constraints," and Part 144, "Requirements for Maximum Competition Under Assistance Programs." This is the first issuance of this NIH GAM.

2. **Filing Instructions:** N/A, this is the first issuance of this NIH GAM.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL:
  http://oma.od.nih.gov/manualchapters/

A. Purpose:

This NIH Grants Administration Manual (NIH GAM) sets forth the requirements for maximum competition under NIH grants and cooperative agreements (hereinafter referred to as "grants"). Further, it implements PHS regulations and those portions of HHS Grants Policy Directive (GPD) 2.04, "Awarding Grants," that apply to maximum competition, single-source awards, urgent awards and earmarks, and rescinds PHS Grants Administration Manuals (PHS GAMs) Part 119, "Applications for Projects with Time Constraints," and Part 144, "Requirements for Maximum Competition Under Assistance Programs." This is the first issuance of this NIH GAM.

B. Background:

Organizations that are eligible to apply for NIH grants include institutions of higher education, non-profit and for-profit organizations, hospitals, governments (including Federal agencies and institutions [1]), and individuals. Any special criteria for applicant eligibility or requirements concerning the qualifications of the principal investigator (PI) or other staff or participants will be specified in the program guidelines, or other publicly available documents. This NIH GAM sets forth the requirements for maximum competition for NIH grants. Further, awards shall be made after maximum competition except under the circumstances described in this NIH GAM. The preponderance of applications that are submitted to NIH under the categories of research and research training (including fellowship awards) are for investigator-initiated research and are considered "unsolicited" applications. NIH may develop areas of what are considered "high priority" or "special" research. Several means are used by the NIH to encourage and invite submission of applications and

proposals in those areas (see [NIH Manual Chapter 54110](), "Program Announcements and Request for Applications"). Funding Opportunity Announcements (FOAs) for these are published in the [NIH Guide for Grants and Contracts]() (http://grants.nih.gov/grants/guide/index.html), which are electronically linked to [Grants.gov]() (http://www.grants.gov/), a government-wide site for locating competitive grant opportunities.

C. Definitions:

1. **Hard earmark:** a specific recipient or class of recipients is named or identified in statute to receive funding for a particular project(s). Once specified in statute, the NIH awarding office must comply with the directive. Since, under a hard earmark, the agency is not exercising any discretion with respect to the recipient(s), the awarding office is not required to prepare a justification or issue a public notice.

2. **Limited competition:** occurs when there are administrative requirements which place limitations on (1) the eligibility of entities or type of entities which may apply; (2) the geographic location of the project; or (3) time available for review and award. Unlike single source awards, limited competition allows for more than one eligible entity to apply for funding. Examples include programs that restrict applicants to those currently receiving funding, or that have justifiable program priorities established and published under a funding announcement. This has the effect of restricting competition to that which is less than full and open. However, in accordance with NIH policy, limited competition does not apply to administrative supplements that by definition are neither competitive nor open to applicants beyond current recipients.

3. **Maximum competition:** all eligible entities may apply for funds under a particular financial assistance program. Eligibility may be

restricted to a certain class of entities by the program's appropriation or authorizing legislation, congressional committee reports, regulation, or the funding announcement.

4. **Single source:** occurs when eligibility for an application and award is administratively limited to only one entity.

5. **Soft earmark:** there is a general statement in report language concerning funding for a project or activity, but the language does not specify a single recipient or class of recipients; or a specific entity is identified in report language rather than in statute; or a general statement is included in report language that may point to, but does not specifically identify, a single recipient or a class of recipients. The Institute/Center (IC) is not required to implement a soft earmark and will determine its options in consultation with the IC budget office and the Office of the General Counsel (OGC), as appropriate. If the awarding office plans to make a single-source award on the basis of a soft earmark, it must have a justification prepared by the appropriate IC official (see Section D).

6. **Urgent award:** an award issued in response to a competing grant application received by NIH, and, because of time factors unique to the project for which support is requested, > cannot be held for the next applicable review cycle.

D. Policy:

1. **General:** It is the policy of NIH that applications for grants shall be sought from all eligible entities and that awards shall be made only after maximum competition occurs, except under the exceptions detailed in this NIH GAM:

   a. A single source may be appropriate where a single source award is mandated by NIH's appropriation or statute (see "hard earmark");

b. A single source for an award may be appropriate when there is a general statement in statute concerning funding for a project or activity (see "soft earmark");

c. A single source for an award may be considered when there is compelling evidence of unique and/or superior qualifications of only one entity to the extent that no other source(s) could fill the objectives of the program that are outlined within a funding announcement;

d. Limited competition may be appropriate when there are supplemental applications for the expansion of the project scope or research protocol for which an award may only be issued to an existing recipient;

e. Limited competition may be appropriate when there are justifiable program priorities established and published, under an RFA, which have the effect of restricting competition to less than full and open competition; and

f. Limited competition may be appropriate when the research is limited to a certain geographic location, which would restrict competition to less than full and open competition.

Examples of funding opportunities that limit eligibility for administrative reasons and are reviewed under limited competition are: competing continuation applications or competing supplemental applications for an existing program to current applicants.

Examples of funding opportunities that limit eligibility for legislative/regulatory reasons, Congressional report language or programmatic purposes, and are reviewed under maximum competition are SBIR/STTR awards, endowment awards, clinical career awards or awards issued

in response to an RFA/PA or Notice.

Reminder, statutory language must be followed. However, ICs have some policy discretion to decide whether or not to follow Congressional report language.

2. **Single source awards:** If an IC decides to issue a single-source award that is not a "hard earmark" (see Definitions), the IC must provide written justification of intent to make the award. Single source awards include unsolicited grant applications that are not competitively considered but do receive appropriate peer review. This justification must be approved by the IC Director or a designee who reports directly to the IC Director, and submitted to the Deputy Director for Extramural Research (DDER) for review and approval, prior to award.

   NIH will publish a Notice of Intent simultaneous with the release of the single source award. The Notice is intended as a summary notice and must be consistent with the basis for the award contained in the approved single-source justification. The Notice should be published in the NIH Guide for Grants and Contracts.

   If the basis for issuing the single source award is a requirement by statute (see "C., Definitions," hard earmarks), NIH is not required to provide written justification of intent to make a single source award. However, the IC is to provide a notification of this action to the DDER with a copy to the Director, Office of Extramural Programs and the appropriate individuals at the IC level.

3. **Limited Competition:** A Notice will be published in the NIH Guide for Grants and Contracts to solicit applications for funding opportunities when the competition is limited. A request to publish "Notices of Limited Competition" is submitted to the Director, Office

of Extramural Programs (OEP), and Office of Extramural Research (see G. "Procedures"). Applications that are received under limited competition will be reviewed in accordance with NIH's peer review process and are subject to all of the requirements of the pre-award process.

It is important to note that an assistance award that is to be provided to a single or a very limited number of sources without open competition often changes the characteristics of the mechanism. In selecting only one possible source and specifying the responsibilities of the respective parties to the assistance mechanism, the nature of the action often changes from assistance to acquisition, and thus becomes subject to contract requirements. Reviews and approvals of limited competition or single-source awards should specifically state that the appropriate funding mechanism would be used.

4. **Review of Applications for Projects with Time Constraints and Urgent Awards:** This applies to very unusual situations when competing grant applications are received and, because of time factors unique to the project for which support is requested, cannot be held for the next applicable review cycle. The resulting award is an urgent award. Examples include, but are not limited to, "now-or-never" research projects. Urgent awards may be made on a single source or limited competition basis, or may be made from an unsolicited application.

Although the receipt and review of urgent applications/awards are events that cannot be planned, the Program Administrator (PA) should provide the GMO as much advance notice of intent as possible.

The designation of an application as having a time constraint does not circumvent the requirement for unsolicited applications to be received by NIH in accordance with the applicable receipt date.

Like normal awards, urgent awards must be made for reasons consistent with the authorizing statute and mission of NIH. For example, urgent awards would not be issued for disaster relief that is not otherwise consistent with statutory authority. Urgent awards should be made for performance periods consistent with the nature of the urgency.

When an application has been identified as having a time constraint, and there is not sufficient time to review it under normal review procedures, the Extramural Programs Management Committee (EPMC) member shall convene an ad hoc (NIH staff) review board consisting of::

   a. A scientific PA from the awarding IC who is qualified to pass judgment on the scientific and technical merit of the application;
   b. The Chief Grants Management Officer of the awarding IC;
   c. If available, a scientific PA from outside the awarding IC who is sufficiently qualified to contribute to the evaluation of the application;
   d. If research involving human subjects or animals is proposed in the application, an official from the appropriate Office of Extramural Research office to review that aspect of the research plan (OEP for research involving human subjects or Office of Laboratory Animal Welfare [OLAW] for research involving animals); and
   e. A chairperson.

The ad hoc (NIH staff) review board shall prepare a written assessment of the application, with dissenting opinions noted, if any, that addresses the following issues/questions:

- Is the application worthy of support based on the program guidelines, and criteria for review of all applications?
- Would the application, if reviewed in the next available review cycle probably receive a priority score adequate to permit funding of the project?
- What is the recommended level of support and any special award conditions that should be placed on the award, if the review board is recommending approval?

Promptly after the meeting of the ad hoc (NIH staff) review board, the chairperson shall send the written assessment to the Chief GMO for inclusion in the official file.

A determination to fund a project using an urgent award process does not circumvent the requirement for Council approval of applications greater than $50,000 in direct costs.

As with single source awards, the IC must obtain approval from the DDER prior to issuing an urgent award, and publish a Notice in the NIH Guide for Grants and Contracts simultaneous with the release of the award.

5. **Forms:** All applications for single-source, limited competition and urgent awards must be submitted on the Office of Management and Budget (OMB)-approved grant application form PHS 398 http://grants.nih.gov/grants/funding/phs398/phs398.html or the

appropriate forms from the SF 424 family of forms.

6. **HHS Review and Approval of Pre-Award Documentation:** For all cases described above, NIH has received a waiver from HHS, Office of Grants Management and Policy's Action Transmittal (AT) 2003-3 OGMP AT 2003-3 , which explicitly states that "medical" activities under discretionary grants programs, including investigator-initiated applications that are submitted to NIH's Center for Scientific Review (CSR) do not require HHS Office of Grants Management & Policy review and approval of pre-award documentation.

E. References:

1. 42 CFR 52, Grants for Research Projects,
2. HHS Grants Policy Directive 2.04, Pre-Award - Awarding Grants
3. NIH Grants Policy Statement (rev. 12/03), Part I: NIH Grants— General Information
4. NIH Manual Chapter 54110, Program Announcements and Request for Applications
5. HHS OGMP ACTION TRANSMITTAL, OGMP AT 2003-3 (9/02/2003), "Review of Pre-Award Documentation--Grants and Cooperative Agreements.
6. "One HHS" 10 Department-wide Management Objectives (Updated December 22, 2004)"

F. Responsibilities:

1. **Chief Grants Management Officer (CGMO)**: assures compliance with the policy requirements stated in this NIH GAM, with particular attention to the selection of the appropriate award mechanism, and responsibilities to obtain appropriate approvals within NIH for Notices of Limited Competition and the issuance of single source

and urgent awards.

2. **Grants Management Officer/Specialist:** The GMO/GMS are agents of the CGMO and assigned responsibility for the day-to-day management of a portfolio of grants.

3. **Program Administrator (PA)**: with the Chief GMO, assures that the appropriate award mechanism has been selected, preparation of appropriate justifications for material sent to the DDER, Director of Office of Extramural Programs (OEP), Office of General Counsel (OGC) and other NIH offices.

4. **Extramural Program Management Committee (EPMC) member:** shall convene an ad hoc (NIH staff) review committee for the review of an urgent application.

5. **Deputy Director for Extramural Research (DDER)**: is the approving official for requests for single source and urgent awards.

6. **Director, Office of Extramural Programs (OEP), OER**: is the approving official for Notices of Limited Competition.

7. **Director, Division of Receipt and Referral (DRR), Center for Scientific Review (CSR)**: is the approving official for receipt dates for Notices of Limited Competition.

G. Procedures:

1. **Requests for limited competition**: a request is submitted, via e-mail to the Director of [OEP](#), and the Director, Division of Receipt and Referral, CSR. The request will include the "Notice of Limited Competition," inviting a limited pool of applicants who have been awarded NIH grants or meet other unique criteria such as access to special instrumentation or resources to apply for a funding opportunity. If approved by OEP, a Notice of Limited Competition is published in the NIH Guide for Grants and Contracts.

2. **Requests to issue a single source or urgent grant award**: a

request is submitted to the DDER. The request will include the following: the name of the intended grantee, grant mechanism, proposed period of support and anticipated award amount, description of the project, name of the PA, whether the activity to be funded is a new activity or is a continuation of an ongoing activity or a follow-on to a prior activity, and the basis for the judgment that the intended grantee is the only entity from which an application should be sought. This part of the determination must address all applicable considerations, including the nature and timing of the project, the qualifications of the organization or specified individuals that may be involved, prior or ongoing relationships (between NIH and the grantee, and any other relationship that would be pertinent to this decision), and relation to ongoing activities. The justification sent to the DDER for the issuance of an urgent award should include the same justification as submitted to issue a single source award, and specify any required deviations from the pre-award process (e.g., less than 30 days for preparation of an application).

3. **Issuing an Award in response to an earmark**: when issuing an award in response to a hard earmark, the agency is not exercising discretion with respect to the recipient(s). Thus, the awarding office is not required to obtain DDER approval for the issuance of the award, nor is it required to publish a Notice in the NIH Guide for Grants and Contracts informing the public about the issuance of the award.

   ICs are not required to award a "soft earmark." When considering the suitability of issuing an award in response to a soft earmark, the IC will typically consider the results of the peer review, and include the IC Director or his/her designee, and OGC, as appropriate, when making this determination. If the awarding office plans to make a single-source award on the basis of a soft earmark, a justification

must be prepared by the IC and approved by the DDER (see D, "Policy").

4. **Establishing a grant record for an application reviewed as an urgent application**: when establishing the grant record for an application identified as having a time constraint, the IC shall contact OPERA/OER and CSR to establish the grant record and input appropriate codes (e.g. human subjects and animal) for the proposed research.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, "NIH Records Control Schedule," "Section 4000, "Grants and Awards.

NIH e-mail messages: NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail

messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

The purpose of this NIH GAM is to implement the policies, procedures, and responsibilities for exceptions to maximum competition for grants and cooperative agreements, the review of grant applications that have time constraints, and the issuance of urgent awards.

1. The office responsible for reviewing management controls relative to this NIH GAM is the Office of Extramural Programs (OEP), Office of Extramural Research (OER).
2. Frequency of Review: The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess compliance with this NIH GAM. NIH GAM Chapters with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.
3. Method of Review: OEP will complete an internal risk assessment in the first year after the chapter is in place. Based on this assessment, a decision will be made as to the method of review.
4. Review Reports are sent to: Deputy Director for Management (DDM) and Deputy Director for Extramural Research (DDER) indicating that controls are in place and working well or include any management control issues that should be brought to the attention of the DDM.

Footnote from Section B:

[1]When submitting a grant application to NIH, a Federal agency/institution

must ensure that its own authorizing legislation will allow it to receive NIH grants and to be able to comply with the award terms and conditions.

NIH POLICY MANUAL

4204-204B - Peer Review Process

Issuing Office: OD/OER/OEP 301-435-2768
Release Date: 09/17/13

1. **Explanation of Material Transmitted:**

This National Institutes of Health (NIH) Grants Administration Manual (GAM) implements those portions of the [Department of Health and Human Services (HHS) Grants Policy Directive (GPD) Part 2.04](#) "Pre-Award (Awarding Grants)"; the [HHS Grants Policy Statement Part I.9](#) "Application and Application Review Processes"; the [National Institutes of Health Reform Act of 2006](#); and the [NIH Grants Policy Statement](#) that apply to peer review of grant applications (including cooperative agreements) and Revision applications.

This NIH GAM cites other NIH Manual Chapters. In the event of inconsistency, the language in this NIH GAM supersedes the language of any statement in any of the referenced NIH Manual Chapters which predate this issuance.

The purposes of this revised NIH GAM are to:

a. Integrate NIH policy for:

- the core values of NIH peer review;

- multiple Project Directors/Principal Investigators (PDs/PIs);

- modular budgets;

- modified application submission, referral, and review for appointed members of chartered NIH Advisory Groups (Initial/Integrated Review Groups [IRGs], National Advisory Councils and Boards [herein and after referred to as "Councils"], Boards of Scientific Counselors [BSCs], and Program Advisory Committees [PACs]), and individuals with substantial, recent service on NIH Scientific Review Groups (SRGs);

- late submission of applications for grants, cooperative agreements, and Revisions;

- protecting the confidentiality of NIH application data sent to peer reviewers in electronic format;

- New and Early Stage Investigators;

- post-submission materials;

- prohibition of federally-registered lobbyists serving in NIH peer review;

- conflict of interest (COI) for reviewers;

- scoring during initial peer review;

- handling appeals, grievances, and disputes that arise from the initial peer review process;

- intramural scientists serving as SRG members;

- prohibiting the audio or video recording of closed sessions of NIH SRG meetings;

- representation of individuals from multi-component organizations on individual SRGs;

- handling allegations of research misconduct that may arise during the initial peer review process;

- review criteria for different types of applications and competing revisions;

- review of grant applications at or below $50,000, as required by the [NIH Reform Act of 2006](#);

- receipt and referral of electronic grant applications and Revision applications;

- conducting reviews by site visits to include the use of independent Special Emphasis Panels (SEPs);

- conducting review involving interviews of candidates or applicants;

- preparing summary statements;

- deviating from policy specified in this chapter; and

- managing the submission of videos as application materials;

b. Clarify the roles of:

- Scientific Review Officers (SROs), formerly Scientific Review Administrators, in the management of peer review; and

- grants management staff concerning the peer review process;

c. Incorporate information from and rescind:

- NIH Manual Chapter 54516 "Review of Institutional National Research Service Award Applications": http://oma1.od.nih.gov/manualchapters/grants/54516/;

- NIH Manual Chapter 54517 "Review of Program Project Applications": http://oma1.od.nih.gov/manualchapters/grants/54517/;

- OER Policy Announcement 2000-03 "Coding Unscored Applications for Human Subjects and Animal Subjects": http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2000_0 3.htm;

- OER Policy Announcement 2011-01 "Revised Policy for Appeals of NIH Initial Peer Review": http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2011_01.htm;

- OER Policy Announcement 2011-02 "Additional Policy for Scoring Applications During NIH Initial Peer Review": http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2011_02.ht m;

- OER Policy Announcement 2012-01 "Prohibiting the Audio or Video Recording of Closed Sessions of NIH Scientific Review Group Meetings": http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2012_01.htm;

- OER Policy Announcement 2012-02 "Additional Policy for Appeals of NIH Initial Peer Review: SRO Response Letter: http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2012_02.htm; and

- OER Policy Announcement 2013-02 "Blanket Waiver for Individuals from Applicant Organizations to Serve on Initial Scientific Review Groups Evaluating Requests for Applications": http://nih-extramural-intranet.od.nih.gov/nih/policies/OER_announce_2013_02.htm

d. Rescind:

- NIH Guide Notice NOT-97-232 "Appeals of Initial Scientific Peer Review": http://grants.nih.gov/grants/guide/notice-files/not9 7-232.html;

- NIH Guide Notice NOT-97-010 "Review Criteria for and Rating of Unsolicited Research Grant and Other Applications": http://grants.nih.gov/grants/guide/notice-files/not97-010.html; and

- NIH Guide Notice NOT-OD-11-120 "Revised Policy: Managing Conflict of Interest in the Initial Peer Review of NIH Grant and Cooperative Agreement Applications" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-120.html).

For information regarding the administration and management of Councils, and the rules applicable to the Special Government Employee (SGE) members of Councils, PACs, and BSCs, see NIH Manual Chapters 1805 "Use of Advisors in Program and Project Review and Management", 1810-1 "Procedures for Avoiding COI for NIH SGE Advisory Committee Members", 3005 "Review and Evaluation of Intramural Programs", and 54513 "Management and Procedures of NIH National Advisory Councils and Boards in Their Review of Extramural Activities".

For information regarding the ethical conduct rules applicable to Federal employees, see 5 C.F.R. Part 2635 "Standards of Ethical Conduct for Employees of the Executive Branch", 5 C.F.R. Part 5501 "Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services". Note that employees of certain Federal agencies are subject to additional, agency-specific rules. For information on additional ethical conduct rules applicable to NIH employees, go to the NIH Ethics Program Web site (http://ethics.od.nih.gov/).

2. **Filing Instructions:**

   Remove: NIH GAM 4204-204B, issued 7/12/2006.
   Insert: NIH GAM 4204-204B, dated 09/17/13.

PLEASE NOTE:

- For questions on the content of this chapter, contact the issuing office listed at the top of the document; or

- For on-line information on the NIH Manual System, contact the Division of Management Support, OMA on (301) 496-2832 or go to: http://oma.nih.gov/public/MS/manualchapters/pages/default.aspx.

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NIH POLICY MANUAL

4204-204B - Peer Review Process

Issuing Office: OD/OER/OEP 301-435-2768
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I. Table of Contents:

II. Purpose:

The NIH GAM is intended to ensure that applications (as specified below) submitted to the NIH are evaluated in a fair, equitable, informed, and unbiased process. The NIH initial peer review process (see Appendix B. Definitions) is defined in regulation at 42 C.F.R. Part 52h for:

- applications to the NIH for grants or cooperative agreements for biomedical and behavioral research, and

- biomedical and behavioral research and development contract project concepts and proposals for contract projects administered by the NIH,

and is extended by policy to other types of applications submitted to the agency.
In addition to the updated guidance listed in the Explanation of Material Transmitted, above, this NIH GAM:

- explains the policies, procedures, and responsibilities for the first level of peer review for all applications for competing research project grants and Revisions (formerly competing supplements); program projects; resources, including but not limited to instrumentation; center grants (42 C.F.R. Part 52a) and cooperative agreements; institutional and individual National Research Service Awards (NRSAs; 42 C.F.R. Part 66); and academic, clinical investigator, and career development awards. Hereafter "application" refers to all these types of application. The policies, procedures, and responsibilities in this NIH GAM do not necessarily apply to the peer review of other submissions, such as applications for construction grants (42 C.F.R. Part 52b), pre-applications, and contract proposals, including applications to the NIH Loan Repayment Program;

- specifies the requirements for peer review and describes the types of review and processes that may be used to review applications in the absence of specific statutory or regulatory

requirements;

- provides supplementary guidance, to the extent consistent with the statutory or regulatory requirements, for programs subject to statutory or regulatory requirements that differ from the general policies in this GAM. In such a case, the statutory or regulatory requirements will control; and

- primarily addresses issues of policy and principle, although procedures and implementations are specified in certain cases.

Additional or differing policies applicable to the reviews of particular types of applications are found in [NIH Manual Chapters 54105](#) "NIH Support of Scientific Meetings and Conferences by Grants and Cooperative Agreements," [7410](#) "Review And Documentation Of Protections For Human Subjects In Extramural Grant Applications And Research And Development Contract Proposals," [54110](#) "Program Announcements and Requests for Applications," [54810](#) "National Research Service Awards," and [54815](#) "Implementation of Cooperative Agreements".

In some cases, waivers of certain policies and procedures addressed in this NIH GAM may be justified, as discussed further in this chapter.

III. Core Values:

The core values of NIH peer review, described below, drive NIH to seek the highest level of ethical standards, and form the foundation for the NIH peer review process.

A. Expert Assessment

NIH policy requires that the scientific expertise in the Scientific Review Group (SRG see Appendix B. Definitions) be suitable for evaluating the potential impact of the proposed work. Close attention is given to equitable geographic distribution and to ethnic and gender representation in the SRG. Appointments are made without discrimination on the basis of age, ethnicity, gender, sexual orientation, disability, cultural, religious, or socioeconomic status.

B. Transparency

Applications submitted to the NIH are evaluated for scientific and technical merit using established review criteria, which must be published in the Funding Opportunity Announcement (FOA) (see Appendix B. Definitions). The NIH also strives for transparency by publicizing descriptions of standing SRGs, the rosters of individuals who participate on SRGs, information on each funded grant, the guidelines sent to reviewers, and descriptions of the NIH peer review process.

C. Impartiality

Any circumstance that might introduce COI, the appearance of COI, bias, or predisposition into the review process must be managed to avoid inappropriate influence in the review process. Bases for COI in NIH peer review include, but are not limited to, financial interests, professional relationships, employment, study section membership, and personal relationships, as well as interests and interactions that may cause NIH extramural staff or reviewers to question the propriety of their involvement, or the perceived integrity of the review process. Finally, NIH policies for managing appeals of initial peer review are based on documentable flaws in the review process.

D. Fairness

All applications received for NIH review are evaluated using equivalent review processes. To ensure equitable evaluation, the NIH uses a nine-point scoring scale in reviewing all types of applications, and standard review criteria for the evaluation of all applications of a particular funding mechanism, as defined by authorizing legislation. Finally, a written outcome of review – the NIH Summary Statement - is provided to the Advisory Council, the Project Director/Principal Investigator (PD/PI), relevant NIH staff, and reviewers for Resubmission and Renewal applications.

E. Confidentiality and Non-disclosure

Portions of NIH review meetings are closed or partially closed to the public if grant applications (and/or contract proposals) are being reviewed or discussed, although Federal employees with a need to know, reviewers, and support contractors are allowed to attend. Reviewers must certify their understanding of the NIH confidentiality and non-disclosure rules, which cover SRG discussions, application materials (except those in the public domain), and information about COI and assignments of individual reviewers to particular applications. Review communications and grant applications are handled so as to protect sensitive data and confidential information.

F. Integrity and Ethical Considerations

The NIH is fully committed to maintaining public trust in the NIH research enterprise by supporting our grantees in adhering to the highest standards of research integrity. Reviewers and Council members are instructed to report any suspicion or allegation of research misconduct directly to the Designated Federal Official (DFO) (see Appendix B. Definitions) in charge of the meeting, and to do so in strictest confidence. Allegations that involve NIH funding and have sufficient detail to allow consideration are forwarded by the NIH to the DHHS Office of Research Integrity for consideration and appropriate action.

G. Efficiency

With the steadily increasing pace of biomedical research, the NIH peer review system continuously strives to reduce the time from submission of applications to awards for the most

meritorious projects. (In some cases, an accelerated schedule from application submission to award is mandated in statute.) These efforts include streamlining operations when possible, and incorporating new technologies as they arise.

IV. Statute and Regulation:

In accordance with section 492 of the Public Health Service Act (PHS Act; 42 U.S.C. 289a "Peer Review Requirements") and Federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects" (42 C.F.R. Part 52h), applications submitted to the NIH will be evaluated by the NIH peer review process to ensure a fair, equitable, informed, and unbiased evaluation of their scientific and technical merit.

Section 492 of the PHS Act requires that, to the extent practical, peer review be conducted in a manner consistent with the system for technical and scientific peer review applicable on November 20, 1985, the date of enactment of the Health Research Extension Act of 1985 (P.L. 99-158).

A. Dual Review System

The NIH peer review process comprises two sequential levels of review, as required by the PHS Act. Each level of review must be conducted in accordance with applicable laws, regulations, and policies, including the requirements set forth in this NIH GAM.

The first level of review is carried out by an SRG composed primarily of non-Federal experts qualified by training and experience in particular scientific or technical fields, or recognized as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review. The composition of an SRG may be up to one-fourth Federal employees (PHS Act). Hereafter, these experts are referred to as peer reviewers or reviewers (see Appendix B. Definitions). Section 492 of the PHS Act requires that the reviewing entity be provided a written description of the research to be reviewed, and that the reviewing entity provide the Advisory Council of the national research institute involved with such description and the results of the review by the entity.

The second level of review is performed by Councils (see Appendix B. Definitions) composed of scientific and public members who are chosen for their expertise, interest, or activity in matters related to a specific NIH Institute or Center (IC), and who are appointed as Special Government Employees (SGEs; see Appendix B. Definitions). Each Council is advisory to an IC Director, the NIH Director, or the Secretary, HHS. With the exception of individual NRSA fellowship applications (see NIH Manual Chapter 54513), awards may not be approved without concurrence by the Council of the involved IC. For additional information regarding the administration and management of these Advisory Committees, see NIH Manual Chapters 1805; 1810-1; and 54513.

B. The Federal Advisory Committee Act

Section 402 of the PHS Act states that the Director, NIH, may establish and appoint such review groups as needed ([42 U.S.C. 282(b)(16)](#)); the Federal Advisory Committee Act (FACA), [5 U.S.C. App.](#) 2, governs the establishment and operation of these review groups. All NIH SRG meetings are carried out under provisions of the [FACA](#) and are closed to the public in accordance with its provisions (see [5 U.S.C. Section 552b](#)).

C. The NIH Reform Act of 2006

As required by the [National Institutes of Health Reform Act of 2006](#), P.L. 109-482, all research grant and cooperative agreements must undergo Advisory Council/Board review and approval prior to funding, regardless of the dollar level requested

V. Policy:

New policy is issued in the NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide/index.html) and in OER Policy Announcements (http://nih-extramural-intranet.od.nih.gov/nih/sources/sources_nih_oer_policy.htm). Changes to NIH peer review policy generally are presented to, and discussed by, staff functional committees e.g., the Review Policy Committee (RPC) and the Extramural Program Management Committee (EPMC).

A. **Expert Assessment**

Consistent with HHS policy, each application subject to the peer review requirements of this NIH GAM must be reviewed objectively by a minimum of three qualified independent reviewers ([HHS Grants Policy Directive 2.04](#) "Pre-Award - Awarding Grants"). NIH policy requires that each application be reviewed in a meeting of at least five SRG members who participate in discussion and scoring of the application. SRG meetings with three or four SRG members require a waiver approved by the Review Branch Chief.

1. **Balanced Representation**

HHS policy requires the recruitment of SRG members to include representation of both genders, a variety of racial/ethnic groups, and a variety of geographic areas (see [HHS General Administration Manu al, Part 9-00-70](#) "Nomination, Selection and Appointment of Federal Advisory Committee Members").

Policy applicable to concurrent committee service of reviewers, and representation of individuals on a peer review meeting roster who are from the same, non-Federal institution in the same city (often termed a "dyad"), may be found in the Office of Federal Advisory Committee Policy [OFACP Policy Announcement 2008-01](#) "Waiver of Requests for Advisory Committee Member Appointments and Meeting Attendees".

As appropriate for the applications under consideration, the NIH recruits reviewers to encompass broad and diverse scientific views, and to assess specific aims and methodology. In certain cases, public representatives may be recruited to provide perspective from the patient or advocacy point of view, or individuals with knowledge of technology transfer or accounting practices may serve as reviewers. In addition, for evaluations of NRSA applications, reviewers should have substantial experience in graduate research training, with an active interest in the methods and planning of research training in their discipline, field, or specialty, and a record of accomplishment in training predoctoral and/or postdoctoral students.

Scientists from around the globe are recruited as peer reviewers. Foreign scientists are recruited for their scientific and technical expertise, and are not recruited on the basis of their official position or duties.

2. **Continuous Submission**

The NIH implemented the Continuous Submission policy (e.g. NIH Guide Notice NOT-OD-11-093) to recognize outstanding review and advisory service by members of the scientific community, and to minimize disincentives to such service. The policy is in effect for submission and review of applications from appointed members of NIH Advisory Groups (Initial/Integrated Review Groups, NIH Boards of Scientific Counselors, NIH Councils, and NIH Program Advisory Committees) and individuals who have performed substantial, recent advisory service on NIH peer review committees (who have participated in NIH peer review committees as regular or temporary members six times in a defined 18–month period). For applications that normally would be received on standard submission dates (but not special receipt dates), appointed regular (not temporary or ad hoc) members of NIH Advisory Groups and individuals with substantial, recent service on NIH peer review committees may submit R01, R21, and R34 applications and the applications under the continuous submission option.

The NIH allows applicants and their institutions to identify more than one PD/PI on most research grant applications (see NIH Grants Policy Statement, Chapter 9). The continuous submission process applies to any multi-PD/PI application if one or more of the PDs/PIs are appointed member(s) of an NIH Advisory Group or have substantial, recent service on NIH peer review committees.

B. **Transparency**
   1. **Scored review criteria**

Each application must be evaluated on its own merit according to established review criteria, which must be stated clearly in relevant FOAs, Requests for Applications (RFAs) (see Appendix B. Definitions), and program announcements (PAs, PARs, and PASs) (see Appendix B. Definitions), and made available to the SRG members when the applications are provided to them. The SRO is responsible for ensuring that all SRG members are made aware of review criteria specific to the applications they are asked to review and that the SRG members apply these specific criteria to all applications of each type under review.

For each type of application, at least five review criteria are assigned individual criterion scores. Criteria to be used for the evaluation of applications for research grants and cooperative agreements are identified in 42 C.F.R. Part 52h. Although all of these criteria must be used for evaluation of applications submitted for all FOAs for research applications (NOT-OD-09-025), in unusual circumstances, they may be re-defined to facilitate the goals of the initiative and/or specific criteria may be added, if specified in the FOA.

In addition, the criteria identified in 42 C.F.R. Part 52h are used for the evaluation of other types of applications, as appropriate. Other criteria are used for the evaluation of other types of applications:

- 42 C.F.R. Part 52a for select NIH Health Center grant applications;

- 42 C.F.R. Part 52b for applications for NIH construction grants;

- 42 C.F.R. Part 66 for applications for NIH NRSA fellowship and training awards (see also NIH Manual Chapter 54810; NOT-OD-09-074 and NOT-OD-11-110); and

- NIH Manual Chapter 54105 for NIH applications for scientific meetings and conferences.

2. **Emphasis**

Generally, the emphasis on each criterion may vary from one application and reviewer to another, as determined by each reviewer's individual judgment. Although all of the established, scored review criteria must be considered in the evaluation of scientific and technical merit, in certain PARs or RFAs special emphasis may be placed on certain of the established review criteria. Such special considerations must be:

- applied to all applications received in response to a particular PAR or RFA;

- specified clearly in the FOA; and

justified by the goals of the program.

Approval from the Office of Extramural Programs (OEP) is required to use review criteria with nonstandard definitions, or nonstandard criteria, in an FOA.

3. **Additional Review Criteria**

Additional review criteria must be considered by the SRG in their evaluation of scientific and technical merit, and overall impact, if applicable for the work proposed, including:

- Protection for Human Subjects (see NIH Manual Chapter 7410 "Review And Documentation Of Protections For Human Subjects In Extramural Grant Applications And Research And Development Contract Proposals");

- Inclusion of Women, Minorities, and Children;

- Vertebrate Animals;

- Biohazards;

- Resubmissions;

- Renewals; and

- Revisions

Additional review criteria that are specific for a particular PAR or RFA may be included in the FOA, if approved by OEP.

C. **Impartiality**
   1. **Conflict of Interest (COI)**

This section articulates policies governing the management of COI, appearance of COI, prejudice, bias, or predisposition on the part of individuals who are not Federal employees participating as SRG reviewers, and in the selection and use of Federal employees to participate as SRG reviewers, in the initial peer review of all applications submitted to the NIH (see definition above), with the exception of applications for NIH construction grants and proposals for R&D contracts.

   a. **Responsibilities for managing COI or appearances of COI**
      1. **NIH Scientific Review Officers (SROs)**

         Procedures and measures to be taken by the SRO and non-Federal SRG members in advance of, during, and after SRG meetings in relation to COI and appearance of COI are based on the peer review regulations at 42

C.F.R. Part 52h. NIH SROs may not assign review responsibilities to a non-Federal reviewer or Federal employee that would violate the policy set forth below, unless the Deputy Director for Extramural Research (DDER) first grants a waiver.

As noted throughout, Federal employee peer reviewers must abide by statutory and regulatory rules governing COI and appearance of COI and should consult their ethics officials as needed.

2. **Non-Federal SRG Members**

An SRG member who is not a Federal employee and has a real COI or an appearance of a COI with an application may not participate in its review, unless a waiver has been granted consistent with the peer review regulations at 42 C.F.R. Part 52h. As defined in regulation, several bases exist for COI for non-Federal SRG members, including employment, financial benefit, personal relationships, professional relationships or other interests.

All non-Federal SRG members, including Mail Reviewers (see Appendix B. Definitions), must certify that they have identified to the SRO, before the SRG meeting, the existence of all known COI and all situations perceived as the appearance of COI, and must certify after the SRG meeting that they did not participate in the discussion or evaluation of any application with which they have a COI or the appearance of a COI.

3. **Federal Employee SRG Members**

Federal employees may participate in the NIH initial peer review process as part of their official duties. At all times, these Federal officials are subject to the comprehensive body of law governing the conduct of Federal employees. The applicable statutes and regulations include 18 U.S.C. Sections 201-216, the government-wide Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Parts 2634, 2635, and 2640, and agency-specific regulations such as the Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services (5 C.F.R. Part 5501). A Federal employee serving as a member of an NIH SRG is responsible for complying with all applicable ethical conduct rules and obtaining any clearance for his/her SRG service required by/in his/her employing institute, agency, or office.

An SRG member who is a Federal employee and has a COI under the criminal statute, 18 U.S.C. Section 208, or an apparent COI under the Standards of Ethical Conduct for Employees of the Executive Branch (5 C.F.R. Section 2635.502), with an application may not participate in its review, unless a waiver or authorization, respectively, has been granted by the appropriate authority at the employing agency, consistent with agency delegations of authority. Federal employees should be strongly encouraged to consult with their ethics officials regarding any questions regarding the application of the COI statute and the Standards of Ethical Conduct in the context of their service as NIH peer reviewers.

Federal employees should be reminded to consider all potential sources of conflict when engaging in initial peer review, including outside activities, such as clinical practice and teaching, speaking, or writing, spousal employment, and investment interests. In the event any applicable statute or regulation requirement imposes greater restrictions than NIH policy, employees must abide by the legal requirement.

All Federal SRG members and review participants must certify that they will maintain the requisite confidentiality of all materials and matters associated with their participation in initial peer review; and certify after each SRG meeting that they have received information regarding the COI rules applicable to Federal employees and did not participate in the discussion or evaluation of any application with which they have a COI or apparent COI, unless a waiver or authorization was issued consistent with government ethics requirements.

b. **Managing COI or Appearance of COI**

1. **Multiple Project Directors/Principal Investigators (PDs/PIs)**

For purposes of determining COI or appearance of COI in initial peer review, multiple PDs/PIs are considered interchangeable and to have the same level of professional involvement in the work proposed.

2. **Financial Benefit**

The NIH Peer Review Regulation (42 C.F.R. Part 52h) states that a non-Federal reviewer has a real COI if he/she or a close relative or professional associate of the reviewer 1) has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review; or 2) has received or could receive an indirect financial benefit from the applicant institution or Principal Investigator of an

application that in the aggregate exceeds $10,000 per year. The NIH Peer Review Regulation further states that if a reviewer has a real or apparent COI, he/she must recuse him/herself from the review of the application.

Regardless of the role he/she plays in the application and regardless of the complexity of the application, if a reviewer could receive, or the reviewer's close relative could receive, a direct financial benefit of any amount from an application, and the conflict is known to the reviewer and/or the SRO managing the review, the reviewer has a real conflict of interest and may not serve on the SRG (termed "out of the SRG" or "may not serve") unless a waiver is granted by the DDER in advance of the meeting.

In addition, in connection with an application of any complexity, a reviewer who has received in the twelve months preceding his or her receipt of the application, or who could receive, an indirect financial benefit from the applicant institution or any of the multiple PD(s)/PI(s) of an application of any complexity, that in the aggregate exceeds $10,000 per year, may not review the application (termed an "out of the room" conflict).
Federal employees are precluded under the criminal statute, 18 U.S.C. 208, and the ethical conduct regulations at 5 C.F.R. Part 2635.502, from participating in any review that would affect a personal or imputed financial interest or that involves an entity with which they have a covered relationship, including close relatives, household members, and others (see Appendix B. Definitions).

3. **Employment**

The NIH Peer Review Regulation (42 C.F.R. Part 52h) states that a reviewer who is a salaried employee, whether full-time or part-time, of the applicant institution or Principal Investigator, or is negotiating for employment, shall be considered to have a real conflict of interest with regard to an application from that organization or Principal Investigator.

A reviewer who is a salaried employee, whether full-time or part-time of any of the multiple PDs/PIs and/or any of the institutions of an application of any complexity, will be considered to have a real COI with that application. Provided that any other real or apparent COI is resolved, a reviewer who has a COI due to their current or pending employment may not participate in the review of the application in question ("out of the room" or "may not review") but may review other applications under

consideration in the SRG (however, see the exception for multi-component organizations below). Federal reviewers are subject to such restrictions under applicable government ethics standards.

4. **Individuals Participating with Major Professional Roles**

An individual participating in a project with a major professional role may not serve as a member of the SRG where the application in question is reviewed ("out of the SRG" or "may not serve") unless a waiver is granted by the DDER in advance of the meeting. This restriction also applies to a Federal employee reviewer, even when no government ethics violation would result from participation. Individuals participating with major professional roles include the PD/PI or any one of multiple PDs/PIs, and individuals listed on an application as Senior/Key Personnel, Project/Site/Core Directors, Other Significant Contributors, and certain collaborators and consultants.

5. **Professional Associates**

Provided that any other real or apparent COI is resolved, professional associates may not participate in the review of the application in question ("out of the room" or "may not review") but may review other applications under consideration in the SRG. In addition, an SRG member, including a Federal employee (even where participation in the review would not violate government ethics rules), may serve on the SRG but may not, in the absence of a waiver granted by the DDER, participate in the review of a specific application if the reviewer:

- within the preceding three years, has collaborated with, co-authored a publication with, and/or mentored or trained an individual named on the application as participating with a major professional role;

- is in collaboration, is negotiating collaboration, or is preparing an application(s) or publication(s) with an individual named in the application as participating with a major professional role;

- writes a reference letter for an applicant or candidate to accompany a fellowship or career award application and that application is the one in question;

- writes a letter of general support or enthusiasm for the application in question but plays no substantive role in the proposed work;

- serves as a member of an Advisory Board (AB) for the application in

question, or for an individual investigator(s) who has(have) a major professional role in the application pending review;

- is named as a speaker in a conference/meeting grant application and that application is the one in question;

- serves as a member of a Data and Safety Monitoring Board (DSMB) for the project or investigator(s);

- has a primary professional appointment in the same organizational component/school of a multi-component academic institution, hospital, health center, or research institute as that of an individual listed on the application as participating with a major professional role. Situations involving a secondary appointment of a named individual and an SRG member at the same component of a multi-component academic institution, hospital, health center or research institute will be assessed by the SRO on a case-by-case basis.

6. **Applicants to an RFA**

Unless a deviation from a limitation set forth in this Section is granted by the DDER, an investigator who participates with a major professional role on an application submitted in response to an RFA, or a Federal employee subject to one of the above-stated limitations in relation to an application submitted in response to an RFA, may not serve as a reviewer of that application or other applications submitted in response to the same RFA ("out of the SRG" or "may not serve"). Federal employee reviewers seeking a deviation based on financial benefit or employment, as described above, must also obtain a waiver or authorization through their ethics official prior to service.

A reviewer from an applicant organization that submitted an application for an RFA may serve on an SRG that is evaluating applications submitted for that RFA, without a waiver, provided that the following conditions are met:

- That reviewer must be recused from the evaluation and discussion of any applications submitted by his/her institution for that RFA.

- A reasonable number of applications (≥ 10) were submitted for that RFA and will be evaluated by that SRG. If a small number of applications were submitted for that RFA or will be evaluated by that SRG, every attempt should be made not to include reviewers from any of the applicant organizations.

- All other conflicts of interest should be managed in keeping with NIH policy ([NOT-OD-13-010](#)).

7. **SRGs that Meet Regularly**

According to the NIH Peer Review Regulation ([42 C.F.R. Part 52h](#)), when a peer review group meets regularly it is assumed that a relationship among individual reviewers in the group exists and that the group as a whole may not be objective about evaluating the work of one of its members. When a peer review group meets regularly, a member's application or an application that lists the member as participating with a major professional role will be reviewed by another qualified SRG to ensure a competent and objective review. In addition, an application that is from an individual who serves regularly on the same SRG, or that lists such an individual as participating with a major professional role, may create an appearance of COI for review in that SRG. The SRO will monitor such situations and appropriately manage the potential COI.

In addition, SROs are normally barred from managing or conducting the initial review of applications from members of their own committees. Additionally, the chairperson of disqualified committees may not chair those reviews.

8. **Exceptions**

Applicant Institution. An SRG member who is named in an application but has no other affiliation with the applicant institution may participate in the review of other applications from that applicant institution, provided that any other real or apparent COI is resolved. Federal reviewers must also ensure that any real or apparent COI under government ethics rules is resolved by appropriate officials consistent with agency delegations of authority.

Multi-component Institutions. For non-Federal reviewers, separate organizational components/schools of multi-component academic institutions, hospitals, health centers, and research institutions, as well as different NIH ICs, and Federal agencies, are sufficiently independent that an employee of one component serving on an SRG can review an application from another component, if the reviewer has no responsibilities at the institution that would significantly affect the other component and

any other real or apparent COI is resolved. For example:

- the separate campuses of the California State system are considered separate components in the same way that the separate campuses of the University of California system are so noted in [42 C.F.R. Part 52h](#);

- the separate affiliates of the Harvard system are considered separate components;

- the Johns Hopkins Bayview Medical Center and the School of Arts and Sciences, Homewood Campus, are considered separate components;

- the Johns Hopkins Schools of Arts and Sciences and of Engineering, Homewood Campus, are considered separate components; but

- the Departments of Biology and Chemistry within the School of Arts and Sciences of the same academic institution are not considered separate components.

A Federal employee who has, under government ethics rules, a covered relationship with or financial interest in an applicant institution may not participate in the review of an application even if the institution is a multi-component institution ("out of the room" or "may not review"), except in the case of State multi-campus institutions of higher education where the individual has no cross-campus responsibilities. The separate campuses of, for instance, the University of California qualify, but the separate campuses of Johns Hopkins do not. Members of the NIH Intramural Research Program (IRP) may not participate in the review of an application involving another member of the NIH IRP participating with a major professional role in an application for an allocation from the NIH Common Fund, regardless of IC affiliation, unless a waiver is granted by the DDER.

Individuals Participating with Minor Professional Roles. An individual listed in an application as participating with a minor professional role may review the application and other applications in the SRG without a waiver, provided that any other real or apparent COI is resolved. Situations involving minor professional roles will be assessed by the SRO on a case-by-case basis.

Federal reviewers also must ensure that any real or apparent COI under

government ethics rules is resolved by appropriate officials consistent with agency delegations of authority.

Examples of a minor professional role include an individual who:

- supplies a resource or service to the applicant, and that resource or service is freely available to anyone in the scientific community;

- donates data, specimens, or other resources to a central repository or consortium effort to which an individual(s) named on the application also donates data, specimens or other resources, unless both individuals play major professional roles in the consortium;

- co-authored a review article, position paper, professional group or conference report with an individual listed on the application;

- is from an institution that is part of a multi-center network (e.g., accrual sites for a multi-center clinical trial) or consortium (e.g., Genome Wide Association Study) that includes the applicant institution, where the SRG member is not involved in the work of the network or consortium.

Mail Reviewers. COI or the appearance of COI for Mail Reviewers is managed primarily for those applications that they have been asked to evaluate, not for all applications pending review in the SRG. However, a Mail Reviewer may not review an application pending review in the same SRG where another application is pending review that lists him/her as participating with a major professional role, in the absence of a waiver.

Howard Hughes Medical Institute (HHMI). HHMI peer reviewers serving on SRGs may review applications from other HHMI investigators provided they do not work at the same component/school of a multi-component academic institution and any other real or apparent COI is resolved.

c. **Federally Registered Lobbyists**

All SRG members must certify that they are not federally registered lobbyists in order to serve in the NIH peer review system (see OFACP Policy December 2011).

d. **Undue Influence**

An individual may not participate in both an application's initial peer review and

Council review, to avoid any one individual from having undue influence on the evaluation of an application. Similarly, an individual may not participate as a Mail Reviewer and fully participating SRG member evaluating the same application.

e. **Requests for Waivers**

For non-Federal reviewers, the NIH Peer Review Regulations at 42 C.F.R. Part 52h.5(b)(4) specify that in the review of grant and cooperative agreement applications, the Director, NIH (or his/her designee) is authorized to waive the requirement for recusal due to a real COI, as defined in those regulations, when the Director (or his/her designee) determines that there are no other practical means for securing appropriate expert advice to provide a competent review of a grant or cooperative agreement application, and that the COI is not so substantial as to be likely to affect the integrity of the advice to be provided by the reviewer. In addition, the regulations at Part 52h.5(c) authorize the Director, NIH (or his/her designee) to waive the requirement for recusal due to the appearance of COI, when the Director (or his/her designee) determines that it would be difficult or impractical to carry out the review otherwise, and the integrity of the review process would not be impaired by the reviewer's participation.

The authority to grant such waivers has been delegated to the DDER, and further delegation is prohibited. The DDER may waive the requirements for recusal in specific instances after review of adequate written justification submitted by an SRO or other official designated by an IC. The justification must explain fully the circumstances for the requested deviation. The SRO or other designated IC official either must exclude the reviewer or obtain advance written approval from the DDER to allow the individual to serve.

While the NIH Peer Review Regulations do not apply to Federal employees engaged in initial peer review, the policy limitations on the selection and use of Federal employees in initial peer review are modeled on those regulations. In order to facilitate a thorough and competent review of applications, the DDER may waive the policy limitations set forth above in specific instances after review of adequate written justification submitted by an SRO or other official designated by an IC. The justification must explain fully the circumstances for the requested deviation. The SRO or other designated IC official either must exclude the reviewer or obtain advance written approval from the DDER to allow the individual to serve.

Situations that may be considered for waivers are of the types that exist between an individual reviewer and an individual application, and co-authorship of multi-authored publications (other than review articles, position papers, or professional group or conference reports) within the preceding three years. Situations that are disallowed by law, regulation, or designated authority cannot be waived and should never be allowed.

For Federal employees serving as NIH peer reviewers, waivers and authorizations of conflicts of financial interest and appearance concerns under government ethics rules, 18 U.S.C. Section 208 and 5 C.F.R. Section 2635.502, must be obtained from appropriate ethics and agency officials prior to participation.

2. **Separation of Functions for NIH Staff**

NIH extramural staff members, consisting of the DDER, Referral Officers, SROs, Program Officials (POs; see Appendix B. Definitions), Grants Management Officers (GMOs; see Appendix B. Definitions), and review support staff have important and complementary roles and responsibilities in the initial peer review process. During the review process, the balance of cooperation and independent responsibilities among these staff members is intended to ensure fair and objective review, and is essential to making well-reasoned funding decisions that maximize the quality of the award decisions and ensure proper stewardship of Federal grants.

3. **Disputes, Appeals, and Grievances**

Applicant concerns that involve application receipt, referral, and/or responsiveness are termed "disputes" (see Appendix B. Definitions) and are handled within the Division of Receipt and Referral (DRR) in the NIH Center for Scientific Review (CSR). Concerns that are raised by the PD/PI and/or applicant organization after the initial peer review, and meet certain criteria (described below) are termed "appeals" (see Appendix B. Definitions), and are handled by the primary IC. Concerns that are raised by the PD/PI and/or applicant organization after the initial peer review, and do not meet certain criteria (described below) are termed "grievances" (see Appendix B. Definitions). In all situations:

- issues involving potential COI or violation of ethical conduct rules on the part of an NIH staff member or other Federal employee will be referred to the appropriate Deputy Ethics Counselor or agency Designated Agency Ethics Official (DAEO) for consideration and resolution before any action on the dispute, appeal, or grievance is taken;

- additional information may be obtained from review, program, and grants management staff, as well as the applicant, before a decision is reached through the processes described below; and

- issues among the ICs that cannot be resolved through the processes described below will be decided by the DDER.

  a. **Disputes of Receipt and Referral Decisions**

  1. Receipt

     DRR makes final decisions on the acceptability of an application for review, often in consultation with IC staff and consideration of factors including:

     - relevance to the NIH mission;

     - conformity with published guidelines or instructions for submission and/or revision;

     - appropriate match between activity codes and IC programs;

     - timeliness of receipt; and

     - responsiveness to an RFA; normally this determination is made by the issuing IC(s) and conveyed to DRR.

  2. **Referral**

     DRR is responsible for initial assignments of applications to CSR SRGs or ICs for initial peer review and to IC(s) as the potential awarding component(s). However, disputes regarding the specific SRG assignments of IC-reviewed applications are handled by the IC that is managing the review.

  3. **Resolution**

     In all cases related to receipt, referral, and responsiveness, the dispute should be handled by evaluating the disagreement, determining whether corrective action is necessary, and conveying the decision to the PD/PI and Authorized Organizational Representative (AOR) (see Appendix B. Definitions) with an explanation of the reasons for the decision. That decision is final, and the pre-review disposition of the application may not be disputed further. Every effort should be made to resolve disputes of receipt and referral efficiently so that delay of the review is minimized. Issues involving potential COI or violation of ethical conduct rules on

the part of an NIH staff member or other Federal employee will be referred to the appropriate Deputy Ethics Counselor or agency DAEO for consideration and resolution before any action on the dispute is taken.

b. **Appeals of Initial Peer Review**

To preserve and underscore the fairness of the NIH peer review process, NIH established a peer review appeal system to provide investigators and applicant organizations the opportunity to seek reconsideration of the initial review results if, after consideration of the Summary Statement (see Appendix B. Definitions), they believe the review process was flawed as outlined below.

1. **Applicability**

The appeals policy applies to appeals received with respect to most competing applications submitted to the NIH for support, including those such as fellowship applications that typically do not require Council review. However, unless an exemption is approved by OEP before the FOA is issued, appeals of initial peer review are not accepted for applications submitted in response to an RFA. The appeals policy specified in this NIH GAM does not cover appeals of funding decisions or appeals of decisions concerning extensions of Method to Extend Research in Time (MERIT) Awards.

2. **Appeal Letters**

A PD/PI and/or official of the applicant organization (but not necessarily the AOR) who is concerned about procedural aspects related to the completed, initial peer review of his or her application should be advised to first consider the comments in the Summary Statement, and then to contact the appropriate NIH PO. The PO can answer questions about the Summary Statement and review outcome, and provide advice to the applicant. For example, the PO may recommend modifying the application according to NIH policies for Resubmission applications and the issues that were raised in the review and communicated in the Summary Statement, or may recommend reconsidering the basic intent of the project and submitting a new application that has substantial differences in aims and approach (see NIH Guide Policy Statement, Section 2.3.7.4). Following discussion of concerns with the PO, if the PD/PI and/or

organizational official (not necessarily the AOR) wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send his/her concurrence to the PD/PI who will forward the materials and institutional concurrence to the PO. A communication from the PD/PI or organizational official (other than the AOR) only or with a "cc" to the AOR will not be accepted.

The ICs may establish deadlines by which appeal letters must be received in order to be made available at the Council meeting. However, in no circumstance will an appeal letter be accepted before the Summary Statement has been transmitted to the PD/PI or later than 30 calendar days after the relevant Council meeting.

An appeal letter will be accepted only if the letter 1) describes a flaw(s) or perceived flaw(s) in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- evidence of bias on the part of one or more peer reviewers;

- COI, as specified in regulation at 42 C.F.R. Part 52h, on the part of one or more non-Federal peer reviewers, or COI statutes and ethical conduct regulations applicable to Federal employees serving as peer reviewers;

- lack of appropriate expertise within the SRG; or

- factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

3. **NIH Staff**

   Every IC must have an internal administrative process to ensure that appeal letters are handled by the IC Appeals Officer (in coordination with the agency ethics official in any case premised on the conduct of a Federal employee) and that the written response to the PD/PI and/or institutional official reflects the official IC position or Council decision. The Appeals Officer (see Appendix B. Definitions) must be included in all written communications between the PO and the PD/PI or AOR concerning an appeal, including:

   - the acknowledgement of the appeal letter;

   - notification that the application is administratively deferred for re-review; and

   - notification that the appeal letter has been withdrawn.

   The PO who receives the incoming correspondence from a PD/PI and/or organizational official may or may not have the primary responsibility for addressing the issue raised. However, the PO must acknowledge such incoming correspondence in writing within 10 days of receipt, and must ensure inclusion of the original communication in the official file with documentation of his/her response.

   Appeals involving potential COI or violation of ethical conduct rules on the part of an NIH staff member or other Federal employee will be referred to the appropriate Deputy Ethics Counselor or agency DAEO for consideration and resolution before any further review of, or action on, the appeal is taken.

   The PO, SRO, and Appeals Officer will consider the basis for the appeal letter, and evaluate the merit of the appeal. If review staff (SRO and supervisor) and program staff (PO and supervisor) support an appeal, then the original application, without additional materials or modifications except those allowed as post-submission materials (see NOT-OD-10-115), will be re-reviewed by the same or a different SRG, depending on the flaw(s) that led to the decision for a re-review. The Referral Liaison in the IC of the PO will contact DRR. Once the new assignment has been processed, the PD/PI will receive an automatic mailer informing him or her that the application

has been re-assigned, and the new assignment will appear in the PD/PI's NIH eRA Commons account. Only the results of the re-review, and not of the first review, are made available to Council, and information about the appeal is not made available to Council.

If review staff (SRO and supervisor) and/or program staff (PO and supervisor) do not support the appeal, the PD/PI and/or organizational official may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official (not necessarily the AOR), the AOR must send the request directly to the PO, or must send his/her concurrence to the PD/PI who will forward the materials and institutional concurrence to the PO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

If review staff (SRO and supervisor) and/or program staff (PO and supervisor) do not support the appeal, and the appeal letter is not withdrawn, the appeal letter must be made available to Council. The IC cannot deny the PD/PI and/or the applicant institution the opportunity to have an appeal letter made available to Council, regardless of their assessment of its merit. However, the IC may decide which appeal letters warrant formal discussion by Council and may implement IC-specific procedures for making the appeal letter available to Council.

4. **Consideration by Council**

Only two outcomes are possible following consideration of an appeal letter by Council:

- the Council may concur with the appeal, and recommend that the application be re-reviewed; or

- the Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. If the Council takes no action, the outcome is

equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process. The result of an appeal does not represent a reversal or overturning of the recommendations of an SRG.

5. **Resolution**

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know (SRO and PO). If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting.

If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation to the PD/PI, AOR, SRO, and PO of the IC's plan for making the appeal available to Council. If the Council recommended that the application be re-reviewed, the original application will be re-reviewed, without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending on the flaw(s) in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. If the application is deferred for re-review in the same SRG that reviewed the application originally, the SRO may explain to the SRG that the application was deferred administratively for re-review, but not that the re-review resulted from an appeal of their original review.

6. **Resubmissions**

The NIH permits a single Resubmission application (A1) for all original new applications (i.e., never submitted) and Renewal applications; any second amendment (A2) will be administratively withdrawn and not accepted for review. Applicants who fail to receive funding after two submissions may resubmit but only if the application is fundamentally changed or comes in as another activity code to qualify as new (seethe NIH Grants Policy Statement, Section

2.3.7.4).

The NIH will not review a Resubmission (A1 version) if an appeal of initial peer review is pending on the original application (A0 version) (see the NIH Grants Policy Statement, Section 2.4.2). Longstanding NIH policy states that the NIH will not accept any application that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. Also, if an appeal has been submitted concerning the initial peer review of an application, the NIH considers that application to be pending initial peer review until the appeal has been resolved. Resolution of an appeal occurs when the initial peer review outcome is finalized, by issuance of the final overall impact score and Summary Statement. Resolution can follow a decision that the initial peer review outcome will stand or that the application will be deferred and re-reviewed, with subsequent issuance of the final overall impact score and final Summary Statement.

The NIH will not accept a Resubmission that is submitted later than thirty-seven months after the date of receipt ("receipt date") of the initial new, Renewal, or Revision application. The initial submission of a new, Renewal or Revision application constitutes the starting point for the thirty-seven month policy. After thirty-seven months, NIH views a submission as a new application, regardless of whether an unsuccessful Resubmission (A1) was submitted during the thirty-seven month time period (see the NIH Grants Policy Statement, Section 2.3.7.4).

7. **Applications Submitted to an RFA**

The NIH will not accept appeals of the initial peer review of applications submitted to an RFA. Exceptions will be granted by OEP before issuance of the RFA in the NIH Guide for Grants and Contracts (the Guide; http://grants.nih.gov/grants/guide/) and clearly indicated in the published RFA.

8. **Temporary Suspension**
On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions must be announced in NIH Guide Notices and/or the relevant FOAs when they are issued in the Guide.

<ol type="c" start="3">
Grievances Related to Initial Peer Review

A written correspondence from a PD/PI and/or official of the applicant institution about the initial peer review of a particular application that does not meet the criteria for an appeal and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

Issues involving potential COI or violation of ethical conduct rules on the part of an NIH staff member or other Federal employee will be referred to the appropriate Deputy Ethics Counselor or agency DAEO for consideration and resolution before any action on the grievance is taken.

D. Fairness

1. Scoring

Final scoring – assignment of the overall impact score - is performed during the SRG meeting by all eligible (without COI or the appearance of COI) SRG members using private ballots. All fully participating reviewers (see Appendix B. Definitions) who participate in person, or by teleconference, videoconference, internet-assisted meeting, or other electronic means in the evaluation of an application may vote and score the application. SRG members who have a COI or appearance of a COI with an application may not participate in the discussion, streamlining, voting, or scoring of the application for which the COI or appearance of COI exists.

A completed review results in one of the following committee recommendations:

- Numerical overall impact score;

- Not Discussed (ND);

- Not Recommended for Further Consideration (NRFC; see Appendix B. Definitions); or

- Deferral (DF; see Appendix B. Definitions).

Applications that receive numerical overall impact scores proceed to the second level of peer review (Council). Applications that are ND may proceed to Council if they are being considered for funding. Only applications that are recommended favorably (that is, not designated as NRFC) by both the SRG and the Council may be recommended for funding.

a. **Overall Impact Scores**

The NIH adopted a nine-point scoring scale beginning with applications received for funding consideration for Fiscal Year 2010, and for applications received in response to initiatives under the American Recovery and Reinvestment Act (ARRA) of 2009 (see NOT-OD-09-024). The numerical overall impact score for each discussed application is determined by calculating the mean score from all the eligible members' impact scores, and multiplying the average by 10; the overall impact score is reported on the Summary Statement. Numerical overall impact scores are not reported for applications that are designated by the SRG as ND, NRFC, or DF.

b. **Scores for Individual Criteria**

Before the SRG meeting, each reviewer assigned to an application independently provides a separate, numerical score for each of at least five designated review criteria. The criterion scores of the assigned reviewers are reported individually on the Summary Statement.

For multi-component or complex applications, the standard criteria for the type of mechanism involved must be used in the evaluation of: 1) Overall Impact for the entire center, network, consortium, or project, and/or 2) the individual components. Criterion scores must accompany the standard criteria wherever they are used with standard definitions (Overall Impact or the individual components).

A waiver of scoring policy from OEP is required to eliminate the use of criterion scores in any FOA.

c. **Streamlined Review Procedure**

In some reviews, a streamlining procedure is used to focus the discussion of the SRG on the more meritorious applications pending review. In SRGs using the streamlining procedure, following assignment of initial overall impact scores and individual criterion scores by the assigned reviewers, the applications that are considered by the SRG to be less meritorious are considered eligible for designation as ND and are not discussed further by the SRG. Because the ND designation is a committee recommendation (in lieu of a numerical score), full concurrence of all eligible (without COI or appearance of COI) voting SRG members is required for an application to be streamlined. Although an SRG member with COI or appearance of COI with an application may be present during the streamlining process, that member must leave the room if the

identities of the assigned reviewers are revealed or any discussion of the application ensues. In addition, an SRG member with COI or appearance of COI may not overturn the consensus of the remaining SRG members.

Percentages of streamlined applications may be adjusted as needed for certain mechanisms or programs; for example, when applied to reviews for RFAs, following consultation between program and review staff, the targeted percentage of applications to be discussed may be adjusted in advance as appropriate for the amount of support available.

Before making an award for a streamlined application an IC must bring the matter to the Council and present a compelling reason for considering the streamlined application for an award.

d. **Voting Outside the Range**

In order for the SRG to make an informed recommendation, all scientific opinions concerning an application that is discussed at the SRG meeting should be raised during that discussion. Therefore, SRG members whose evaluations or opinions of an application fall outside the range of those presented by the assigned reviewers should ensure that their opinions are brought to the attention of the entire committee. In addition, the SRO and SRG Chairperson (see Appendix B. Definitions) should ensure that all opinions are voiced before final scoring is conducted.

e. **Not Recommended for Further Consideration (NRFC)**
Applications that lack significant and substantial merit, or that present serious ethical problems in the protection of human subjects from research risks, use of vertebrate animals, biohazards, and/or select agents may be designated NRFC by the SRG. Applications designated as NRFC do not proceed to the second level of peer review (Council) because they cannot be funded.

f. **Scoring the Entire Application**

Members of an SRG must score an application as presented in its entirety, and SROs are responsible for enforcing compliance with this policy.   Under no circumstance may members of an SRG or the SRG as a whole:

- modify their final overall impact scores for an application based on the assumption that a portion of the work proposed and/or budget requested will be deleted or modified according to the SRG's recommendations;

- recommend reducing the complexity of an application and score on the

basis of the more meritorious components; or

- provide a numerical overall impact score for an application if the SRG votes that a portion of the application be NRFC.

g. **Deferral (DF)**

In rare instances applications may be deferred for review at a later time. Grounds for deferral include:

- flaws in the review process, including COI discovered during initial peer review, or an allegation of research misconduct presented in critiques or during discussion;

- lack of qualified reviewers to evaluate an application because a critical reviewer is unable to participate in the meeting due to unforeseen circumstances such as personal or family emergency or weather-related travel problems; and

- insufficient information for the SRG to evaluate the application.

h. **Mail Reviewers**
Preliminary scores from Mail Reviewers or the first stage of an Editorial Board review (see Appendix B. Definitions) may be used in creating the initial streamlining list or score order of review, but are not used in any final scoring at the meeting or in calculating the final, overall impact score. Because Mail Reviewers or reviewers in the first tier of an Editorial Board review do not attend meetings, they do not vote final scores, cannot participate in streamlining decisions and cannot rescue an application from the ND category.

2. **Summary Statements**

The SRO prepares the Resumé and Summary of Discussion section of the Summary Statement (see Appendix B. Definitions) (unless the application was designated ND) and includes the written critiques and criterion scores submitted by SRG members in essentially unedited form absent personal identification of the SRG members. The content and format of these written evaluations are produced with reference to the NIH review criteria and specific guidelines.

The nature and complexity of a program are determining factors in establishing the number of written critiques from reviewers that will be required in Summary Statements. In unusual circumstances such as large numbers of submitted applications, the DDER may approve a policy waiver to reduce the requirement for written critiques from reviewers. Because the PHS Act (42 U.S.C. 289a) requires that

the reviewing entity provide the Council of the national research institute involved with a written description of the research to be reviewed and the results of the review by the entity, under no circumstance may the DDER approve a policy waiver to bypass the statutory requirements that a written review be provided to Council.

Summary Statements are prepared for streamlined (ND) applications to convey the reviewers' written comments, individual criterion scores, and administrative codes.

In special situations, NIH may opt to modify the Summary Statement format. Such special procedures require approval by the DDER and must be specified in the FOA.

3. **Post-submission Materials**

Post-submission grant application materials are those submitted after submission of the grant application but prior to the initial peer review. In order to provide consistent practice across the agency, this option is to be used when an unexpected event such as the departure of a participant, natural disaster, etc. has occurred, not to correct oversights/errors discovered after submission of the application. Post-submission materials must be received by the NIH SRO at least one month (30 calendar days) prior to the SRG meeting (see the NIH Grants Policy Statement, Section 2.3.7.7).

Concurrence from the AOR of the applicant organization is required. Although the content of post-submission materials may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send his/her concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Certain NIH FOAs for institutional grant applications, and other types of FOAs, may allow specific other types of post-submission materials to facilitate the goals of the program (see the NIH Grants Policy Statement, Section 2.3.7.7). Such stipulations must be specified in the FOA in the NIH Guide for Grants and Contracts.

E. **Confidentiality and Non-disclosure**

All deliberations of the SRG are confidential. Most information and materials related to the review of applications are confidential, including the submissions, site visit reports, discussions and notes taken at meetings, critiques that can be directly linked to an individual reviewer, individual criterion scores, individual and aggregate impact scores, reviewer assignment lists and lists of COI, drafts and final versions of Summary Statements, and staff recommendations. Rosters and Minutes of FACA meetings that are edited appropriately so as not to reveal confidential information are public documents.

The SRO must:

- provide all SRG members with instructions related to the confidentiality and non-disclosure requirements of the NIH peer review system prior to the meeting of the SRG;

- provide all SRG members with instructions for protecting the security of NIH applications and related materials (such as appendices, prior Summary Statements, reviewer critiques, criterion scores, and scores);

- distribute NIH applications and related materials to SRG members through secure websites or portable media that meet NIH security requirements (NOT-OD-08-071);

- instruct SRG members that they may not discuss under any circumstance the review proceedings, content of applications or SRG recommendations with anyone except other members of the SRG and appropriate NIH staff members;

- instruct SRG members to refer all queries about the review to the SRO; and

- following the review, dispose of all confidential materials provided to the reviewers and pertaining to the review in accordance with established NIH procedures (see NIH Manual Chapter 1743 "Keeping and Destroying Records").

All SRG members are required to certify that they have read the confidentiality rules for reviewers and agree to comply with those instructions.

NIH staff members are required to maintain the confidentiality of the NIH review process, according to applicable laws and regulation. Requests for information about the review outcome from individuals other than the PD/PI must be referred to the applicable Freedom of Information Act (FOIA) Coordinator. In addition, NIH staff members may not discuss applications and the review or review outcome with individuals other than the contact PD/PI, although all PDs/PIs of a multiple PD/PI application have access to review information for that application on the NIH eRA Commons system (Commons; http://commons.era.nih.gov). Communications by NIH staff members or reviewers that violate the confidentiality of the review process are prohibited and are subject to criminal and civil penalties.

F. **Integrity and Ethical Considerations**
   1. **Research Misconduct**

      An individual who has been found guilty of research misconduct and been sanctioned from serving on a federal advisory committee or from receiving federal funds may not serve as an NIH reviewer during his or her debarment period. These individuals and

their sanctions are listed with the [PHS Administrative Actions List](#), and the [System for Award Management](#).

Each NIH IC designates a senior official, a Research Integrity Officer (RIO), to handle incoming allegations of research misconduct, and each DFO is instructed to contact the appropriate RIO immediately should an allegation of research misconduct be received. The DFO may decide to defer the application from review until the proper authorities can deliberate on the situation. Under no circumstance, however, may the DFO discuss the allegation with members of the SRG or with the respondent against whom the allegation is made, or attempt to resolve the issue.

2. **NIH Staff Involvement**

   In addition to the criminal statutes, applicable ethical conduct regulations, and NIH Manual Chapters (e.g. [NIH Manual Chapter 2400-01](#) "Introduction to Government Ethics at the NIH") with which NIH staff members must comply in relation to all of their official duties, NIH management exercises its inherent authority to assign work in a manner that protects the perceived integrity of the peer review process.

   No member of the NIH extramural staff may serve as a reviewer on an NIH SRG, and no member of the NIH review staff may manage peer review and a programmatic portfolio in the same scientific area.

   a. **Professional Activities**

      NIH extramural staff may engage in professional activities that are part of their official duties and involve outside entities or organizations, and these activities may be perceived as biasing NIH decisions, actions, or the peer review process. Examples include scientific collaborations, co-authorship of publications, and positions in professional societies. The employee will report such situations to his/her Deputy Ethics Counselor and supervisor, and the supervisor will designate an appropriate, alternate NIH staff member to serve in the appropriate role. The NIH extramural staff member is responsible for recusing him/herself from involvement in the review of any application if his/her official duty professional interests or relationships could be perceived as biasing the peer review process. Moreover, even where no such professional interest exists, a member of the NIH review staff, program staff, or grants management staff may have a COI or the appearance of a COI (as defined in [18 U.S.C. 208](#) or [5 C.F.R. 2635](#)) with an application, and the COI or appearance of a COI may be of such significance that s/he must not participate in any part of the review process pertaining to that application unless a waiver or authorization is granted in accordance with applicable law or regulation. Where recusal is necessary,

the employee's supervisor will designate an appropriate, alternate NIH staff member to serve in the appropriate role. In no instance may the DDER grant a waiver or authorization to allow an NIH extramural staff member to participate in the review process for an application with which the staff member has a COI or the appearance of a COI (as defined in 18 U.S.C. 208 or 5 C.F.R. 2635). For information and assistance regarding waivers and authorizations, employees should consult their Deputy Ethics Counselor.

b. **Substantial Involvement**

Project Scientists who have substantial scientific involvement in a cooperative agreement, and Project Coordinators who have substantial programmatic involvement in a cooperative agreement, may not attend the SRG meeting evaluating Renewal or Revision applications for that cooperative agreement unless an IC waiver is obtained per IC procedures for management of concern about bias. In addition, POs who also have substantial scientific and/or programmatic involvement in a cooperative agreement (e.g., Project Collaborator) may not attend the SRG meeting or the closed session of the IC Council or Board where the Renewal or Revision application for the cooperative agreement is evaluated, unless an IC waiver is obtained per IC procedures for management of concern about bias. These IC procedures may include a grant of permission to attend from the staff member's immediate supervisor and next higher level supervisor or EPMC member (if applicable) or designee.

c. **Activities that Span the Intramural/Extramural Boundary**

Numerous activities span the intramural/extramural boundary, and present conflict of interest situations, including:

- An application for allocation of, or an award from, the Common Fund to an intramural investigator I that IC.

- An application from, or permission for, an extramural investigator to access intramural resources in that or another IC, such as the NIH Clinical Center.

- An application or award that lists an intramural investigator from the IRP, the close relative (see Appendix B. Definitions) of an extramural staff member, or the IC Director as playing a major professional role (see Appendix B. Definitions).

- An application that contains a letter of institutional commitment signed by the Scientific Director (SD) of that IC. Numerous FOAs that involve the IRP

require that a letter of institutional commitment from the submitting institution be included with the application, and in many cases the letter of institutional commitment is signed by the intramural SD.

Staff first should determine that no personal or imputed financial interests or outside relationships preclude their participation in the proposed activity under the government-wide ethics statutes and regulations. Situations that would preclude participation include owning stock valued above the de minimis level in the company that manufactures the product being tested; having a spouse who would receive salary support from the pending grant application; and/or seeking employment with the grant applicant or research collaborator.

Senior staff should exercise their best judgment in managing situations that are not expressly addressed below, and the IC representative on EPMC should be consulted if questions arise.

The initial peer review (and the Advisory Council level of review) of applications that involve the IRP can be managed by the funding IC where the applicant, resource, or intramural investigator is appointed or the intramural resource is located, unless the application involves a request for an allocation from the Common Fund and is from a member of the IRP or the IC Director has a major professional role (see Appendix B. Definitions) in the activity.

NIH extramural staff who have intramural research duties must be recused from the review process for applications from, or awards to, the IRP where they are affiliated, unless their intramural duties are simply providing routine clinical care and they are not directly involved in the research activity.

NIH extramural staff whose close relatives are employed in the IRP may participate in matters that involve the IRP of the ICs where their close relatives have appointments, unless the close relative has a direct involvement in the research activity. If the application or award is part of an RFA, then the matter is the entire RFA.

If the IC Director, or his or her close relative, is listed with a major professional role on an application, the initial peer review (and Advisory Council review) of the application must be managed by another IC. Should the IC-level recusal approach prove to be impracticable, the IC must develop and propose an alternate COI mitigation strategy for consideration, review and approval by the DDER.

The SD may not serve as a peer reviewer for an application containing a letter of institutional commitment that he or she signed. If the application was submitted for an RFA, he or she may not serve as a reviewer for any of the applications submitted to that RFA, and may not attend or observe the initial peer review meeting.

See OER Policy Announcement 2013-01.

3. **NIH Intramural Research Investigators**

Provided they have no COI or appearance of a COI (as defined in 18 U.S.C. 208 or 5 C.F.R. 2635) with an application that precludes their participation, members of the NIH IRP may, generally, serve as reviewers on SRGs that are not managed by their own ICs and also may serve on SRGs managed by the NIH CSR without regard to the IC funding assignment of the application, because intramural scientists have no responsibility in the extramural awards process. A waiver is needed from the DDER to allow a member of the NIH IRP to participate as a reviewer on an SRG managed by his/her own IC. If, however, a COI or appearance of a COI exists (as defined in 18 U.S.C. 208, 5 C.F.R. 2635, or 42 C.F.R. 52h), NIH intramural staff may only participate in SRGs if a waiver or authorization is granted in accordance with applicable law or regulation. For more information regarding the issuance of waivers and authorizations, employees should consult their Deputy Ethics Counselors or the NIH Office of Extramural Research (OER).

a. **Common Fund Initiative**

In 2007, NIH announced that NIH intramural research investigators may submit applications requesting allocation of funds for certain designated Roadmap Initiatives (now Common Fund Initiatives). This announcement declared policy for allowable submission of and process for peer review of such applications (see NOT-RM-07-011).

According to this policy, CSR is responsible for the initial peer review of requests for allocations of funds to the NIH IRP for projects within the Common Fund. Applications involving requests for allocations of funds submitted by members of the NIH IRP for projects within the Common Fund are considered on a competitive basis with Common Fund applications submitted by members of the extramural scientific community. If circumstances warrant, the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) or other appropriate office in the NIH Office of the Director, in consultation with the relevant IC Director(s) and OER, will consider on a case by case basis a request submitted by the Chair of a Common Fund Working Group for an

exception from this general approach (for example, for initial peer review to be conducted by an IC other than CSR).

b. **Substantial Involvement**

An NIH intramural scientist with substantial scientific involvement in a cooperative agreement may not attend an SRG meeting evaluating an application that involves that cooperative agreement and is conducted by extramural SROs (see [NIH Manual Chapter 54815](#)). These plans may include a grant of permission to attend from the staff member's immediate supervisor and next higher level supervisor or EPMC member (if applicable) or designee.

G. **Efficiency**

1. **Electronic Submission**

As a funding agency in the United States government, the NIH has converted a large portion of its operations for receiving applications to the Grants.gov portal, and the ASSIST capability (see [NOT-OD-12-161](#)), for electronic submission of all grant applications to the NIH. Grants.gov is the central receiving point for applications submitted electronically to the U.S. Federal government. ASSIST is a new on-line application system for electronic submission of NIH multi-project applications, and should be fully implemented in 2014.

2. **Receipt and Assignment of AIDS and Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) Applications**

Expedited award is mandated for AIDS, Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) applications. The Health Omnibus Program Extension Act of 1988 ([P.L. 100-607](#)) mandates this for AIDS applications. The Small Business Administration's [Small Business Innovation Research (S BIR) Program Policy Directive](#) and [Small Business Technology Transfer (STTR) Program Policy Directive](#) mandate expedited award for SBIR and STTR applications respectively. The law stipulates that receipt dates may be no more than three months after the date of publication of an AIDS or SBIR/STTR RFA or PA solicitation and, if possible, no more than six months should elapse from the receipt date for these applications to their award decision (the Council round). Under unusual circumstances, the NIH Director may determine that such solicited applications cannot be processed within these time limitations and may adjust the time limitations accordingly.

3. **Internet Assisted Review (IAR)**

The [Internet Assisted Review (IAR) module](#) of IMPAC 2 is a secure, online system

that allows reviewers to submit critiques, criterion scores, and preliminary overall impact scores for applications they are reviewing. IAR also allows reviewers, SROs, and review support staff to view critiques in preparation for a meeting, except those with which they have COI or the appearance of COI. IAR creates a preliminary Summary Statement body containing submitted critiques for the SRO or review support staff.

4. **Reviewer Critique Templates**

In order to expedite production of Summary Statements, reviewers are provided formatted templates for their written critiques, and are instructed to provide their written comments in concise, bulleted format rather than lengthy prose. The critiques present the definition of impact, scored review criteria, additional review criteria, and additional review considerations for the type of application being reviewed.

H. **Deviations from Policies**

Any deviations from the policies described in this NIH GAM must be approved by OER in advance of the SRG meeting. Such deviations must be approved by the NIH Review Policy Officer, the Director of the Office of Extramural Programs, and the DDER. See OER Policy Announcement 1997-02 for other types of deviations of NIH grants policy.

VI. Responsibilities:

A. **IC Directors**

IC Directors are responsible for ensuring that peer review groups are established, operated, and renewed in compliance with FACA and NIH policies. IC Directors also have authority and responsibility for designating a senior official who is not otherwise involved directly in the initial peer review process as the Appeals Officer for the IC.

B. **NIH Extramural Staff**
   1. **Appeals Officers**

Appeals Officers are responsible for ensuring implementation of the NIH appeals policy, and ascertain that the standard procedure has been followed for each appeal letter, confirming that:

- the PO has worked with the PD/PI and/or official of the applicant organization (not necessarily the AOR), and the SRO to resolve issues and has not been able to resolve the issues;
- the PO has communicated with the SRO and fully discussed the specifics of the

PD/PI's and/or AOR's complaint;

- the PO has prepared and placed the appropriate materials in the Council folder;

- the IC Director is informed of the appeal letter;

- the Executive Secretary of Council is informed of the appeal letter; and

- the Executive Secretary of Council has provided written explanation to the PD/PI and/or AOR of the resolution of the appeal.

2. **Deputy Director for Extramural Research (DDER)**

The DDER, NIH, has the responsibility for developing, implementing, and monitoring policy for the NIH peer review system; upholding the core values of peer review; continuously evaluating the soundness and objectivity of the entire process, including sending observers to SRG meetings and site visits; and facilitating consistent review practices across the agency. The DDER also has delegated authority to issue waivers of peer review COI regulations and, under certain circumstances, deviations to NIH review policy.

3. **Review Support Staff**

Extramural support services for grants management, review and program support activities are located within the extramural offices at each IC.

4. **Grants Management Officers (GMOs)**

GMOs serve as resources on budgetary matters and may be called upon to provide assistance in budgetary matters and to interpret or clarify budget rules and administrative and fiscal policy guidelines. Grants management staff members also monitor the initial and second-level review processes to certify that they were conducted in accordance with applicable policies.

5. **Program Officials (POs)**

POs attend SRG meetings as part of their official duties, as observers, when applications for which they are responsible are being reviewed. When requested by the SRO or by the SRG members through the SRO, POs serve as resources at the meeting to explain or amplify grants policy, clarify administrative matters that may bear on the application(s) under discussion, and provide information about pertinent program policies or practices. Often POs are invited to give a brief introduction of a program to the SRG before an RFA or PAR review. Further, POs attend SRG meetings to gather background information regarding the review of applications to benefit their communications with Council and applicants, and their subsequent

management of the grant. (Refer to [NIH Manual Chapter 54815](#) for instructions on handling bias for POs who have substantial involvement in cooperative agreements.)

Attendance at SRG meetings by POs, other NIH staff members and other Federal staff members will be recorded and documented by NIH review staff.

6. **Referral Officers**

Using NIH referral criteria, CSR Referral Officers are responsible for assigning individual applications to (an) NIH IC(s) for funding consideration and referring them to an IC or CSR SRG for initial peer review. Referral Officers in the ICs are responsible for assigning applications to an IC SRG for initial peer review.

7. **Review Policy Committee (RPC)**

The RPC is the principal forum for the development, implementation, and evaluation of review policies and procedures for all types of applications submitted to the NIH. The RPC provides recommendations in matters directly affecting peer review; its overall goals are to promote and maintain excellence and consistency in NIH peer review. At the discretion of the DDER, those matters also may be discussed at various levels of NIH governance, such as the Extramural Activities Working Group and EPMC.

8. **Review Policy Officer (RPO)**

The NIH RPO serves as the principal staff advisor to the DDER on overall administration of scientific review functions for extramural programs. The RPO develops, refines, advises on, and monitors policies, procedures, methods, and necessary guidance documents governing NIH extramural review functions to ensure compliance with law, regulation, and policy as applied to the review and evaluation of extramural assistance award instruments. The RPO works to ensure standard approaches to peer review across the agency, evaluates and provides oversight for the performance of SRGs and other NIH advisory groups, serves as liaison to the Office of General Counsel on review policy issues, and serves as co-Chair of the RPC.

9. **Scientific Review Officers (SROs)**

To meet requirements of [FACA](#), the SRO is the DFO with legal responsibility for managing the SRG. The requirements specified by [FACA](#) for the DFO are:

- call, attend and adjourn the committee meeting;
- approve agendas;

- maintain required records on cost and membership;

- ensure efficient operations;

- maintain records for availability to the public; and

- provide copies of committee reports to the IC Committee Management Office (CMO).

In terms of NIH policy, the SRO is responsible for:

- managing and monitoring the course of the review process to strive for fair, equitable, informed, and unbiased evaluations; compliance with applicable laws, regulations, and policies; and scientifically and technically appropriate evaluation of the applications;

- communicating with the applicant or candidate regarding the application following its receipt and assignment to a review committee until the conclusion of the SRG and release of the Summary Statement. Thereafter, program and grants management staff members are responsible for oral and written communications with the applicant or candidate;

- checking applications for completeness and conformance to all relevant regulations, policies and administrative requirements;

- recruiting reviewers with appropriate expertise as needed and assigning a minimum of three qualified reviewers to each application, while managing COI and appearance of COI;

- arranging for SRG meetings and managing site visits, reverse site visits, and applicant interviews, as appropriate;

- providing guidance on and implementing NIH review policies and procedures;

- ensuring proper entry and timely release of all scores, codes, and a Summary Statement for each application reviewed by the SRG;

- identifying appropriate reviewers for SRG membership to maintain proper scientific balance while taking into account other requirements; and

- selecting the SRG Chairperson(s).

C. **Inherently Governmental Functions**

Several essential and substantive aspects of managing peer review are considered to be inherently governmental functions, including:

- monitoring the entire review process to ensure that it is fair, equitable, informed, and unbiased, and that it conforms to applicable law, regulation and policy;

- ensuring that appropriate individuals are recruited to serve as reviewers;

- assigning SRG members to evaluate particular applications while managing and documenting COI and appearances of COI;

- presiding as the DFO at review meetings;

- ensuring accurate recording and dissemination of scores following review meetings; and

- summarizing discussion at the review meeting and incorporating recommendations of reviewers in documentation of the review.

These inherently governmental functions are the responsibility of the SRO and may not be contracted out. In an emergency situation, wherein the assigned SRO cannot fulfill his/her duties, the responsibility for assigning another employee to these duties lies within the IC managing the review.

Functions determined to be logistical support may be performed by NIH review support staff in accordance with IC specific guidelines, or may be contracted out as cost, workload, and other considerations may dictate. Logistical support consists of the following activities: 1) arranging for meeting rooms; 2) arranging travel and accommodations for reviewers; 3) disseminating the applications and related materials to reviewers; and 4) assembling reviewer critiques into draft Summary Statements. Because the applications contain confidential information, special requirements on access to, and handling of, these materials must be stated clearly in any contract for logistical support of peer review.

Only Federal officials who have a need-to-know or pertinent related responsibilities are permitted to attend closed SRG meetings (see OFACP Policy Announcement 2003-01). All individuals in the category of "other institute or Federal staff" who wish to attend SRG meetings must obtain advance approval from the SRO responsible for the meeting.

VII. Peer Review Approaches:

An SRG may be organized either as a standing SRG or SEP (see Appendix B. Definitions), depending on numerous review and FACA considerations. Either type of SRG may be conducted as an in-person meeting; site visit or applicant interview; teleconference, videoconference, internet-assisted meeting or virtual committee meeting; or Editorial Board style of review.

A. **Standing SRGs**

A standing SRG may be used when required by law or regulations or when all of the following conditions prevail:

- a sufficient number of applications to justify the use of a standing committee(s) is received by the program on a regular basis in accordance with a pre-determined review schedule;

- a sufficient number of persons with the required expertise is willing and able to accept appointments, serve over reasonably protracted periods of time, and convene at regularly scheduled intervals or at the call of the SRO; and

- the legislative authority for the particular program(s) involved extends for more than one year.

B. **Special Emphasis Panels (SEPs)**

A SEP should be used when the use of a standing SRG either is not feasible or economical due to one or more of the following circumstances:

- a small number of applications is received on an intermittent basis;

- the program is one of limited duration, usually not more than a year, and only one competition or review cycle is expected;

- the applications to be reviewed have been solicited to meet a special nonrecurring need and cannot be reviewed appropriately by a standing committee because of considerations such as subject matter or time constraints;

- the volume of applications received necessitates convening another committee(s) in addition to a standing SRG;

- the applications submitted have special review requirements, e.g., the complexity of subject matter cuts across the areas of expertise of two or more standing SRGs;

- a real or apparent COI exists between the SRO and one or more applications, which cannot be reviewed by the standing SRG;

- a COI exists between a standing SRG and an application(s) that was submitted by a member(s) of that SRG and cannot be reviewed by that standing SRG;

- applications submitted under the continuous submission policy must be reviewed; or

- a need exists for additional expertise currently not available on the standing SRG.

C. **Site Visits, Reverse Site Visits, and Applicant Interviews**

A site visit to the investigator's institution or interaction with the PD(s)/PI(s) via an applicant interview or a reverse site visit at the NIH or at another convenient location may be

necessary to provide adequate review, as might be the case:

- with large multifaceted types of applications;

- so that reviewers can:
    - assess the quality of certain physical facilities, laboratories, or specific equipment to assure their adequacy for the proposed research;

    - observe and discuss particular techniques, experimental preparations, unusual items of equipment or proposed procedures;

- evaluate the participants' research experience, knowledge of the research field, commitment to the project, functions, and interrelationships with other investigators on the project; when an application has been recommended for deferral by an SRG, which usually results because the SRG does not have sufficient information from the application to arrive at a score or recommendation and the information they request cannot be obtained satisfactorily through correspondence or by telephone if they assess the information at hand to be insufficient;

- for an application for an institutional training grant:
    - if the experience of the applicant institution in research training is not extensive or well known; and/ or

    - issues or concerns in the application can be clarified for the SRG with the benefit of information obtained during a site visit, such as concerns about faculty or departmental interactions and collaborations, multiple applications from the same department, qualifications and abilities of participating faculty, or quality of training;

- when a Council does not concur with the recommendation of the SRG and wishes additional information that can be obtained only by a site visit.

As discussed below, the need for a site visit, reverse site visit, or other applicant interview may be determined by the SRO in consultation with his or her supervisor; these actions are not to be taken for the purpose of improving an applicant's chances for award. The applicant is responsible for submitting an application that is sufficiently complete for review. Site visits are not automatic for any type of application, even for large, multifaceted applications, but are conducted because on-site discussion and observation are the only reasonable means of obtaining the desired information.

For certain initiatives, an applicant interview may be a component of the initial review process for applications submitted to a particular FOA. If the interview is integral to the review process for an FOA, then the evaluation criteria for the interview must be outlined in

the FOA.

Site visits may be carried out by a standing SRG, a subcommittee (or working group) of a standing SRG, or a SEP. Site visits, reverse site visits, or applicant interviews related to evaluation of an application must be conducted with the DFO in attendance. The principles for selecting reviewers, managing COI or appearances of COI, maintaining confidentiality and non-disclosure, and conducting the site visit or applicant interview are the same as those used for other SRG meetings.

A site visit is not a prerequisite for evaluating an NRSA application. Site visit should be made only if the additional information needed by the SRG to evaluate the application cannot be obtained by letter or telephone call. If the review of an NRSA application involves a site visit, the chairperson should be experienced in the review of training grant applications and knowledgeable in the general scientific area of the training program. Also, current trainees should be available for interview. However, this interview should be conducted with only the SRO, trainees, and site visit team present.

The SRO, with the approval of his or her supervisor, is responsible for judging the need for a site visit or applicant interview, determining the scientific disciplines to be represented, and selecting and contacting individuals with the qualifications needed for adequate scientific review to serve as members of the site visit or applicant interview team. As appropriate, the SRO may seek the advice of SRG members, program staff and grants management staff regarding the need for a site visit or applicant interview. An SRG reviewer assigned to an application also may identify a need for a site visit prior to an upcoming SRG meeting, by contacting the SRO. In this case, the SRO should be informed of the reasons for this request and determine their validity.

D. **New technologies**

Permission from the DDER is required before new technologies and approaches are introduced into the initial peer review process.

VIII. Receipt and Referral of Applications:

Applications relevant to the NIH mission receive two types of assignments: a) to an SRG for initial peer review, and b) as a primary or dual assignment to the IC(s) whose program interests correspond most closely to the aims and objectives of the application, for funding consideration. The DRR in CSR serves as the central receipt and referral point for all competing applications to the NIH and certain other agencies within HHS.

A. **Receipt/Submission Dates**

The instructions and forms for the Public Health Service Grant Application (PHS 398) and

the Standard Form 424 (Research and Research-Related) Grant Application (SF424R&R) used to apply for grant awards from the NIH specify the requirements and due dates for grant applications. To view forms and their instructions, access the OER NIH Forms and Applications Web site: http://grants.nih.gov/grants/forms.htm.

Unsolicited applications submitted in paper format will be considered on time if mailed on or before the published receipt date and a proof of timely mailing is provided. Proof of timely mailing consists of a legibly dated U.S. Postal Service postmark or a dated receipt from a commercial carrier or the U. S. Postal Service. Private metered postmarks are not acceptable.

For both standard and special due dates, electronic applications must be submitted to Grants.gov by 5:00 p.m. local time (of the applicant institution/organization) on the due date. If the due date falls on a weekend or Federal holiday, the date will be extended to the next business day.

1. **Late Applications**

   For standard due dates, a paper application is considered on time if it is sent on the due date. For special due dates, a paper application received after the due date may be accepted if: 1) it carries a legible proof-of-mailing date assigned by the carrier, and 2) the proof-of-mailing date is not later than one week prior to the deadline date.

   Requests from the PD/PI to waive the due date must be in writing and must accompany the application. Unless submitted under the continuous submission option, permission for a late submission is not granted in advance, and no NIH staff member whether in CSR or another IC has the authority to give permission in advance for a late application.

   Staff should make clear to applicants that they should not request waiver of the due date by telephone. Individual requests for waiver of a receipt deadline will be considered on a case-by-case basis. The final determination will be made by the Director, DRR (DDRR), or his/her designee.

   In the event of a wide-spread natural disaster or comparable event which could interfere with the ability of investigators to submit applications by the receipt deadline, the DDRR will determine whether and conditions under which a broad waiver of receipt deadlines will be considered.

2. **Special Due Dates**
   Special due dates are used for grant applications submitted in response to RFAs or,

under special circumstances, other kinds of announcements (typically PARs). Such special receipt dates must be negotiated by NIH staff with DRR in advance of issuing the announcement. Arrangements for the assignment of applications submitted in response to the RFA will be made at that time.

3. **Resubmission Applications**

PDs/PIs may not submit Resubmission applications until after they access their Summary Statements.

The NIH will not accept a Resubmission application that is submitted later than thirty-seven months after the date of receipt of the initial New, Renewal, or Revision (see the [NIH Grants Policy Statement](#), Section 2.3.7.4). If the initial submission (A0 version) was accepted late, the Resubmission (A1 version) must be received within thirty-seven months of the original due date, not thirty-seven months after the extended receipt date for the initial application. With respect to NIH continuous submission policies:

- If an investigator were eligible for continuous submission for the first submission (A0 version) of the application and remains eligible for continuous submission for the Resubmission (A1 version), the 37 month time limit begins with the receipt date for the initial application (A0 version);

- If an investigator submitted the first (A0) version of the application after the standard due date under the continuous submission option, but is not eligible for continuous submission for the Resubmission (A1 version), the Resubmission (A1 version) must be received by the standard due date; and

- If an investigator were not eligible for continuous submission for the first submission (A0 version) but becomes eligible after that submission, the window remains 37 months from the first submission (A0 version).

B. **Acceptability of Applications**

To be accepted for NIH peer review, applications must meet minimum requirements. These include technical requirements on form, format, and content, as well as substantive relevance to the mission of the NIH. These requirements are specified in the relevant announcements and in the instructions for the application forms. NIH will not review applications that do not meet minimum requirements or are outside its mission.

Most RFAs have additional special requirements, and responsiveness to an RFA is determined by IC staff issuing the RFA in conjunction with DRR staff. Applications that are determined to be non-responsive to an RFA are not reviewed, or when appropriate, may be treated as unsolicited submissions to regular grant programs.

Applications received at the NIH are cross-checked against the PHS Administrative Action Bulletin Board (http://ori.hhs.gov/phs-admin-action-bulletin-board). When an application is received from an individual on that listing, the NIH consults with the HHS Office of Research Integrity (ORI) to make sure that the PD/PI and the applicant organization have complied with any restrictions imposed.

An individual may be prohibited from receiving federal government funds without having committed research misconduct. These individuals similarly cannot serve on advisory committees to the federal government. SROs are required to manually verify an individual's eligibility against the Excluded Parties List System (EPLS) now consolidated under the U.S. government's System for Award Management (SAM) (www.sam.gov).

C. **Referral Assignments**
  1. **Initial Peer Review**

     NIH policies determine the locus of review for incoming applications. The DRR implements these policies in assigning incoming, competing applications to ICs and Integrated Review Groups (IRGs) in CSR for initial peer review, based on written guidelines. Factors considered in making review assignments include responsiveness to an RFA issued by the IC, unusual content of an application or its relevance to a particular IC's program interests, the type of application (such as institutional training grant applications), and other features such as those in certain clinical trial applications, applications in which an essential planning phase must precede the actual research phase, and specialized types of multifaceted activities such as program projects or centers.

     Differences of opinion among DRR, CSR and an IC concerning the assignment and plan for the review of an application(s) will be resolved by the DDER or his/her designee.

  2. **Awarding Components**

     DRR also assigns incoming competing applications to an awarding component of the PHS based on the Referral Guidelines for Funding Components of the NIH, which outline the scientific program areas and interests of each awarding organization and identify programmatic overlap.

     If the subject matter of an application lies within the stated interests of two or more ICs, dual or multiple assignments may be made. The IC to which the application is most clearly relevant is designated as the primary assignee. When the best assignment is not clear, the DRR may consult with the interested parties before

making a determination.

A number of trans-NIH initiatives (Roadmap/Common Fund, Neuroscience Blueprint, OpNet, etc.) have special designations.

Regardless of the number of program assignments made, only one SRG will review the application. If an application is to be considered for support by one or more ICs, the Council of each IC must provide a second-level review and recommend the application favorably (see NIH Manual Chapter 54513).

Differences of opinion between DRR and an IC concerning the assignment for funding considerations for an application(s) will be resolved by the DDER or his/her designee.

D. **Dispute of Receipt and Referral Decisions**
  1. **Acceptance of Dispute**

     Disputes of receipt and referral issues will be accepted beginning immediately after the initial assignments have been made and before the initial review has taken place. Disputes of responsiveness will be accepted immediately after the decision not to accept an application for review has been made.

  2. **Resolution of Dispute**

     Disputes of receipt and referral issues should be resolved in a manner that minimizes delay of the review. In all cases, the dispute should be handled by evaluating the issues, determining whether corrective action is necessary, and conveying the decision to the investigator with an explanation of the reasons for the decision. That decision is final, and the pre-review disposition of the application may not be disputed further.

     When issues concerning the receipt, assignment to a funding component for an application, or assignment to an SRG are contested before the initial review has taken place, the dispute should be directed to the DDRR, who may handle the matter directly or refer it to the appropriate Division Director in CSR or Referral Liaison in the appropriate IC.

     Issues concerning the assignment to an SRG or the responsiveness of an application to an RFA for applications reviewed by ICs should be handled according to the procedures established by the IC where the application is assigned.

     Matters involving potential COI or violation of ethical conduct rules on the part of an NIH staff member or other Federal employee will be referred to the appropriate

Deputy Ethics Counselor or agency DAEO for consideration and resolution before any review of, or action on, the dispute is taken.

IX. Procedures:

A. **SRG Meeting Preparation Procedures**

The following procedures are required for all NIH SRGs. In addition, detailed guidance regarding best practices and procedures may be developed by individual ICs and provided to staff and reviewers in guidance documents.

1. **Administrative Review of Materials**

   SROs and review support staff, in accordance with IC specific guidelines, are responsible for checking the application for completeness, and may share this responsibility.

2. **Recruiting and Assigning Reviewers**

   The SRO managing the review is responsible for recruiting SRG members to ensure adequate expertise for the review, and for making the assignments of reviewers to particular applications. In addition, the SRO determines whether real or apparent COI, as defined in the peer review regulations at 42 C.F.R. Part 52h, exist for reviewers in relation to any application and takes appropriate actions to manage them. The SRO further determines that potential reviewers are not de-barred or have other administrative sanctions that prevent them from serving (see PHS Administrative Actions Bulletin Board and the System for Award Management).

   All SRG members are assessed by the SRO regarding COI and must sign COI Certifications before and after participating in the review. In addition, reviewers must certify that they are not federally registered lobbyists (see OFACP Policy December 2011).

   POs may prepare and submit to the SRO a list of the scientific expertise they consider necessary for the review of applications and the names of qualified potential reviewers. POs may not communicate with actual or potential reviewers about the review. Names of potential reviewers may not be solicited or accepted from applicants, although applicants are encouraged to indicate in the cover letter the areas of expertise that may be pertinent to the review of the application.

   In the case of a standing SRG, the SRO also can invite temporary members to participate in the review, if the SRO determines that additional expertise is needed.

Ordinarily, the number of temporary members should not exceed the number of regular members participating in the meeting. In addition, the SRO of a standing SRG or SEP may solicit outside written opinions that are provided by Mail Reviewers.

3. **Assignments**

For each application, the SRO selects a minimum of three qualified SRG members to serve as reviewers, by matching the science in the application to the reviewers' expertise and managing COI. Mail Reviewers must be assigned in addition to at least three reviewers who will be present during the meeting for the discussion and scoring of the application(s) to which they are assigned.

4. **Materials for Reviewers**

SROs and review support staff share responsibility for distributing the applications, related materials, and instructions for SRG members, either through the mail, secure internet-assisted sites, or secure portable media that meet NIH security requirements (see NOT-OD-08-071). Mail Reviewers may have access to the written critiques and preliminary scores provided by other reviewers assigned to those applications that they are asked to evaluate.

B. **SRG Meeting Procedures**
   1. **Attendance**
      a. **Designated Federal Official (DFO)**

      Review meetings may be conducted only when a DFO is in attendance. The SRO serves as the DFO. If the SRO is called out of the meeting, the meeting must be recessed until the SRO returns or another appropriate member of the NIH staff is designated by the IC managing the review to assume this role. For internet assisted meeting type reviews, the DFO must monitor electronic discussions in real time.

      b. **Other NIH and Federal Staff**

      Attendance at closed sessions of Councils and SRGs is restricted to committee members, Federal officials involved in the operation of the committee, other Federal officials with an authorized reason to be present, non-Federal staff assisting in the performance of specific duties, persons required to attend the meeting to assist a committee member with a disability, and non-member attendees who are invited to attend the meeting to assist the committee in carrying out its functions . Adherence to COI and confidentiality policies must be documented for those non-members who attend closed sessions to assist the committee in carrying out its functions (see OFACP Policy Announcement 2001-

).

For reviews involving collaborations with other governments, representatives of the other governments may not preside over the review meeting, serve as SRG members on the basis of their official duties, or attend the meeting as an observer.

2. **Reviewer Roles**

The assigned reviewers lead the discussion of individual applications at the SRG meeting. When a reviewer has a real or apparent COI with an application, s/he leaves the room for the duration of the discussion and scoring of the application, and must not discuss it with SRG members who were present during its evaluation. During the review meeting, all SRG members (except those with real or apparent COI or who were otherwise not present during the discussion) are expected to:

- listen to the assigned reviewers, who provide evaluations of the applications with reference to the appropriate NIH criteria;

- contribute to the discussion of applications as appropriate; and

- provide final, overall impact scores for all applications on the agenda.

Following the discussion and scoring, the SRO may request that members of the SRG who were not assigned to the application contribute written critiques and if appropriate criterion scores, if their views were not represented in critiques submitted by the assigned reviewers but had an impact on the final evaluation. Written critiques and criterion scores from Mail Reviewers also are included in the summary statement.

3. **Clustering**

Where feasible, certain types of applications are clustered (see Appendix B. Definitions), so they are discussed and scored in a similar context:

- applications from New Investigators, including applications from Early Stage Investigators;

- clinical applications involving human subjects research; and

- applications of the same mechanism or activity code.

4. **Additional Review Criteria**

SRG members are required to comment on the acceptability of certain aspects of the proposed work, as applicable, through consideration of additional review criteria.

Because these criteria do not apply to all applications, they are not given individual criterion scores.

5. **Applications from Foreign Institutions**

   For applications from foreign institutions, SRGs are asked to identify special resources or other characteristics (human subjects population, animals, disease, equipment, techniques, etc.) of the proposed research project, whether similar research is being done in the United States, and whether a need exists for additional research in this area. This information is communicated through a specifically formatted section in the Summary Statement but is not considered in assigning an overall impact score. (For more information, see NIH Manual Chapter 54104).

6. **Significant Foreign Component**

   If an application from a domestic institution has a substantial foreign component (see Appendix B. Definitions), reviewers are asked to identify special resources and characteristics of the foreign component and comment on them in their critiques, typically under the Approach criterion (For more information, see NIH Manual Chapter 54104).

7. **Avoiding Bias at Review Meetings**

   At no time may NIH staff members attempt to influence the outcome of peer review other than by ensuring that the process is in conformance with existing laws, regulations, and policies.

8. **Research Integrity**

   As noted above, the SRO should consider deferring the review of an application if the issue of research misconduct is raised at the review meeting or if an SRG member asks about the disposition of a case and refers to an application under review. If the SRO determines that the integrity of the review for that application could have been compromised by the introduction of comments concerning possible research misconduct, then the application must be deferred so that it may be given an unbiased review.

   See Research Misconduct.

9. **Streamlined Review of Applications**

   Under the streamlining procedure, applications are categorized by the SRG as either more or less meritorious, in terms of scientific and technical merit, on the basis of preliminary overall impact scores offered by, at a minimum, the assigned reviewers. A

streamlining decision for a particular application requires the unanimous consent of all the eligible members (without COI or the appearance of COI) of the entire SRG (that is, not Mail Reviewers).

If all of the eligible (without COI or appearance of COI) SRG members concur, the application is not discussed at the meeting and is designated as ND. The more meritorious applications are given full discussion at the SRG meeting and a numerical overall impact score, and are taken routinely to Council for second-level review.

Unless specified otherwise in the FOA, all applications receive criterion scores and written critiques from the assigned reviewers. Assigned reviewers should be encouraged to focus written critiques primarily on major strengths/weaknesses, issues and concerns, and to follow the specified review criteria.

Summary Statements for applications that are ND consist of the reviewers' criterion scores and essentially unedited critiques. Summary Statements compiled in this fashion allow for prompt feedback to the NIH staff, IC Councils, and the investigator/applicant/candidate.

10. **Voting Actions and Minority Reports**

Motions and votes are required for the SRG to defer an application or designate an application as NRFC. All motions are passed by a simple majority of eligible SRG members (those without COI or appearance of COI). If one or more eligible SRG members dissent on a vote related to a motion on the application, the dissenting member(s) may (but are not required to) provide a minority report on the pertinent action for inclusion in the Summary Statement.

If the motion to designate an application as NRFC fails and the application is scored subsequently, those who voted for the NRFC motion may (but are not required to) provide a minority report for inclusion in the Summary Statement. When formal votes are taken on a NRFC motion, the number of members who vote for, and against, the motion, as well as the number of members who abstain, must be recorded in the Summary Statement.

11. **Review of the Budget**

The NIH requires a modular budget format on new, Renewal, Revision, and Resubmission applications that request up to a total of $250,000 direct costs in each year (less Consortium F&A) and fall in one of the following mechanisms:

- Research Project Grants (R01)

- Small Grants (R03)

- Academic Research Enhancement Award (AREA) Grants (R15)

- Exploratory/Developmental Research Grants (R21)

- Clinical Trial Planning Grant Program (R34)

- Some RFAs/PAs

SRG members evaluate specific aspects of the budget in an application after they have assigned their overall impact scores:

- if the application includes a detailed budget request, SRG members should evaluate the duration of the project period, and examine the costs for all years requested, to evaluate the need for specific items and their requested costs;

- if the application includes a modular budget request, SRG members should consider the entire project period and the total direct costs needed to complete the project in that length of time. For a modular budget request, based on the reviewers' understanding of the research proposed and the costs and services associated with such research, the annual recommended budgets should be made in modules of $25,000; and

- if the application includes a "lump sum" budget request, SRG members should consider the entire project period and the total direct costs needed to complete the project in that length of time.

Other recommended changes in staffing, effort, specific aims, consortium arrangements, etc., should be described in the budget section without assigning an amount. If the SRG recommends reducing the scope of work and/or duration of support as a result of the scientific and technical assessment, the recommended reductions and the reasons for them should be recorded in the Committee Budget Recommendations section of the Summary Statement.

SRG members should not address facilities and administrative costs, pay lines, or funding considerations during the discussion of scientific and technical merit.

C. **Post Review Meeting Procedures**
   1. **Communicating Review Outcomes**

   The primary purpose of the Summary Statement is to provide a written report of the outcome of the review, including the application's strengths and weaknesses, to the IC Council(s) and/or NIH program staff. The secondary purpose of the Summary

Statement is to communicate the review outcome to the PDs/PIs. The Summary Statement is not prepared as a tutorial for the PD/PI. Summary Statements are available to all PDs/PIs on an application, or the candidate, and appropriate NIH staff, prior to the meeting of the Council.

Council members use Summary Statements as the main sources of information about applications and as the primary basis for their recommendations. IC staff members use Summary Statements as guides in the management of the resulting grants and when discussing with investigators certain IC actions.

Summary Statements call to the attention of Council and NIH staff concerns about the adequacy of assurances and information on research proposed that involves human subjects, inclusion plans, vertebrate animals, resource sharing, foreign applications, or biohazards.

Summary Statements for previous submissions of Resubmission, Revision, or Renewal applications also may be made available to SRG members and Councils.

The PDs/PIs have access automatically via their Commons accounts to the review outcome (overall impact score and percentile ranking [see Appendix B. Definitions] when applicable) of the application shortly after the scores have been released in the NIH electronic data system and before the meeting of the Council.

2. **Summary Statements**

The Summary Statement is prepared by the SRO to report, objectively, the SRG's evaluation of the application and to record the salient features of the group's evaluation, deliberations and recommendations with documentation of and justification for their actions (e.g., changes in budget, personnel, and/or project period). The Summary Statement is based on the written comments submitted by assigned reviewers and the discussion that occurred during the review meeting. Summary Statements are prepared using uniform, formatted templates, which may be prepared by the SRO as appropriate for the mechanism. In general, a Summary Statement will contain:

- the final overall impact score or review outcome;

- the percentile ranking when appropriate;

- administrative codes (such as codes for human subject protections, inclusion plans, or vertebrate animals);

- contact information for assigned program staff;

- the unedited Description section as provided by the applicant in the PHS398 or SF424 application form;

- a Resumé and Summary of Discussion prepared by the SRO for applications that are discussed, to document the discussion of the scientific and technical merit of the application. The resumé summarizes the basis for the overall impact score or NRFC recommendation, including both strengths and weaknesses of the application in relation to the review criteria;

- a Critique section, consisting of: 1) criterion scores provided by each reviewer assigned to the application; 2) the essentially unedited comments of the assigned SRG members; 3) written comments that may be provided by other SRG members who participated in the discussion of the application; and 4) mail reviews that were obtained and presented to the SRG during its deliberation;

- committee budget recommendations (for applications that are discussed), including recommended project period;

- the official meeting roster of all members of the SRG, including Mail Reviewers, site visitors or interviewers (when appropriate), and NIH staff conducting the meeting; and

- a footnote indicating that SRG members whose presence would constitute a COI were not present during the review of those applications.

A well-composed Resumé and Summary of Discussion should be written in such a manner that a scientifically astute reader who is not trained in the specific scientific area should be able to understand the key discussion points that contributed to an application's final overall impact score. Moreover, at a minimum, it should include the following elements:

- a one or two sentence description of the proposed research;

- a summary of the discussion, emphasizing strengths and weaknesses that had a major influence on the overall impact score;

- issues of consensus and differences of opinion; and

- concluding comments that convey the overall scientific evaluation and reflect the overall impact score, while indicating the area(s) of science impacted.

Supervisors must ensure that adequate time and resources are available for SROs to generate Summary Statements with high-quality Resumé and Summary of Discussion sections.

As appropriate, the Summary Statement also will include:

- summaries of committee recommendations, prepared by the SRO, on the Protection of Human Subjects (see the [Grants Policy Statement](#), Section 4.1.15); Inclusion of Women, Minorities, and Children (see the [Grants Policy Statement](#), Section 4.1.15); Vertebrate Animals (see the [Grants Policy Statement,](#) Section 4.1.1); and Select Agents (see the [Grants Policy Statement](#), Section 4.1.23), on the basis of the outcome of discussion during the meeting; and

- SRO Administrative Notes (see Appendix B. Definitions), such as resumé sections for administrative issues that may include the Resource Sharing Plan(s), Biohazards, or Foreign Components.

Summary Statements for streamlined (ND) applications:

- generally do not include sections that reflect committee deliberations (e.g., Resumé and Summary of Discussion; Committee Budget Recommendations); but

- do contain codes for protection of human subjects and vertebrate animals that, in the judgment of the SRO, best reflect the comments contained in the reviewers' written evaluations. Concern raised by any reviewer is sufficient for a streamlined application to be coded "Unacceptable" for human subjects protections or vertebrate animal use.

Summary Statements are not prepared for applications that have been deferred. If an application is deferred, the SRO prepares a memorandum to the official file, and a letter to the Contact PD/PI with a copy to the file, which documents the rationale for the deferral, and informs appropriate program staff about the reasons for the deferral. However, in the case of deferral due to an allegation of research misconduct, the Contact PD/PI cannot be informed that an allegation of research misconduct has been received. Rather, the Contact PD/PI can be told that the application was deferred for administrative reasons.

3. **Meeting Minutes, Records, and Reports**

When the Summary Statement has been completed, working documents, except those that are sent routinely to the official file, are destroyed in conformity with applicable law (e.g., the Privacy Act, the Freedom of Information Act), regulation, and policy (such as [NIH Manual Chapter 1743](#), Appendix 1, Part 3, Section 4000-B-1.)

Minutes of the SRG meeting are prepared by the SRO, and are signed and dated by the SRO and the SRG Chairperson. The Minutes contain the starting time, date, and location of the meeting; data on the total number of applications reviewed in the meeting (for each award mechanism reviewed); the total requested direct costs of all applications reviewed in the meeting; and the adjournment time and date. The original Minutes, meeting roster, log of attendees, original pre-meeting COI certifications and post-meeting COI certifications, confidentiality certifications, copies of approved waivers and policy deviations, and the COI report listing COIs for each application are maintained in the IC Committee Management Office or the office of the DFO for the committee.

All significant documents, either paper or electronic, that are identified as part of the official grant file system (as described in NIH Manual Chapter 55808 "Establishment and Documentation of Files and Other Records, Including Monitoring Actions, For NIH Grant Programs") and are used in the initial review or the management of awarded grants, whether initiated or received by the SRO, program staff, or grants management staff, shall be maintained in the electronic grant file and thereby shall be available to NIH staff as needed.

4. **Appeal of SRG Review Outcome**
    a. **Acceptance of Appeal Letters**

       Appeal letters will be accepted during the period from transmission of the Summary Statement to the PDs/PIs or contact PD/PI, up to 30 calendar days after the relevant Council meeting.

       Matters involving potential COI or violation of ethical conduct rules on the part of an NIH staff member or other Federal employee will be referred to the appropriate Deputy Ethics Counselor or agency DAEO for consideration and resolution before any review of, or action on, the appeal is taken.

    b. **Initial Review Issues**

       Procedures for responding to concerns of PDs/PIs and officials of applicant organizations vary according to the stage of the peer review process in which their application exists.

       1. **Submission and Initial Institute Response**

          A PD/PI or institutional official (not necessarily the AOR) should be instructed to discuss concerns about the review process for a particular application with the NIH PO responsible for the application.

For matters that do not involve an NIH staff member or other Federal employee, the PO will attempt to resolve the applicant's concerns. If, after discussion with the PO, the PD/PI or institutional official still has concerns, s/he may submit an appeal letter that details his/her specific concerns about the review of the application to the PO, who will forward copies to the Appeals Officer and the SRO. Within ten business days of receiving the appeal letter, the PO will acknowledge its receipt in writing, indicating that a final decision will be communicated within 30 calendar days after either the Council meeting or the date the appeal letter was received (if too late to be made available to the Council at its meeting). The PO will send copies of the appeal letter and the acknowledgement letter to the Appeals Officer and the SRO.

For all written correspondence, the response to the PD/PI or AOR should be written and communicated in a manner that, where possible, preserves the PD/PI's or institution's right to confidentiality and does not jeopardize his/her future standing with reviewers, Council members, or NIH staff. Where the response cannot be final, an interim written response should be provided to indicate that the matter is under examination, or other status as applicable. The response should, at a minimum: (a) confirm that the issues raised in the appeal letter were accepted as a dispute, appeal, or grievance; and (b) indicate the timing and possible outcomes of the examination of the dispute, appeal or grievance in arriving at the IC's final response.

Upon receiving the appeal letter and response from the PO, the SRO should contact his/her supervisor to discuss the basis for the appeal; provide the PO a written response to the issues raised by the PD/PI and/or organizational official; and continue discussions with the PO as necessary.

All original correspondence on the matter received from the PD/PI and/or institutional official, and copies of NIH-originated correspondence to the PD/PI and/or institutional official, shall be placed in the official grant file for the application in the IC and should be retained in accordance with the NIH Manual Chapter 1743, Appendix 1, Part 3, Section 4000.

2. **Administrative Resolution**

Certain appeals can be resolved administratively through direct communication between the PO and the SRO. The PO will consult with

his/her supervisor about the appeal, and with the SRO of the SRG that reviewed the application, who in turn will consult with his/her supervisor. If all agree that the application should be deferred for re-review, the PO will notify the PD/PI or organizational official, and the SRO will proceed with the re-review. The Appeals Officer must be notified of this resolution.

A re-review consists of a second evaluation of the same application, not a resubmitted or modified version or one with any added materials other than those allowed as post-submission materials, by either the same or a different SRG. The reviewers involved in the re-review will not have access to the Summary Statement that resulted from the disputed review or to the appeal letter. The outcome of the re-review is final and may not be appealed.

3. **Applicant Decision to Resubmit and Withdraw an Appeal Letter**

In cases where an appeal letter has been received and program staff and review staff agree that the review was not flawed, the PO will communicate this information to the PD/PI and/or institutional official, and indicate that he or she may consider submitting a new or Resubmission application, rather than pursuing an appeal. If the investigator agrees with that option, s/he should submit a letter to the PO withdrawing the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or organizational officials (not necessarily the AOR), the AOR must send the request directly to the PO, or must send his/her concurrence to the PD/PI who will forward the materials and institutional concurrence to the PO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted. The PO will forward a copy of this letter to the Appeals Officer and SRO.

4. **Handling of Unresolved Appeals**

In those cases where program staff and review staff do not agree on the resolution of an appeal or together they disagree with the appeal, and the appeal letter has not been withdrawn, the IC will make available to the Council, at a minimum, a list of the appeal letters received for that meeting and the relevant Summary Statements. The IC may not deny the PD/PI and/or applicant organization the opportunity to have an appeal taken to Council. The SRO's and PO's responses, and additional items may be

included, and access to the application image may be provided, as deemed necessary by the Appeals Officer. However, the IC may determine which appeal letters warrant discussion by the Council members, and Council members may raise certain ones for discussion if they so choose.

5. **Resolution by Council**

The PO and SRO are responsible for being present and available for the Council's discussion of the appeal letter, so that they may answer questions that arise. The SRO can provide to Council members, verbally but not in writing, the names of reviewers with conflicts of interest for a particular application. The PO or SRO can provide to Council members, PD/PIs or organizational officials areas of expertise that were represented on the SRG where the application was reviewed, but cannot provide such information with reference to a particular reviewer(s).

The Council has two usual options with regard to appeal letters: (1) recommend that the application be re-reviewed, whether by the same or a different SRG, or (2) concur with the initial scientific review (thus, reject the appeal letter). The Council must vote on the final decision to request re-review or deny the appeal. The result of this vote must be documented in the official grant file.

The PD/PI and AOR will be advised in writing of the Council decision by the Executive Secretary of the Council. The letter should contain the following information:

- acknowledgement of receipt of the appeal letter and its date;
- a brief restatement of the bases of the appeal;
- a brief summary of the decision by the Council;
- a caution that this letter implies nothing with respect to a funding decision;
- notice that this decision is final and no other administrative recourse is available;
- suggestion that the PD/PI and/or AOR should discuss the situation with the PO; and
- if the letter is not sent directly to the AOR, a "cc" to him or her.

This notification should inform the PD/PI and AOR that the decision is final, that no further avenues exist for administrative recourse, and that the appeal letter will be retained in the official file for the application.

6. **Resubmissions**

   NIH POs and DRR monitor the receipt of appeal letters and Resubmission applications. Should an appeal for the initial peer review of the A0 version of an application be pending resolution and an A1 version of that application is submitted, or an A1 version of an application be pending peer review and an appeal for the initial peer review of the A0 version of that application is received, the applicant organization must choose to have either the appeal or the A1 version withdrawn. This decision must be sent in writing to the PO, with concurrence of the AOR within five business days of being notified by the PO (see NOT-OD-11-101).

D. **Council Review of Applications**

Applications that have been assigned numerical overall impact scores by the SRG are provided routinely to Councils for review. Applications designated as ND need not be provided routinely to Councils for their review. Councils may recommend that a scored or ND application be remanded for re-review. Applications designated as NRFC are not provided routinely to Councils, cannot be awarded, and are withdrawn administratively after the Council round. Council members may request that those applications designated as NRFC be provided to them for review, and the IC must present such an application to Council if an appeal is received concerning the initial peer review (see NIH Manual Chapter 54513).

E. **Records Retention and Disposal**

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual Chapter 1743, Appendix 1, Part 3, Section 4000-B-1, which covers Funded Grant and Award Applications, Official Files. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. The IC Records Officer should be contacted for additional information.

All e-mail messages are considered Government property and, if requested for a legitimate

Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must be provided also to Congressional oversight committees if requested and are subject to Freedom of Information Act and Privacy Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

X. Internal Controls:

The purpose of this NIH GAM is to implement and explain the policies, procedures, and responsibilities for the review of grant applications.

A. **Office Responsible for Reviewing Internal Controls Relative to this NIH GAM**

   The Office of Extramural Programs (OEP), OER, NIH.

B. **Frequency of Review**

   The frequency of review will be based on the outcome of a risk assessment that will determine how often an internal control review will be conducted to assess compliance with this NIH GAM. NIH GAMs with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

C. **Method of Review**

   OEP will complete an internal risk assessment in the first year after the NIH GAM is in place. Based on this assessment, a decision will be made as to the method of review.

D. **Review Reports**

   Review reports are sent to the Deputy Director for Management (DDM) and DDER indicating that controls are in place and working well or include internal control issues that should be brought to the attention of the DDM.

XI. Appendices:

Appendix A. References:

This GAM cites other NIH Manual Chapters. In the event of conflict, the language in this GAM supersedes the language of any statement in any of the referenced NIH Manual Chapters which predate this issuance.

Code of Federal Regulations, 5 C.F.R. Part 2634 "Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture": http://www.gpo.gov/fdsys/pkg/CFR-2012-title5-vol3/pdf/CFR-2012-title5-vol3-part2634.pdf

Code of Federal Regulations, 5 C.F.R. Part 2635 "Standards of Ethical Conduct for Employees of the Executive Branch": http://www.gpo.gov/fdsys/pkg/CFR-2012-title5-vol3/pdf/CFR-2012-title5-vol3-part2635.pdf

Code of Federal Regulations, 5 C.F.R. Part 2640 "Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting a Personal Financial Interest)": http://www.gpo.gov/fdsys/pkg/USCODE-2010-title18/pdf/USCODE-2010-title18-partI-chap11-sec208.pdf

Code of Federal Regulations, 5 C.F.R. Part 5501 "Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services": http://www.gpo.gov/fdsys/pkg/CFR-2012-title5-vol3/pdf/CFR-2012-title5-vol3-part5501.pdf

Code of Federal Regulations, 42 C.F.R. Part 52a "National Institutes of Health Center Grants": http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part52a.pdf

Code of Federal Regulations, 42 C.F.R. Part 52b "National Institutes of Health Construction Grants": http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part52b.pdf

Code of Federal Regulations, 42 C.F.R. Part 52h "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects": http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part52h.pdf

Code of Federal Regulations, 42 C.F.R. Part 66 "National Research Service Awards": http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part66.pdf

Federal Advisory Committee Act, 5 U.S.C. app.: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title5/pdf/USCODE-2010-title5-app-federalad.pdf

Federal Information Security Management Act of 2002, Title III of P.L. 107-347: http://csrc.nist.gov/drivers/documents/FISMA-final.pdf

Government in the Sunshine Act, 5 U.S.C. Section 552b: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title5/pdf/USCODE-2010-title5-partI-chap5-subchapII-sec552b.pdf

Health Omnibus Programs Extension Act of 1988, P.L. 100-607: http://history.nih.gov/research/downloads/PL100-607.pdf

Health Research Extension Act of 1985, P.L. 99-158: http://history.nih.gov/research/downloads/PL99-158.pdf

HHS General Administration Manual, Part 9-00-70 "Nomination, Selection and Appointment of Federal Advisory Committee Members": http://www.hhs.gov/hhsmanuals/gam/chapters/part9.pdf

HHS Grants Policy Directive, Part 2.04 "Pre-Award (Awarding Grants)": http://www.hhs.gov/asfr/ogapa/aboutog/ogpoe/gpd2-04.pdf

NIH Grants Administration Manual Chapter 4.1.03.203—Applicability (including Deviations): http://nih-extramural-intranet.od.nih.gov/nih/sources/nihgam_4.1.03.203.pdf

NIH Grants Administration Manual Chapter 4.1.04.204—Responsibilities of NIH Grants Administration Staff: http://nih-extramural-intranet.od.nih.gov/nih/sources/nihgam_4.1.04.204.pdf

NIH Grants Policy Statement: http://grants.nih.gov/grants/policy/policy.htm#gps

NIH Guide Notice NOT-OD-08-071 "NIH Implements New Procedures to Protect NIH Application Data Sent to Peer Reviewers on Compact Disks": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-071.html

NIH Guide Notice NOT-OD-09-013 "Revised New and Early Stage Investigator Policies": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html

NIH Guide Notice NOT-OD-09-024 "Enhancing Peer Review: The NIH Announces New Scoring Procedures for Evaluation of Research Applications Received for Potential FY2010 Funding": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html

NIH Guide Notice NOT-OD-09-025 "Enhancing Peer Review: The NIH Announces Enhanced Review Criteria for Evaluation of Research Applications Received for Potential FY2010 Funding": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html

NIH Guide Notice NOT-OD-09-074 "Enhancing Peer Review: The NIH Announces Consolidation of Review Criteria for Institutional Research Training Grant Applications (T32) Submitted for FY 2010 Funding": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-074.html

NIH Guide Notice NOT-OD-10-115 "Enhancing Peer Review: New NIH Policy on Post-Submission Application Materials": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html

NIH Guide Notice NOT-OD-10-140 "New Time Limit for NIH Resubmission Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html

NIH Guide Notice NOT-OD-11-035 "NIH Policy on Late Submission of Grant Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html

NIH Guide Notice NOT-OD-11-046 "Reminder of Requirement for Certification Letter for Applications in Response to Kirschstein-NRSA for Individual Predoctoral Fellowships to Promote Diversity in Health-Related Research (PA-11-112) and Deadline for Their Receipt": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-046.html

NIH Guide Notice NOT-OD-11-047 "Notice of Change in Policy on the Submission of Reference Forms (Letters of Reference) for Kirschstein-NRSA Fellowship (F) Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-047.html

NIH Guide Notice NOT-OD-11-064 "Appeals of NIH Initial Peer Review": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html

NIH Guide Notice NOT-OD-11-079 "Notice of Change in Policy on the Submission of Letters of Reference for Career Development (K) Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-079.html

NIH Guide Notice NOT-OD-11-093 "Change in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-093.html

NIH Guide Notice NOT-OD-11-110 "Clarification of Instructions for the Review of Renewal Applications for Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (Parent T32 and T35)": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-110.html

NIH Guide Notice NOT-OD-12-111 "Notice of Impending Change in Peer Review Criteria and Submission Requirements for NIH Applications Involving Human Embryonic Stem Cells": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-111.html

NIH Guide Notice NOT-OD-12-141 "Interim Guidance for Videos Submitted as NIH Application Materials": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-141.html

NIH Guide Notice NOT-OD-12-161 "NIH Announces Plans to Transition to Electronic Submission of Multi-Project Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-161.html

NIH Guide Notice NOT-OD-13-010 "Advance Notice: Revised Policy for Managing Conflict of Interest in the Initial Peer Review of NIH Grant and Cooperative Agreement Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-010.html

NIH Guide Notice NOT-OD-13-038 "New Review Criteria for NIH Construction (C06 and UC6) and Modernization (G20) Grant Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-038.html

NIH Guide Notice NOT-OD-13-047: Notice of Correction to NOT-OD-13-010 "Advance Notice: Revised Policy for Managing Conflict of Interest in the Initial Peer Review of NIH Grant and Cooperative Agreement Applications": http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-047.html

NIH Guide Notice NOT-RM-07-011 "The NIH Intramural Research Program and the NIH Director's Roadmap Initiative – Locus of Review": http://grants.nih.gov/grants/guide/notice-files/NOT-RM-07-011.html

NIH Manual Chapter 1743 "Keeping and Destroying Records": http://oma1.od.nih.gov/manualchapters/management/1743/

NIH Manual Chapter 1805 "Use of Advisors in Program and Project Review and Management": http://oma1.od.nih.gov/manualchapters/management/1805/

NIH Manual Chapter 1810-1 "Procedures for Avoiding Conflict of Interest for NIH SGE Advisory Committee Members": http://oma1.od.nih.gov/manualchapters/management/1810-1/

NIH Manual Chapter 2400-01 "Introduction to Government Ethics at the NIH": http://oma1.od.nih.gov/manualchapters/ethics/2400-01/

NIH Manual Chapter 3005 "Review and Evaluation of Intramural Programs": http://oma1.od.nih.gov/manualchapters/intramural/3005/

NIH Manual Chapter 54104 "NIH Research Grants Involving Foreign Institutions and International Organizations": http://oma1.od.nih.gov/manualchapters/grants/54104/

NIH Manual Chapter 54105 "NIH Support of Scientific Meetings & Conferences by Grants and Cooperative Agreements": http://oma1.od.nih.gov/manualchapters/grants/54105/

NIH Manual Chapter 54110 "Program Announcements and Requests for Applications": http://oma1.od.nih.gov/manualchapters/grants/54110.htm

NIH Manual Chapter 54513 "Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities": http://oma1.od.nih.gov/manualchapters/grants/54513/

NIH Manual Chapter 54810 "National Research Service Awards": http://oma1.od.nih.gov/manualchapters/grants/54810/

NIH Manual Chapter 54815 "Implementation of Cooperative Agreements": http://oma1.od.nih.gov/manualchapters/grants/54815/

NIH Manual Chapter 55808 "Establishment and Documentation of Files and Other Records, Including Monitoring Actions, For NIH Grant Programs":

http://oma1.od.nih.gov/manualchapters/grants/55808/

NIH Manual Chapter 7410 "Review And Documentation Of Protections For Human Subjects In Extramural Grant Applications And Research And Development Contract Proposals": http://oma1.od.nih.gov/manualchapters/comgc/7410/

NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm;

NIH Reform Act of 2006: http://www.nih.gov/about/reauthorization/HR6164EnrolledVersion.pdf

OER Policy Announcement 1997-02: "Single Case Deviation from PHS/NIH Grants Policy": http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_1997_02.htm

OER Policy Announcement 2013-01 "Managing Conflicts of Interest for NIH Staff Handling Activities that Span the Intramural/Extramural Boundary": http://nih-extramural-intranet.od.nih.gov/d/nih/policies/OER_announce_2013_01.htm;

OFACP Policy Announcement 2001-01 "Attendance at Closed Sessions of Meetings of National Advisory Councils, Scientific Review Groups, and Special Emphasis Panels": http://ofacp.od.nih.gov/policies/pdfs/AttendanceatClosedSessionsPolicy2005.pdf

OFACP Policy Announcement (REVISED April 2011) "Use of Electronic Communications by NIH Advisory Committees": http://ofacp.od.nih.gov/policies/pdfs/OFACPPolicyonUseofElectCommNIHAdvCommApril2011.pdf

OFACP Policy Announcement 2003-01 "Attendance at Closed Sessions of Meetings of Boards of Scientific Counselors": http://ofacp.od.nih.gov/policies/pdfs/OFACPPolicyAnnouncement2003-01.pdf

OFACP Policy Announcement 2008-01 "Waiver Requests for Advisory Committee Member Appointments and Meeting Attendees": http://ofacp.od.nih.gov/policies/pdfs/FinalOFACPPolicy2008-01.pdf

OFACP Policy "OFACP Policy: Implementing Ban on Lobbyists Serving on Advisory Committees (REVISED September 2012)": http://ofacp.od.nih.gov/policies/pdfs/BanonLobbyistsOFACPPolicy_Final.pdf;

"Policies and Procedures for NIH Extramural Staff: Handling Allegations of Research Misconduct": http://nih-extramural-intranet.od.nih.gov/nih/policies/research_integrity/misconduct_guidance_2010.doc

Public Health Service Act, 42 U.S.C. 289a "Peer Review Requirements":

http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapIII-partH-sec289a.pdf

Small Business Association Small Business Innovation Research (SBIR) Program Policy Directive: http://www.sbir.gov/about/sbir-policy-directive

Small Business Association Small Business Technology Transfer (STTR) Program Policy Directive: http://www.sbir.gov/about/sttr-policy-directive

United States Code, 18 U.S.C. "Crimes and Criminal Procedures" may be searched for sections 201-216 through accessing: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title18/pdf/USCODE-2010-title18-partI-chap11.pdf

United States Code, 18 U.S.C. 208 "Acts Affecting a Personal Financial Interest": http://www.gpo.gov/fdsys/pkg/USCODE-2010-title18/pdf/USCODE-2010-title18-partI-chap11-sec208.pdf

Appendix B. Definitions:

The following terms are used in this NIH GAM:

1. **Administrative Note**
   An Administrative Note is placed at the end of the Summary Statement by the SRO to indicate aspects related to the application or committee deliberation other than scientific and technical merit or overall impact.

2. **Appeal**
   An appeal is a written communication from a PD/PI and/or official of the applicant institution which meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw in the review process for a particular application, 3) is based on one or more of four allowable issues, and 4) displays concurrence of the AOR.

3. **Appeals Officer**
   An Appeals Officer is a senior IC official who is not otherwise directly involved in the initial peer review process and is designated by the IC Director to ensure that proper procedures are followed in handling appeal letters.

4. **ASSIST**
   ASSIST is the Application Submission System and Interface for Submission Tracking for the preparation and submission of multi-project applications.

5. **Authorized Organization Representative (AOR)**
   The AOR is the individual, named by the applicant organization, who is authorized to act for

the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is equivalent to the Signing Official in the eRA Commons, i.e., holds the SO Role.

6. **Close relative**

   As defined in the NIH Peer Review Regulation ([42 CFR Part 52h](#)) for non-Federal reviewers, a close relative for the purposes of this policy means a parent, spouse, domestic partner, son or daughter.

7. **Clustering**

   Clustering is the process of grouping applications that share a similar attribute within the order of review for an SRG meeting, so they are considered and deliberated in succession.

8. **Conflict of Interest (COI)**

   Regardless of the level of financial involvement or other interest, if a reviewer feels unable to provide objective advice, he/she is expected to recuse him/herself from the review of the application at issue. The peer review system relies on the professionalism of each reviewer to identify to the designated government official the existence of any real or apparent COI that are likely to bias the reviewer's evaluation of an application.

   - Non-Federal Reviewer: COI in scientific peer review exists when a non-Federal reviewer has an interest in an application that is likely to bias his or her evaluation of it. A non-Federal reviewer who has a real or apparent COI with an application, as defined in [42 C.F.R. Part 52h](#), may not participate in its review unless a deviation is granted by the DDER.

   - Federal Employee: A Federal employee has a COI when s/he participates in a particular matter, such as the review of a funding application, that will have a direct and predictable effect on his or her personal or imputed financial interests, unless a statutory or regulatory exemption or exception applies, or a waiver of the COI is granted by the individual responsible for the employee's federal employment (the appointing authority), consistent with agency delegations of authority. Imputed interests include those of the employee's spouse, dependent children, general partner, and any non-federal entity the employee serves as officer, trustee, director, or employee(see [18 U.S.C. 208](#) and [5 C.F.R. Part 2640](#)).

9. **Conflict of Interest – Apparent**

   Non-Federal Reviewer: The appearance of COI occurs when a reviewer or close relative or professional associate (see Appendix B. Definitions) of the reviewer has a financial or other interest in an application that is known to the reviewer or the government official managing the review, and this circumstance would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review. The SRO or equivalent

managing the review will evaluate the appearance of COI and determine, in accordance with the regulations at 42 C.F.R. Part 52h, whether or not the interest would likely bias the reviewer's evaluation of the application.

- Federal employee: An appearance of a COI arises when a Federal employee is involved in a particular matter involving parties, such as the review of a grant application, and a reasonable person with knowledge of the relevant facts would question the employee's impartiality in the matter. This may happen when the matter is likely to have a direct and predictable effect on the financial interests of a member of the employee's household or involves a person with whom the employee is deemed to have a covered relationship as a party or the representative of a party to the matter. Federal employees have a covered relationship with, among others, the following: a person or organization with whom he or she seeks a business or financial relationship; a close relative; an entity that employs the employee's spouse, parent, or dependent child; an organization in which the employee's spouse serves as an officer, director, or other position; and, any organization in which the employee is an active participant. Where an appearance of a COI arises, an employee should not participate in the official matter unless he or she is authorized to do so by the appropriate designee of his or her employing agency (often the ethics official). (See 5 C.F.R. Part 2635.502).

10. **Criterion Score**

    A criterion score is a separate numerical score given by an assigned reviewer for each of five established review criteria.

11. **Deferral**

    Deferral is the process by which a recommendation on an application under review is delayed because specific information is needed to complete the review, or because the review has been otherwise compromised.

12. **Designated Federal Official (DFO)**

    The DFO is the NIH staff member who has legal responsibility under FACA for managing the peer review meeting in a manner consistent with applicable statute, regulation, and policy.

13. **Deviation**

    Deviations from established NIH Peer Review policy are warranted under unusual circumstances in order to facilitate the review of applications and to maintain a fair, equitable, informed and unbiased review process. A request for a policy deviation from the policies discussed in this GAM chapter must be approved by the DDER in advance of the review meeting.

14. **Dispute**

A dispute is an applicant concern about the pre-review handling of an application with regard to receipt and/or referral decisions. Final authority for resolving disputes rests with DRR in CSR.

15. **Early Stage Investigator (ESI)**

    An ESI is an individual who is classified as a New Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent). An extension of ESI eligibility may be granted for a number of reasons (military service, extended clinical training, illness, family obligations, etc.) (For further information, see [NIH Guide Notice NOT-OD-09-013](#) "Revised New and Early Stage Investigator Policies").

16. **Editorial Board review**

    In Editorial Board reviews, the first stage involves evaluation of each grant application by two to three specialist Mail Reviewers, also known as the Editorial Board, for technical merit. This stage is followed by an in-person meeting of reviewers with broader expertise, called Editors, who focus on the impact and significance of the science.

17. **Fully Participating Reviewer**

    A fully participating reviewer is one who is formally assigned as a reviewer; is present at the SRG meeting, or for the teleconference or web-based discussion; has reviewed and evaluated the application; and has participated in the deliberation on its scientific and technical merit or in the deliberation to streamline the application at the review meeting, or during the teleconference or web-based discussion. Only fully participating reviewers are eligible to give overall impact scores for an application.

18. **Funding Opportunity Announcement (FOA)**

    A Funding Opportunity Announcement (FOA) is a publicly available document (e.g. published in Grants.gov or the NIH Guide for Grants and Contracts) by which a Federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

19. **Grants Management Officer (GMO)**

    A GMO provides expertise in business, fiscal, and other non-programmatic areas of grants administration. GMOs ensure that NIH and grantee staffs fulfill requirements of laws, regulations, and administrative policies. GMOs monitor the review process to certify that it was conducted in accordance with applicable policies which require an objective review of grant applications. Grants management staff may be called upon to provide assistance in budgetary matters and to interpret or clarify fiscal and administrative policy guidelines.

20. **Grievance**

    A grievance is a written communication from a PD/PI and/or official of the applicant

organization that presents concerns about the peer review process for a particular application and does not meet the criteria for an appeal.

21. **Mail Reviewer**

    A Mail Reviewer provides written critique(s), criterion scores, and an initial overall impact score(s) on a particular grant application(s), by some form of mail, electronic, or internet-assisted communication to the DFO, but does not attend the meeting or participate in the discussion of the application(s) and does not provide a final overall impact score(s).

22. **Major Professional Role**

    A major professional role means that an individual is participating in a project by contributing to the scientific development or execution of the project in a substantive, measureable way, whether or not compensation is requested.

23. **Minor Professional Role**

    A minor professional role means that an individual is participating in a project in a role that does not contribute to the scientific development or execution of the project in a substantive, measureable way.

24. **National Advisory Council/Board (Council)**

    Council is a Federal advisory committee composed of both scientists and, in most cases, public members, who perform the second level review of applications and provide advice and recommendations on matters of significance to the policies, missions, and goals of the IC they advise (see [NIH Manual Chapter 54513](#)).

25. **New Investigator**

    A New Investigator is an NIH research grant PD/PI who has not yet competed successfully for significant, independent NIH research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. See [NIH Guide Notice NOT-OD-09-013](#).

26. **Not Recommended for Further Consideration (NRFC)**

    An application may be designated NRFC by the SRG if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

27. **Other Significant Contributor (OSC)**

    An OSC is an individual who has committed to contribute to the scientific development or execution of the project, but has not committed to any specified measurable effort (in

person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed" (individuals with measurable effort cannot be listed as OSCs).

28. **Overall Impact Score**

The overall impact score is the rating assigned to an individual application by an SRG, and designates the reviewers' assessment of the likelihood for the research project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. For certain mechanisms (e.g., Fs and S10s), overall impact may be redefined in terms of merit for the candidate's career or benefit for the research community. The overall impact score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Overall impact scores may be numeric or alphabetical (e.g., ND).

29. **Peer Review**

The NIH initial peer review process is defined in regulation at [42 C.F.R. Part 52h](#) and involves the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of applications, Revision applications, and Research and Development contract proposals based on an evaluation of scientific and technical merit or other relevant aspects of the application. The process defined in regulation is extended by policy to other types of applications submitted to the agency. The initial review is performed by experts (Peer Reviewers) in the field of endeavor for which support is requested. The initial review is intended to provide guidance and recommendations for the second level of review by experts on the IC Council(s), who make funding recommendations to the NIH individuals responsible for making award decisions.

30. **Peer Reviewers**

Peer reviewers are experts qualified by training and experience in particular scientific or technical fields, or are authorities knowledgeable in the various disciplines and fields related to the applications under evaluation. These individuals provide expert advice on the scientific and technical merit of applications.

31. **Percentile**

The percentile is the numerical representation of the relative position or rank of each overall impact score (along a 100.0 percentile band) among the scores assigned by a particular SRG, based on one or more review cycles. When it is appropriate to the mechanism being reviewed, a percentile is applied to every application that is given a numerical overall impact score.

32. **Professional Associate**

A professional associate is any colleague, scientific mentor, or student with whom an individual is conducting research or other significant professional activities currently or with

whom the individual has conducted such activities within three years of the date of the review (see [42 C.F.R. Part 52h](#)).

33. **Program Announcement**

    A program announcement is a formal published document describing a new or re-emphasized ongoing NIH extramural activity that is publicized through an FOA. The program announcement specifies subject matter, scope and objectives, application requirements, eligibility criteria, and other requirements. A program announcement with set-aside funds is designated PAS, and a program announcement with one or more special receipt/referral/review considerations is designated PAR.

34. **Program Official (PO)**

    A PO is an NIH official who is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC SROs; communication with applicants both pre- and post-award; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO. The PO and the GMO work as a team in many of these activities.

35. **Request for Applications (RFA)**

    An RFA is an initiative sponsored by one or more NIH Institutes or Centers that stimulates targeted research by requesting grant applications in a well-defined scientific area. RFAs identify funds set aside for the initiative and the number of awards likely to be made.

36. **Scientific Review Group (SRG)**

    An SRG is a peer review committee of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications.

37. **Scientific Review Officer (SRO)**

    The SRO is the NIH official who serves as the DFO and has responsibility for identifying individuals to serve as peer reviewers, the assignment of review responsibilities, managing the peer review meeting and procedures for evaluating the applications assigned to the SRG, and reporting outcomes of the review in the Summary Statement.

38. **Special Emphasis Panel (SEP)**

    A SEP is a chartered Federal advisory committee that reviews grant and cooperative agreement applications and contract proposals for research, research projects and training activities and provides concept review of proposed contract or grant solicitations. SEPs have a fluid membership and individuals are designated to serve for only the meeting(s)

they are requested to attend. Individuals who serve on SEPs are designated to serve by the DFO in charge of the meeting, usually through a letter to the individual inviting them to serve on a particular panel meeting.

39. **Special Government Employee (SGE)**

   As defined by 18 U.S.C. § 202(a), an SGE can be an officer or employee of the Executive Branch who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 days, either on a full-time or intermittent basis. Members of NIH Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors who are not otherwise employed by the Federal Government are appointed as SGEs.

40. **SRG Chairperson**

   The SRG Chairperson is an SRG member who serves as the moderator of the discussions of the scientific and technical merit of the applications assigned to the SRG. The Chairperson works cooperatively with the SRO, who has legal responsibility for managing the meeting (see definition, above).

41. **SRG Member**

   For purposes of this policy, SRG members include all fully participating reviewers and mail reviewers unless otherwise designated. The term SRG member bears no connotation about appointments, temporary service, or assignments to particular applications.

42. **Standing SRG**

   A standing SRG is a type of committee that is established in compliance with FACA to review applications on a continuing basis for a specified program area(s) or mechanism(s) with duration expected to exceed one year. A standing SRG may be in the form of a separate committee for each type of application (e.g., on a program mechanism basis, such as training grant applications) or a single committee to review two or more kinds of applications (e.g., on a discipline basis, such as applications for projects related to a particular health area).

43. **Streamline**

   Streamlining is a part of some reviews in which the SRG determines whether specific applications should be discussed by the group and given numerical overall impact scores. The process provides for review and critique of all applications but generally limits discussion to applications for which scientific merit and impact are judged to be among the strongest of those under consideration.

44. **Substantial Foreign Component**

   A substantial foreign component of a grant to a U.S. institution is defined as:

   - The use of grant funds to provide support to any significant scientific element or

segment of the project which is to be performed outside the U.S. either by the grantee project staff or by a researcher employed by a foreign institution.

- The use of grant funds in such a manner that it may impact on U.S. foreign policy through the involvement of grantee project staff in the affairs or environment of the foreign country.

- Any activity as described above or including the involvement of human or animal subjects whether or not grant funds are expended. (See NIH Manual Chapter 54104.)

45. **Summary Statement**

A Summary Statement is the official NIH record and transmittal document for recommendations made by an SRG to Council regarding the evaluation of the scientific and technical merit of a specific application. The Summary Statement is customarily provided to NIH program staff, the PD/PI, and reviewers of Resubmission and Renewal applications.

NIH POLICY MANUAL

4204-204C - Notification of Funding

Issuing Office: OER/OPERA/DGP (301) 435-0949

Release Date: 6/15/06

1. **Explanation of Material Transmitted:** This NIH Grants Administration Manual (NIH GAM) implements those portions of HHS Grants Policy Directive (GPD) Part 2.04 – "Pre Award – Awarding Grants" that apply to awarding grants, and rescinds NIH Manual Chapters 54808, "Procedure For Congressional Notification Of Grant Awards," 54700, "Notice of Grant Award;" 55003, "Issuance and Recording of Grant Award Obligations; "PHS GAM Part 120, "Notice of Grant Award;" OER Policy Announcement 1996-02, "Just-In-Time Procedures for FIRST Awards, Career Awards and Solicited Mechanisms"; and GMAC Policy and Procedure Announcement 2000-03, "Determination of Funding Levels for NIH Assistance Awards." Also, this NIH GAM rescinds those portions of PHS GAM Part 118, "Ranking, Approval, and Funding of Grants" that pertain to the ranking, approval and funding of grant applications. Further this NIH GAM states key policies and procedures relevant to funding NIH grants. This is the first issuance of this NIH GAM.

2. **Filing Instructions:** N/A, this is the first issuance of this NIH GAM

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This NIH Grants Administration Manual (NIH GAM) implements those portions of HHS Grants Policy Directive (GPD) Part 2.04 – "Pre Award – Awarding Grants" that apply to awarding grants, and rescinds NIH Manual Chapters 54808, "Procedure For Congressional Notification Of Grant Awards," 54700, "Notice of Grant Award;" 55003, "Issuance and Recording of Grant Award Obligations; "PHS GAM Part 120, "Notice of Grant Award;" OER Policy Announcement 1996-02, "Just-In-Time Procedures for FIRST Awards, Career Awards and Solicited Mechanisms"; and GMAC Policy and Procedure Announcement 2000-03, "Determination of Funding Levels for NIH Assistance Awards." Also, this NIH GAM rescinds those portions of PHS GAM Part 118, "Ranking, Approval, and Funding of Grants" that pertain to the ranking, approval and funding of grant applications. Further this NIH GAM states key policies and procedures relevant to funding NIH grants. This is the first issuance of this NIH GAM.

B. Background:

This NIH GAM is applicable to all new and competing continuation (a.k.a. renewal) grants, noncompeting continuation grants and cooperative agreements (hereinafter referred to as "grants") as well as revisions (a.k.a. resubmissions) and competing supplements (a.k.a. revisions). (Note as NIH transitions to a new application form—the SF424 (Research and

Related [R&R]), terminology is transitioning as well. Competing continuations are now known as renewals; revisions as resubmissions; and competing supplements as revisions.)

C. Policy:

1. ***Completing the Pre-Award Process***

   For details surrounding NIH policy on completing the Pre-Award process please see "Completing the Pre-Award Process" in the NIH Grants Policy Statement (NIHGPS, rev. 12/03).

   a. ***General Policy:*** After the initial review of an application is completed (the first level of the two-tier peer review process), the applications are reviewed for a number of other considerations, including but not limited to, as applicable, NIH's funding principles, program relevance and priorities of the proposed research, review of the project budget, and assessment of an applicant's management systems.

   As part of the pre-award process, an administrative review is conducted. Applicant(s) may be asked by NIH awarding office staff to submit additional information under the Just-in-Time (JIT) procedures (see D., "Procedures") or begin to work on other documentation that would be required prior to receiving an award.

   b. ***Eligibility:*** NIH awards are made only to eligible applicant organizations. Eligibility must be maintained in order to retain NIH grants. Generally, domestic, foreign, public, private, non-profit or for-profit organizations, and Federal organizations and agencies are eligible to receive NIH grants. When submitting a grant application to NIH, a

Federal agency and/or institution must ensure that its own authorizing legislation will allow it to receive NIH grants and be able to comply with the award terms and conditions. Typically, eligibility is determined at time of award.

c. ***Just-in-Time (JIT):*** In keeping with HHS' grants management streamlining efforts, NIH developed a pre-award streamlining mechanism called, Just-in-Time for certain NIH programs and award mechanisms. JIT procedures defer the submission of several elements of an application until after the review process and prior to funding. These elements currently include: 1) certification of an Institutional Review Board (IRB) approval of the project's proposed use of human subjects; 2) verification of Institutional Animal Care and Use Committee (IACUC) approval of the project's proposed use of live vertebrate animals; 3) evidence of compliance with the education in the protection of human research participants requirement; and, 4) information concerning other support for all individuals designated as scientifically key to the project (Senior/Key personnel). Review of other support ensures that significant levels of effort are committed to the project and that there is no scientific, budgetary, and/or commitment overlap.

d. ***Determination of Funding Levels and/or Funding Principles:*** Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Centers (IC) staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of IC priorities, constraints on the growth of average grant costs, and the availability of funds.

e. ***Cost Analysis and/or Financial Responsibility Evaluation:*** It is NIH policy that awarding offices perform an appropriate cost analysis for every grant application to be funded, with the exception of those awards that do not require detailed budget statements, e.g. modular and fellowships. The form and extent of the cost analysis will vary among mechanisms and/or projects that should be determined by the Grants Management Officer (GMO) on the basis of the comments in the Summary Statement, the amount and types of costs that are involved, the nature of the project, and past experience with the applicant organization.

In addition, it is recommended that NIH awarding offices, prior to award or within a reasonable time thereafter, conduct a financial responsibility evaluation of applicants with no prior Federal awards (e.g. Small Business Innovative Research grants) or in cases where there are known financial or management deficiencies.

f. ***Funding Strategies:*** When reductions are 25 percent or more below the Initial Review Group (IRG)-recommended level, staff will request the Principal Investigator (PI) to submit a revised statement of specific aims, a revised budget, and/or a revised timetable, as appropriate, which must be approved and countersigned by the authorized organizational representative and accepted by program and grants management staff. To ensure initial review group understanding of the modified scope of a funded project, the approved statement of revised aims should be submitted by the PI in any renewal (previously known as competing continuation) application.

Therefore, acceptance of any revised scope by program and grants management staff should be communicated back to the PI and the grantee institution. Communication can be in the form of a letter or as an IC-specific term and condition on the Notice of Grant Award NGA.

2. **Modular Applications**

Modular applications expand the existing streamlining initiatives that are designed to concentrate the focus of investigators, their respective institutions, peer reviewers, and NIH staff on the science NIH supports, rather than on the details of budgets. A typical modular application requests modules in increments of $25,000 direct costs. For the most part, requests for modules are consistent each year; however, well-justified modular increments (up to the specified ceiling) or decrements in the total direct costs for any year of the project that reflect substantial changes in expected future activities, may be requested at the time of application. In general, applications submitted using the modular format are awarded under the streamlined non-competing award process (SNAP). For additional information, please see the Modular applications/awards section in the NIHGPS: Modular Applications/Awards or to review the application process for Modular Awards in the PHS 398 application instructions at Instructions for PHS 398 . Also, for additional information on SNAP, see the NIHGPS (rev. 12/03), Streamlined Non-Competing Award Process or the PHS 2590 discussion of SNAP.

3. **Project Period**

NIH uses the project period system of funding for most grants. Under this system, projects are programmatically approved for

support in their entirety but are funded in annual increments called budget periods. For additional information regarding the project period system, please refer to NIH GAM 4204-204D, "Project Period System of Awarding Grants and Duration of Recommended Grant Support."

4. ***Ranking, Approval, and Funding***

As soon as possible after the review of an application, a priority score is assigned for each application that will receive a numerical score. In addition to receiving a priority score, many grant mechanisms receive a percentile ranking. On the basis of these scores and/or rankings, a ranking list is prepared of similar kinds of applications that have been recommended for approval. The ranking list is generated by the appropriate designated IC official(s). Many ICs have established electronic systems to accomplish these requirements.

In accordance with the PHS Act and [NIH Manual 54513](#), with the exception of those applications not requiring Council review as noted in NIH Manual 54513, each IC must present for National Advisory Council or Board ("Council") review all applications that may be considered for funding. Council consideration may take either of two forms: action on individual applications or en bloc action (this includes expedited en bloc action).

After receiving Council approval, the appropriate IC officials prepare the list to authorize payment of grant applications ("release list" or "paylist"). This list is sent to the Chief Grants Management Officer (CGMO) for approval, and bears the sender's signature showing which grant applications on the ranking list are approved for funding. ICs are to have appropriate procedures in place to

document any departure from an approved release list and/or pay list. The ranking list and the release/pay list can be accomplished via electronic systems or methods; however the system used must accommodate the documentation of GMO approval.

Funding applications out of rank order must be justified and documented in the official grant files, and approved by the appropriate official at each IC. This documentation requirement applies to those applications with a fundable score that are not funded and those applications beyond a fundable score that are funded. Applications that are recommended for approval during one review cycle, but are not funded due to limitations of available funds, and are administratively carried forward for consideration for funding during the next review cycle must compete for funding with all relevant applications recommended for approval in that review cycle. The applications from both (or several) review cycles will be integrated using appropriate statistical techniques to create a single listing on the basis of assigned scores.

No grant may be awarded except pursuant to a properly approved application. If the CGMO declines to sign an NGA, the NGA may not be issued unless signed by the Director of the IC. The rationale for the decision to override the CGMO's recommendation must be documented in the official grant file.

5. ***Notice of Grant Award (NGA)***

The NGA (also known as Notice of Award or NOA) is the legal document issued to notify the grantee that an award has been made and that funds may be requested from the designated HHS payment system or office.
   a. An NGA is prepared in accordance with this NIH GAM for 1)

each application approved for funding made by an NIH awarding office, 2) each subsequent change in the budget/project period and/or amount of support under such grant, and 3) any additional (new) terms and conditions that are to be made applicable to such grant.

b. All NGA terms and conditions will be binding until such time as they are modified by a revised NGA or other document that is signed by the GMO.

c. All NGA terms and conditions apply to no-cost extension periods during the grant; regardless if the no-cost extension is an automatic action performed by the grantee or approved by NIH.

d. An NGA shall be issued in a timely manner, unless such action is precluded by circumstances beyond control of the awarding office. All appropriate certifications and assurances must be obtained and reviewed by NIH staff prior to award. For the purposes of this NIH GAM, "issued in a timely manner" means issued as soon as possible after the funding decision has been made, and generally prior to the beginning date of the grant budget period. The legal obligation must be recorded in the NIH Accounting System, as soon as possible, in compliance with the requirements of the Antideficiency Act, 31 U.S.C. 1517(a). For additional information refer to the Procedures Section below (D.3.)"Release of NGAs."

e. If the awarding office determines that it is appropriate to limit the scope of activities that were included in an approved application, the NGA must include a special term and condition describing the limitations. Otherwise, grant funds may be expended for any purposes included in the approved application for the applicable period of support. The need to

expressly state scope limitations in the NGA also applies to a no-cost extension of an existing grant, when the awarding office wishes to limit the purposes for which funds may be expending during the extended period. For additional information, please link to the Notice of Grant Awards section in the [NIHGPS: Notice of Grant Award](#).

6. ***Congressional Notification of Award***

    HHS GPD 2.04 requires the NIH GMO to notify the Congressional Liaison Office (CLO), Office of Assistant Secretary for Legislation, of all new and competing continuation awards to domestic organizations, including competing supplements (significant, large program expansion) in order to assure that members of Congress receive prompt notification of grant awards. Generally a 72-hour waiting period is required between CLO notification and e-mailing or mailing of the NGA. Please see 'D. Procedures:" "Congressional Notification of Award," for procedures on CLO notification.

7. ***Pre-Notification ($500,000 Direct Costs) Policy***

    For all applications requesting $500,000 or more in direct costs in any budget period, NIH applicants must seek agreement from the appropriate IC Program Officials to accept applications at least 6 weeks prior to the anticipated submission. The letter, signed by an IC indicating their willingness to accept an application requesting direct costs greater than $500K, should be placed on top of and submitted with the application.
    This policy does not apply to applications submitted to NIH in response to Request for Applications or other announcements that include budgetary limits (e.g. Small Business Innovative Research grants). For additional information, please link to the Pre-notification policy in the [NIHGPS](#), Rev. 12/03: Types of Funding Opportunities.

8. ***HHS Payment Systems***

HHS grant payments to domestic grantee institutions are paid through the Payment Management System (PMS) by one of several advance payment methods, including SMARTLINK II/ACH, CASHLINE/ACH, or cash request, or by cash request on a reimbursement basis, as specified in the NGA. Payments under NIH grants generally are made as advance payments. Although grants may be financed by advance payments, the intent is that grantees draw funds on an as-needed basis, no more than three days before the funds are needed. For additional information, please link to HHS Payment Section in the NIHGPS, Rev. 12/03: HHS Payment Systems.

Payments to foreign grantees are made quarterly and administered by the Office of Financial Management, NIH. For additional information, please link to "Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components.

9. ***Carryover of Unobligated Balances***

NIH grants policy allows grantees to automatically carryover unobligated balances from one budget period to the next for all grants except centers (P50, P60, P30, and others), cooperative agreements (Us), Kirschstein-NRSA training grants, non-Fast Track Phase I SBIR/STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NGA indicates otherwise. For those mechanisms listed above, carryover of unobligated balances may be carried forward to a subsequent budget period and will always require prior approval from NIH unless that requirement is waived by a term or condition of the NGA.

Grantees that do not have automatic carryover authority are required to submit a written request countersigned by an authorized organizational representative to the awarding office GMO. The request should include a scientific justification and a plan for the use of funds. Grantees should allocate the requested carryover to the appropriate budget categories, including F&A costs, if applicable. When reviewing requests, NIH staff should determine if the funds are available, if the request duplicates funding already provided, if the request signifies program expansion, and if approval will generate a recurring cost in the future years. If the request is approved, the current year NGA is revised by the awarding office to reflect the approval of the carryover request.

Availability of carryover funds is determined by (1) comparing the requested carryover amount to the unobligated balance listed on the prior year FSR and (2) checking all award actions subsequent to the FSR acceptance date for previously used offsets and carryovers. An FSR that has been accepted by the Office of Financial Management is used in the determination of availability of funds.

Grantees may submit carryover requests via e-mail. Refer to NIHGPS rev. 12/03, "[Requests for Prior Approval]."

10. ***Large Unobligated Balances and Grant Award Adjustments***

NIH grants policy requires grantees to address, in the PHS 2590 Progress Report, whether they anticipate an estimated unobligated balance (including prior year carryover) that is greater than 25 percent of the current year's budget. The 25 percent threshold is used as a monitoring tool by grants management and program staff

to determine whether significant changes have occurred or will occur in the project. The GMO may request additional information, including a revised budget, from the grantee to: 1) determine if the project requires closer monitoring; 2) evaluate the project's need for continued funding; and 3) assess whether adjustments need to be made to the current year noncompeting continuation award. For additional information, please link to the [PHS 2590 application](#).

D. Procedures:

1. *1. Pre-Award*
    a. *Just-in-Time*
        1. **eRA Commons Submission:** eRA Commons-registered grantee institutions have the ability to electronically submit the four Just-in-Time (JIT) data elements:
            - IRB Approval Date (when applicable);
            - IACUC Approval Date (when applicable);
            - Human Subjects Education Requirements (when applicable); and
            - Other Support.

            At this time, it is a one-time only submission; i.e., grantees must have all of the applicable data elements ready before they "submit." Revisions to the data must be submitted directly to the IC through other means of communication. Currently, this feature is available for any competing grant record that has a percentile score of 30 percent or better. For grants that are only assigned a priority score, the system allows a submission for applications with a priority score of 300 or better. However, the Commons user is

instructed to use this feature only if the information is requested by the IC.

2. **Other (non-Commons) Submission:** For those records where submission through the Commons is not available, submission can be made directly to the IC via e-mail, fax, or hard copy mail.

3. **Just-In-Time eRA Centralized Notification:** The request for JIT information is a standard notice sent to grantees regardless of the IC's pay line. Notifications are automatically generated and e-mailed by the eRA System for application with a percentile of 20 or better. ICs should not duplicate this notification but rather fill the void and generate notifications for anything not covered by the centralized mailer. This notice is **not** a Notice of Grant Award nor should it be construed as an indicator of possible award. NIH ICs have varying pay lines and funding strategies that determine which application will be funded.

Follow-up notifications may be necessary and are handled by the IC. The notifications should be timely so that applicants have sufficient time to respond and outline which specific information remains outstanding as well as a paragraph directing them to the website where JIT information is posted: http://grants.nih.gov/grants/peer/jit.pdf .

When preparing a notification to the grantee, the topics that need not be addressed can be deleted, leaving only the relevant data elements in the request.

b. ***Determination of Funding Levels and/or Funding Principles:*** Refer to Appendix 1, Procedures for Determination of Funding Levels for NIH Assistance Awards.

c. ***Cost Analysis/Financial Responsibility Evaluation:*** When performing a cost analysis on a grant, the GMO and/or Grants Management Specialist (GMS) should review all budget information for reasonableness, necessity, allowability, and allocability; verify the accuracy of the figures provided in the budget; and confirm that appropriate justification has been provided for all costs, as applicable. (Refer to Appendix 2 below, Guide Information for Conducting Cost Analysis).

GMOs should consider performing a financial responsibility evaluation on applications from prospective grantees with no prior Federal awards, inexperienced grantees, grantees known to be experiencing operational and/or financial difficulties, and on any application from an organization that is placed on the HHS Alert List or is otherwise subject to special terms and conditions in accordance with 45 CFR Part 74.14. A financial responsibility evaluation should include, at a minimum, the following:

- A review of the financial statements for the most recently completed fiscal year and other pertinent financial information as needed, e.g., Dun & Bradstreet Report, to determine if the organization has adequate financial resources to meet its fiscal responsibilities during the period of the federal award.
- A review of the accounting system to determine if it is adequate to properly segregate and accumulate expenditures by project.

- A review of the management structure to determine if the organization has appropriate internal controls to adequately safeguard federal funds and assets.

The following websites are provided to assist the GMO/GMS when a financial responsibility evaluation is involved:

1) [Request for Financial Advisory Services Form](). This form is used to request the DFAS/OAMP to conduct an Accounting System Review, Financial Capability Review, Cost Analysis or Other Financial Review; and,

2) [Grants Management Risk Assessment Form](). This risk assessment form is designed primarily for new NIH grantees that have limited or no experience with NIH grants (especially those participating in the SBIR/STTR programs). It is intended to assist the GMS in assessing financial information.

2. *Project Period:* For detailed instructions on procedures concerning "Project Periods" please refer to NIH GAM 4204.204D, "Project Period System of Awarding Grants and Duration of Recommended Grant Support," section G., "Procedures."
3. *Notice of Grant Award (NGA)*
    a. *Standard and/or Special Award Conditions Procedures:*
        0. An NGA is issued with standard and sometimes special terms and conditions of award. NIH NGAs cite a number of standard terms and conditions:
            - The grant program legislation and program regulation cited in this Notice of Grant Award;

- The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award;
- 45 CFR Part 74 or 45 CFR Part 92 as applicable;
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period; and
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.
- (See OER web page for certain references cited above.)

1. For awards that are issued with special terms and conditions of award for an individual or a class of awards the following applies:
   - If the special terms and conditions constitute a class deviation from standard NIH/HHS grants policy, the proposed deviation must receive prior approval by the Director of the Office of Policy for Extramural Research Administration (OPERA). If the special terms and conditions constitute a single-case deviation from standard NIH/HHS grants policy, the CGMO must notify the Director of OPERA of the decision.
   - The NGA should not contain lengthy conditions designed to amend or clarify substantive matters improperly or inadequately addressed in the applicant's proposal. Such matters

should be amended through negotiation prior to approval and award. These matters should be documented either through correspondence referencing applicable portions of the proposal or by a revised proposal.

- When the terms and conditions include a specific action that is required of the grantee by a set date, the condition should be coupled with instructions on how to complete the action.

  Whenever special and/or more restrictive terms of awards are imposed, the awarding office must follow up, as appropriate, on grantee performance to determine compliance. The scope of actions taken by the IC may include a recommendation that the special terms be removed if the stated requirements have been satisfactorily met, or that appropriate action be taken if there is evidence of non-compliance. The removal of special terms of award that are imposed on grantees must be communicated in writing by the GMO. This is typically accomplished via a revised NGA.

b. *Issuance of NGAs:* Once the appropriate GMO has certified that, in his/her opinion, the official grant file is complete and is in accordance with all of the applicable requirements, an NGA is issued. All NIH awards are generated by the appropriate awarding office through the eRA IMPACII system. Most applicant organizations are now "e-mail enabled" allowing receipt of NGAs via the electronic mail

system (e-mail).

Once the GMO/CGMO releases an award in the eRA IMPACII System, it certifies the information in the system is correct. The NIH electronic "sign-off" of NGAs can be used in lieu of the GMO/CGMO physically signing a paper copy of the actual NGA.

When an award is issued, an e-mail version of the NGA is sent not only to the grantee institution but also to the NIH awarding office.

In addition, all NGAs are stored in the eRA system in the Grant Folder. The NGAs are accessible to NIH staff through a variety of eRA systems and to grantee staff through the NIH Commons.

Occasionally, NGAs are issued to grantee institutions that are not e-mail enabled. In those cases, Division of Extramural Support (DEAS) staff will mail a paper NGA to the grantee. Even in these cases, the NGA is still e-mailed to the IC and stored in the Grant Folder.

When an award is revised, it should restate or include all previous terms and conditions that still apply to the revised award so that the revised award can stand alone.

c. *Release of NGAs:* Any award released in the eRA IMPACII System is automatically "bridged" into the NIH Accounting System the same day the award is released. Grants Management staff have until 5:00 p.m. on the day of release to "stop release," if necessary. After 5:00 p.m. on the day of

release, the funds are released into the accounting system and flow to the Payment Management System (PMS). This process gives grantees access to the funds. A grantee indicates acceptance of an NIH award and its associated terms and conditions by drawing down on the funds from PMS.

d. ***Congressional Notification of Award:*** At NIH, this procedure is accomplished automatically and electronically through the eRA IMPACII system. As a result, data on applicable awards flows from the eRA System directly to the Congressional Liaison Office (CLO), Office of the Assistant Secretary for Legislation, HHS. Foreign grants, awards to individuals, Kirschstein-National Research Service Awards individual fellowships, and Research Career Awards are excluded from this process. HHS Policy requires that NIH notify the CLO of these actions in order for HHS to keep the Members of Congress informed as to the HHS activities in their respective districts.

The eRA IMPAC II system is programmed to automatically gather the appropriate information and transmit it electronically to the CLO. The automated system centralized the CLO process for all of NIH; therefore, each IC no longer handles this task independently. The eRA IMPAC II system places an automatic 3-day hold on all new and competing awards. When an award is officially "released" in the system, the actual "issue date" is set for 3-days from that release date. This allows the required 72-hours for CLO notification.

NIH Grants Management staff has until 5:00 p.m. on the day of release to "Stop Release", if necessary. Meanwhile, after

5:00 p.m. on the day of release, the system generates a consolidated report including all grants meeting the CLO notification criteria. This information is transmitted electronically from the eRA system to a server at HHS. The CLO is then responsible for any further distribution; i.e., they sort the information received from the various other agencies and distribute those reports to the appropriate congressional individuals.

The data that is transmitted is as follows: Awarding Office, Grant Number, Name of Grantee, Grantee Address, Grantee Phone number, Congressional District, Name of PI, Project Title, CFDA Number, Amount of Award, Date Issued, Type of Award, Type of Action, e.g., new (Type 1) or competing continuation (Type 2), Type of Financial Assistance, Grant Project Period, Grant Budget Period, NIH/IC Grants Office Contact (assigned GMO), and the NIH/IC Grants Office phone number.

The CLO can authorize exceptions to the 72-hour waiting period. For example, at the end of the fiscal year, the CLO may allow a shorter waiting period for award in accordance with a previous arrangement with the awarding office.

The CLO is responsible for establishing the content of the required notification, the transmission procedures, as well as the means to acknowledge receipt.

e. ***Pre-Notification of Funding ($500,000 Direct Costs Awards):*** Beginning in April 2001, a new HHS pre-notification procedure was implemented. Weekly, ICs are required to submit to the Office for Extramural Research

(OER), NIH a spreadsheet indicating new and competing grants with direct costs in excess of $500,000 or more for the initial year of funding, that each IC expects to award within in the next two weeks.

The pre-notification spreadsheet contains the following data items: Proposed Notification Date, OPDIV, Organization Receiving Award, City, State, Congressional District, Project/Grant Title, First year Award Amount (Total Costs), OPDIV Contact Name, OPDIV Contact Phone, Expressed Special Interest (earmarks, presidential initiative, etc). The list is submitted to OER at least two-weeks prior to funding. The list is consolidated by OER and submitted to the Department (Office of the Secretary/Immediate Office).

This pre-notification procedure in no way modifies the CLO Notification process established in HHS policy. (*Please refer to D.4. above*).

Once an award is placed on the pre-notification list, it cannot be released in the eRA IMPACII system for two weeks unless the IC is otherwise notified.

E. References:

1. [HHS GPD Part 2.04: Pre-Award – Awarding Grants](#)
2. [NIH Grants Policy Statement](#) (rev. 12/2003)
3. NIH Grants Administration Manual, GAM 4104-204, [Responsibilities of NIH Grants Administration Staff](#)
4. [NIH Manual Chapter 55010](#) - Co-Funding Assistance Awards
5. [NIH Manual Chapter 54502](#) - Notification To Unsuccessful

Applicants And Inactivation Of Favorably Recommended But Unfunded Applications

6. [NIH Manual Chapter 54519](#) – Scientific, Budgetary, and Commitment Overlap

7. [NIH Manual Chapter 55808](#) – Establishment and Documentation of Files and Other Records Including Monitoring Actions, for NIH Grant Programs

8. NIH Delegations of Authority: [Program: Grants and Awards 01](#), Grants-in-Aid (Note: this link takes you to an NIH login screen. To access the NIH Delegations of Authority Database, you will be prompted to login using your NIH User Name and Password.)

9. [Division of Extramural Activities Support (DEAS) Standard Operating Procedures](#) (SOPs)

F. Definitions:

1. ***Automatic Carryover:*** An authority delegated to the grantee, under expanded authorities, to move unobligated balances remaining at the end of a budget period to a subsequent budget period, which increases the authorized expenditures. If the grantee does not have automatic carryover authority, the NGA will state so.

2. ***Carryover Balance:*** Unobligated funds remaining from a previous funding period and moved to a subsequent budget period for expenditure.

3. ***Unobligated Balance:*** This NIH GAM uses the term "unobligated balance" in the framework of the total Federal funds authorized for a budget period (direct and F&A costs), according to the NGA. In that context, the "unobligated balance" is the portion of the total Federal authorization which was not obligated and/or expended by the grantee during the stated budget period.

G. Responsibilities:

1. ***Grants Management:***

    The CGMOs/GMOs complete an electronic approval process in the eRA System which certifies that the award(s) is consistent with applicable statutes, regulations, and policies, including, the award instrument selected; the applicant organization has (or is expected to have) adequate business management capability to administer the award; and the award terms and conditions are appropriate for that program and/or type of recipient and for monitoring award terms and conditions. The CGMOs/GMOs are also responsible for ensuring that the HHS Alert List and the List of Parties Excluded from Federal Procurement and Nonprocurement Programs have been consulted prior to making an award.

    The GMO/GMS is responsible for performing budget reviews and cost analyses in order to determine whether the requested costs meet the four tests of allowability, reasonableness (including necessity), allocability, consistency, and conformance to the applicable cost principles and/or terms and conditions of award.

    The GMO/GMS may request the applicant to submit additional information such as other support or verification of an IACUC review. In addition, the GMO/GMS may ask the applicant to undertake certain activities, i.e., the negotiation of an F&A cost rate in anticipation of an award. Such requests by the Grants Management Office do not guarantee that an award will be made. Following a review of all applicable information, grants management and program staff will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

The GMO/GMS is responsible for issuing the Notice of Grant Award once all of the pre-award responsibilities have been satisfied. Only someone with appropriately delegated GMO signature authority and with the GMO role in the IMPAC II system has the authority to officially "sign-off" on the NGA.

Based on budgetary adjustments to the project, ICs will decide whether a new statement of specific aims is required.

The GMO will also assist in the development of Funding Opportunity Announcements (FOAs) (also known as Program Announcements (PAs) and Requests for Applications (RFAs), and must review and clear, in accordance with the IC's approval process, before publication and/or issuance. If the GMO has concerns that are not resolved, the announcement may not be issued unless the IC Director approves.

2. **_Program Official (POs):_**

   The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants.

   The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with Center for Scientific Review (CSR)/IC Scientific Review Administrator; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO.

   Responsibilities specified in this section are generally performed by the designated PO, but could be performed by others within a specific program office. If the function is to be performed by an

individual other than the designated PO, the GMO should be notified in writing, of the responsible individual's name and position.

POs have primary responsibility for defining programmatic objectives; detailing them in program announcements, including how applications will be evaluated for their similarity with those objectives; providing advice on the scientific, technical, and/or programmatic suitability of applications for funding (preceding, as part of, or following peer review); and providing their particular expertise in the post-award administration of projects and activities for which they have responsibility. An important role of the PO is to complement the business management knowledge of GMOs with their scientific and technical expertise. The PO serves as a counterpart to the Principal Investigator or Program Director of the applicant/recipient organization.

The PO is also responsible for initiating the development of FOAs. A draft FOA is circulated through and reviewed by the appropriate scientific program director, the IC's Referral Officer, and Grants Management. The draft is finalized based on comments provided and the IC Referral Officer will initiate the process required to have the document published in the NIH Guide for Grants and Contracts and Grants.gov. Program officials attend and serve as a resource at review meetings.

The PO's defined role can only be carried out in a responsible manner based on effective communication and interaction with grants management officials.

3. ***Division of Extramural Activities Support (DEAS), Office of Extramural Research (OER):*** Extramural support services are located under the Division of Extramural Activities Support (DEAS),

Office of Administrative Operations (OAO), OER.

DEAS is responsible for providing extramural support services to internal customers within the NIH ICs following Standard Operating Procedures and in accordance with the Performance Work Statement (PWS) under the Extramural Activities Support Most Efficient Organization.

4. ***Congressional Liaison Office (CLO), Office of the Assistant Secretary for Legislation, OS/HHS:*** The HHS office that electronically receives notification of all new and competing awards issued by NIH, as well as other HHS agencies.

For additional information see NIH GAM 4104-204, "[Responsibilities of NIH Grants Administration Staff](#)."

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this NIH GAM must be retained and disposed of under the authority of NIH Manual [1743](#),"Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule,' Section 4000 covers NIH Grants and Awards and Section 1100-G covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific instructions.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since

most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

The purpose of this manual issuance is to implement those portions of Grants Policy Directive (GPD) 2.04, Notification of Funding (Awarding Grants).

1. ***Office Responsible for Reviewing Management Controls Relative to this NIH GAM:*** The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

2. ***Frequency of Review:*** The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. GAMs and manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

3. ***Method of Review:*** OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and deter mine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-

Institute review in order to determine NIH-wide compliance.

4. ***Review Reports are sent to:*** The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officer(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

Appendix 1:

Procedures for Determination of Funding Level for NIH Assistance Awards

The steps involved in arriving at the appropriate funding level are peer review, grants management cost analysis or financial responsibility evaluation, and programmatic judgment and adjustments. The attached procedures are not all-inclusive but simply are intended to serve as a guide in the determination of funding levels.

1. ***Peer Review:***
   a. Initial Review Group (IRG) Review: The first level of the dual peer review process primarily involves the evaluation of the scientific merit of grant applications by an initial review group. In addition to scientific merit, the IRG considers the reasonableness and adequacy of justification of the proposed budget and duration of support for each application.
   b. Council Review: The National Advisory Council or Board considers the scientific merit of applications, evaluates program relevance and priorities, and advises IC staff on policy issues. The Council may endorse the IRG review or

make its own recommendations about the priority and/or funding level of applications.

2. ***Grants Management Review:*** The Grants Management Officer (GMO) has the responsibility for determining the form and extent of the cost analysis or financial responsibility evaluation to be performed based on the comments of the application reviewers, the amount and types of costs proposed, the nature of the project, and past experience with the applicant organization. The Grants Management Specialist (GMS), on behalf of the GMO, will evaluate those grant applications with a likelihood of funding to determine the appropriate type of cost analysis review and will perform that analysis prior to award. In view of the substantial number of grants awarded by each IC, it is recognized that in-depth cost analysis is not feasible or necessary on all awards.

Reflected below is a two-tiered approach to grants management review -- cost analysis and financial responsibility evaluation. Appendix 2 provides guidelines for conducting a basic cost analysis review that will assist in determining whether a comprehensive cost analysis is required; whether certain costs should be included in the award; and the ultimate funding level of the award.

If concerns are generated in the course of a basic cost analysis review, a greater degree of analysis may be merited. If the concerns are not resolved in the course of a more comprehensive review, a financial responsibility evaluation may be necessary.

   a. Cost Analysis: Cost analysis entails a review of all categorical budget information for reasonableness, necessity, allowability, and allocability; verification of the accuracy of the figures provided in the budget; and confirmation that appropriate justification has been provided

for all costs. (See Appendix 2 for guidelines on the factors to be considered and reviewed.)

b. Financial Responsibility Evaluation: GMOs should consider performing this level of review on applications from prospective grantees with no prior Government awards, inexperienced grantees, grantees known to be experiencing operational and/or financial difficulties, and on any application from an organization that is placed on the HHS Alert List or is otherwise subject to special terms and conditions of award in accordance with 45 CFR 74.14.

If outside assistance or expertise is deemed necessary for the review of a particular application, resources available include the Office of Management Assessment, NIH, the Division of Financial Advisory Services, Office of Acquisition Management and Policy, NIH and the HHS Office of the Inspector General.

3. **Program Review:** For the purposes of this NIH GAM, the program official evaluates the scientific aspects of each project to assure that the application reflects project needs and program priorities, considering such information as the specific aims, progress achieved (if applicable), long-term goals, and program relevance. The program official also evaluates and reviews information such as other support to ensure sufficient levels of effort are committed to the project and to identify possible scientific and/or budgetary overlap and other factors that may affect the budget recommendation and funding level. Program officials also have the option to recommend restoration of funds or years removed by the IRG or Council subject to individual IC policies and procedures and the considerations noted above.

Programmatic adjustments must be consistent with the IC plan for the current fiscal year that specifies the general rationale and methodology for adjustments based on programmatic considerations. Programmatic adjustments, whenever possible, should represent specific reductions based on the science to be supported. The overall availability of funds and the previous level of support may also be considered. IC staff is encouraged to consult with the principal investigator (PI) and the authorized organizational representative before making budget adjustments other than those due to allocability, allowability, and reasonableness.

4. ***Negotiation of the Funding Level:*** The Grants Management Officer or his/her designee is responsible for negotiating the final budget with the applicant institution. The negotiation shall be closely coordinated with program staff when budget adjustments from the recommended level are due to programmatic aspects of the project.

Based on budgetary adjustments to the project, IC staff will decide whether a new statement of specific aims is required. When reductions are 25 percent or more below the IRG-recommended level, staff will obtain from the PI a revised statement of specific aims, a revised budget, and/or a revised timetable, as appropriate, which must be approved and countersigned by the authorized organizational representative and accepted by program and grants management staff. To ensure initial review group understanding of the modified scope of a funded project, the approved statement of revised aims should be submitted by the PI in any competing continuation application. Therefore, acceptance of any revised scope by program and grants management staff should be communicated back to the PI and the grantee institution.

The GMO/GMS also evaluates and reviews other support information to determine if there is any commitment and/or budgetary overlap. Any overlap issues will be resolved by the IC with the applicant and PI at the time of award.

5. ***File Documentation:*** Any reductions below the requested budgetary level must be documented in the IC's official grant and program information files. In general, the summary statement will suffice for initial review group budgetary recommendations. Any special Council actions must also be reflected in the grant file. Adjustments based on allocability, allowability, or reasonableness and programmatic adjustments should be specifically identified and documented. Programmatic adjustments should be based on the IC plan that specifies the general rationale and methodology for adjustments based on programmatic considerations. This plan is to be available as part of the IC program information file.

If a revised statement of specific aims, budget, and/or timetable was submitted or requested, these should appear in the official grant file.

Appendix 2:

Guide Information for Conducting Cost Analysis

This appendix is intended to serve as a guide to conducting a cost analysis and should not be considered all-inclusive. It is intended as a supplement to, not to take the place of, the [NIH Grants Policy Statement](#), other HHS and NIH policies, and the applicable cost principles.

Appearing below is a series of factors/questions to be considered during the grants management review of the application. The factors/questions are intended to assist in determining whether a comprehensive cost

analysis is required; whether certain costs should be included in the award; and the ultimate funding level of the award.

Due to NIH reinvention initiatives that have been pilot-tested to streamline extramural programs, in some cases certain components of these guidelines may not apply or special staff guidance for the review of applications may have been provided. For example, for certain grant activities NIH has predetermined the direct cost award amount, thus minimizing the need for cost analysis. Nonetheless, NIH staff is still responsible for ensuring that grants are awarded at the most economical level compatible with the approved project.

A. **Direct Cost Analysis:** Cost analysis entails a review of all categorical budget information for reasonableness, necessity, allowability, allocability and conformance with the applicable cost principles and/or terms and conditions of award; verification of the accuracy of the figures provided in the budget; and confirmation that appropriate justification has been provided for all costs. In addition, special attention should be given to the costs and justification for the following items.

1. *Personnel:*
   a. Are all individuals listed under the personnel section employees of the applicant organization? Employees of other organizations should not be included under personnel but rather under consultants, other expenses, or consortium/contractual costs.
   b. Is the total compensation (salary, fringe benefits, and/or tuition remission) reasonable for each of the positions proposed, based on the work being performed and the level of effort proposed? Salary and other forms of compensation must be based on a

formal and consistently applied institutional salary structure.

    c. Are any requested salaries in excess of the salary cap limitation? If so, a reduction must be made to the level of salary and fringe benefits to be awarded for the current year and calculated for future year commitments.

    d. Is there a request for administrative and/or clerical staff? If the applicant is an educational institution, does the request and justification satisfy the OMB Circular A-21 requirements for direct charging of these costs?

    e. Are fringe benefits based on the current rate agreement for each position?

    f. If there is overlap of effort or salary support with other projects (see other support {section D} below), the overlap must be resolved prior to award.

2. **Consultants:** Are costs clearly defined, representing reasonable compensation, and consistent with the applicant institution's policies for consultants?

3. *Equipment:*

    a. Is the requested equipment already available for the project? If so, has the need for duplicate or similar items been justified?

    b. Has adequate justification been provided? It may be necessary for the applicant to provide a price quote for a substantial equipment purchase.

    c. Has general purpose equipment been justified as directly allocable to and necessary for the grant?

4. *Supplies:*

    a. Have a sufficient cost breakdown and justification for

animal costs been provided?

    b. Are supplies requested that are typically charged indirectly? If so, is the request consistent with the applicant organization's indirect cost agreement? Does the organization have a method for accounting for these costs as a direct charge?

5. *Travel:*

    a. Are the travel costs proposed reasonable (a generally acceptable rate may vary based on IC practice), taking into consideration the origination and destination points? If so, has the amount been justified and is it in accordance with the applicant organization's travel policies?

    b. Is the proposed meeting travel appropriately justified and allocable to the project?

6. ***Patient Care Costs*** (see also NIH Grants Policy Statement, Section III, [Research Patient Care Costs](#).

    a. Is a cost breakdown provided (e.g., number of patient days, estimated cost per day, cost per test/treatment)?

    b. Are the requested costs for research care rather than for standard care? If costs for standard care are requested, a justification for the exception must be provided.

    c. Are costs included in this category that should appear elsewhere in the budget (e.g., consultant physician fees, patient travel, per diem, and donor fees)?

    d. Are requested costs $100,000 or greater? If so, verify that there is an HHS-negotiated research patient care agreement. If there is no patient care rate agreement for grantees that expect to incur $100,000 or more in

research patient care costs, then require the awardee to negotiate a rate with the Division of Cost Allocation.

7. ***Alterations and Renovations (A&R):***

   a. Is a basis for cost calculation and adequate justification provided? If not included, the applicant must provide a breakdown of costs.

   b. If A&R costs are in excess of certain dollar thresholds, further limitations apply and additional documentation is required as detailed in the NIH [Grants Policy Statement](#).

8. ***Consortium/Contractual Costs:***

   a. Does the consortium/contractual cost request represent a significant proportion of the research (i.e., the percentage of research support or research activity proposed meets or exceeds that of the parent institution)? If so, has an adequate explanation been provided as to why the applicant organization is the appropriate grantee?

   b. Have a budget and, budget justification been provided?

   c. Verify that the current and correct facilities and administrative cost rate(s) and base(s) have been used. Review the performance sites to ascertain the correct rate (on-site and/or off-site) to be used.

9. ***Other Expenses:***

   a. Are items requested that are normally charged indirectly (e.g., books and journals, dues, rent, space charges, departmental expenses)? If so, is the request consistent with the applicant organization's facilities and administrative cost agreement? Does the organization have a method for accounting for these

costs as a direct charge?

      b. Is a maintenance contract requested for equipment shared by multiple grants or where a warranty is in effect?

B. **Facilities and Administrative Costs:** Verify that the current and correct facilities and administrative rate(s) and base(s) have been used. Review the performance sites to ascertain the correct rate (on-site and/or off-site) to be used.

C. **Future Year Budgets:** Review and verify the accuracy of future year budget estimates. Are any unusual increases or decreases in future years explained and/or justified? Future year escalation may be limited to a standard allowance and/or percentage for recurring direct costs, pursuant to NIH practice.

D. **Other Support:** Other support information is required for all senior/key personnel. Review other support information to identify possible changes since submission and overlap in the budget or levels of effort of personnel. Resolution of scientific, budgetary, and/or commitment overlap, which may include a budgetary reduction, should occur prior to award.

E. **Correspondence**: Review correspondence for any communication with the applicant and/or grantee that could affect the current budget request or award.

F. **Competitive Renewals:** Competitive renewals should also be reviewed as described in A-E above. The following steps are also necessary.

    1. Review previous salary, fringe benefits, and percents of effort for changes since the prior award. Are increases based on existing salary and fringe benefit agreements? Are changes in salary, fringe benefits, and effort reasonable and necessary?

    2. Review previous NGAs to identify any restricted funds or

other restrictions that may have a bearing on the current application/award.

3. Review the Financial Status Report(s) and other financial reports for a history of unexpended balances, large carryover balances, or unusual expenditure patterns, and to verify status of previously restricted funds. Significant unobligated balances may be considered in determining the future funding level, as they may be an indication of previous over funding.

4. Review prior grants management worksheets or comparable file documentation for issues requiring attention and follow-up.

G. **Noncompetitive Renewals:** Budgets included in the noncompetitive renewals and/or progress reports may or may not require a cost analysis review, depending on the type of award, funding level, and other factors as determined by the grants management specialist. If a cost analysis is performed, the file should be documented accordingly. If it is determined that a cost analysis review is not required in the noncompeting year, the following components of the application should nonetheless be reviewed, as well as F&A costs, other support, and correspondence (see B, D, and E above).

The NIH has implemented the Streamlined Noncompeting Award Process (SNAP) and the Modular award process for selected award mechanisms. Under SNAP and Modular practices, grantees may omit certain materials as defined in the respective procedures. Review of omitted portions will not be necessary unless concern merits requesting additional information in order to evaluate the project for continued funding.

1. Compare the categorical budget requested with the

recommended level of funding as shown on the Notice of Grant Award to determine any changes in personnel, salary levels, fringe benefits, percents of effort, consultants, large equipment purchases not originally requested and recommended, alterations and renovations, and patient care costs.

2. If there was a To-Be-Named position(s) included in the previous budget and award, has the position been filled?

3. Review the application for any changes in research involving human subjects and/or vertebrate animals.

4. Review the progress report, as well as the program official's written comments on the progress, for remarks pertaining to the budget not found elsewhere in the application.

5. Review previous NGAs to identify any restricted funds or other restrictions and inquire about the use of the restricted funds to ensure the grantee's compliance. Document the file accordingly.

6. Review the Financial Status Report(s) and other financial reports for a history of unexpended balances, large carryover balances, or unusual expenditure patterns, and to verify status of previously restricted funds. Significant unobligated balances may be considered in determining the future funding level, as they may be an indication of previous over funding.

If concerns are generated in the course of a basic cost analysis review, a greater degree of analysis may be merited.

NIH POLICY MANUAL

4204-204D - Project Period System of Awarding Grants and Duration of Recommended Grant Support

Issuing Office: OER/OPERA/DGP, 301-435-0949

Release Date: 6/15/06

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1. **Explanation of Material Transmitted:** The purpose of this NIH Grants Administration Manual (NIH GAM) is to implement HHS Grants Policy Directive (HHS GPD) Part 2.04, Pre-Award – Awarding Grants" as it relates to grant project periods, and to rescind the PHS Grants Administration Manual (PHS GAM) Part 122 "The Project Period System of Obligating Funds," NIH Manual Chapters 54802, "Extension of Project Period" and 54809, "Duration of Recommended Grant Support," and OER Policy Announcement 1996-05, Authority for Multiyear Funding of NIH Financial Assistance Awards.

2. **Filing Instructions:** N/A, this is the first issuance of this NIH GAM.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

The purpose of this NIH Grants Administration Manual (NIH GAM) is to implement HHS Grants Policy Directive (HHS GPD) Part 2.04, Pre-Award – Awarding Grants" as it relates to grant project periods, and to rescind the PHS Grants Administration Manual (PHS GAM) Part 122 "The Project Period System of Obligating Funds," NIH Manual Chapters 54802, "Extension of Project Period" and 54809, "Duration of Recommended Grant Support," and OER Policy Announcement 1996-05, Authority for Multiyear Funding of NIH Financial Assistance Awards.

B. Background:

This section of the NIH GAM is in accordance with the Federal budgetary and appropriations process, congressional intent, and Department policy which states that most projects that are funded by grants will require more than one year to complete and must be funded in annual increments.

Under the Project Period System of funding grants, projects that will continue for more than one year may be programmatically approved for support in their entirety, or a portion thereof, but funded in annual increments called "budget periods." This system preserves the principles of funding grants on an annual basis, while simultaneously providing the grantee with a statement of intent on behalf of NIH to continue funding the project for the remainder of the approved project period subject to the certain conditions. This system permits both the grantee and NIH (1) to make long range budgetary projections and thereby provides security and stability to each in planning and program execution, and (2) reduces administrative procedures for both the grantee and grantor by obviating the need for an annual, in-depth, formal competitive review.

C. Policy:

All NIH grants and cooperative agreements shall be funded in accordance with the Project Period System as described in this NIH GAM, except to the extent restricted by legislation or regulations. This policy applies to all NIH grants and cooperative

agreements (hereafter referred to as "grants") with the exception of construction grants.

Under the Project Period System, projects are programmatically approved for support in their entirety. The length of an initial competitive segment or of any subsequent competitive segment is determined by the NIH Institute or Center (IC) on the basis of any statutory or regulatory requirements, the length of time requested by the applicant to complete the project, any limitation on the length of the competitive segment recommended by the peer reviewers of the IC's Advisory Council, the IC's programmatic determination of the frequency of peer review, and the NIH funding principles. The competitive segment is funded in annual increments called budget periods. The total project period consists of the initial competitive segment, additional competitive segment(s) authorized by a competing continuation award(s), and any noncompeting extensions. HHS/NIH policy limits each competitive segment to a maximum of 5 years, exclusive of noncompeting extensions. Exceptions to the five-year limitation may be specifically permitted by legislation or regulation, or when a Chief Grants Management Officer (GMO) pursues a deviation from this policy according to OER (Office of Extramural Research) Policy Announcement 1997-02, "Single-Case Deviation from PHS/NIH Grants Policy."

HHS discretionary grants and cooperative agreements generally are funded from annual appropriations. The funds for grants to be awarded from an annual appropriation must be obligated by the awarding office before the expiration (currently September 30) of the fiscal year for which the funds were appropriated. The recipient is not subject to the Federal fiscal year period to obligate or spend funds awarded (i.e., the awarding office, not the recipient, is subject to the requirement to obligate funds by September 30 of the fiscal year for which they were appropriated) but rather they must expend funds in accordance with the terms of the award.

There must be a bona fide need for the funds at the time the awarding office makes the award. An awarding office should not obligate funds for a grant in a current budget period for unknown or contingent activities of the recipient in the current or a future budget period. The IC awarding office must have an expectation that the funds will be

used for the recipient's current year costs and needs, and an assurance that the funds are awarded in previous years have been largely utilized and so are not available to support activity in the current year.

1. ***Notice of Grant Award (NGA):*** An NGA that documents approval of a competitive segment that extends beyond the initial budget period expresses NIH's intention to provide continued financial support to the project. The recommended amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, grantee compliance with the terms of award, and the continued best interests of the NIH. However, there are no guarantees by NIH that the project will be funded or will be funded at those levels. The inclusion of recommended levels on an NGA is not a legal obligation to provide funding beyond the expiration date of the current budget period.

   For example, if a large unobligated balance exists from a prior year(s) and there is no good reason to continue funding the grant at the projected funding level, the IC may make a determination to adjust the funding level for the current fiscal year award and/or subsequent years of support.

   Withholding of a noncompeting continuation grant within a previously approved competitive segment may be justifiable if:
   o a grantee is delinquent in submitting required reports;
   o adequate Federal funds are not available to support the project;
   o a grantee fails to show satisfactory progress in achieving the objectives of the project or otherwise fails to meet the terms and conditions of the award;
   o a grantee's management practices fail to provide adequate stewardship of Federal funds, or
   o any reason which would indicate that continued funding would not be in

the best interests of the NIH.

If a non-competing continuation award is denied (withheld) because the grantee failed to comply with the terms and conditions of a previous award, the grantee may appeal that determination. Details on appeal rights are located at [HHS GPD 3.07](#), Termination and Enforcement, to be implemented in the NIH GAM system at NIH GAM 4307-207 (pending release).

A single award covering the entire period of support is generally used only if the project is solely for construction or alteration or renovation of real property, the total planned period of support will be less than 18 months, or the project is awarded under a special support mechanism, e.g., R15.

2. ***Length of Budget Periods:*** Unless a different funding method is authorized by statute, budget periods within a project period must be committed from successive annual appropriations, beginning with the initial award and continuing through all noncompeting and competing extension grants awarded for the project except under the following conditions:
   o A competing continuation application is determined to be worthy of support but, due to an insufficiency of current year funds, the application cannot be funded until the next fiscal year;
   o A competing continuation application is deferred in the review process and the decision to continue funding the project will not be made until the next fiscal year;
   o A change of grantee occurs which results in a break between the original grant and the replacement grant, and the starting date for the replacement grant will be 2 months or more into the next fiscal year;
   o A project is forced into a period of suspended or significantly reduced activity due to an unanticipated or uncontrollable situation, such as the temporary absence or limited availability of the principal investigator, an adverse event, delays in FDA approval, lack of sufficient research material or access to research tools, terrorism, a natural disaster, or a prolonged

strike by grantee employees, and such a situation delays the need for a continuation award until 2 months or more into the next fiscal year, or

o   A fellowship award is issued and the fellow does not activate the award until 2 months or more into the next fiscal year.

As stated, budget periods within a project period shall be for 12 months. However, shorter or longer budget periods may be established when there are administrative or programmatic reasons, such as:

• More advantageous anniversary dates to better balance workload and provide more efficient and effective service;

• Project periods not evenly divisible into 12 month increments;

• Projects clearly short term in nature requiring less than 18 months in duration;

• An unavoidable extended absence of a principal investigator due to illness or other emergencies as approved by the IC;

• The orderly termination of the project; or

• Poor programmatic performance on a single project

When an IC identifies poor programmatic performance on a single project, it may be appropriate to award the grantee additional time, without funds, to catch up to the approved goals of the research project. This can be done by extending a budget period within the competitive segment by a number of months and including special terms and conditions that detail 1) the concerns with the project and 2) the necessary actions that are expected by NIH to bring the project to a satisfactory performance level. The submission of interim progress reports that will inform NIH on how the performance problem is being resolved is recommended for these situations. Please note that there are other possible actions to consider when an IC has identified poor programmatic performance on an award. Also, the GMO is expected to notify the appropriate IC officials when taking an action such as this.

To request extensions solely to utilize available funds before they lapse is not a compelling administrative or programmatic justification to alter the length of a budget period.

3. ***Extension of Project Period:*** Unless otherwise restricted by a term of award, the grantee may extend the final budget period of the competitive segment one time for a period of up to 12 months beyond the original expiration date shown in the NGA if no additional funds are required to be obligated by the IC awarding office, there will be no change in the project's originally approved scope, and any one of the following applies:

• Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project;
• Continuity of NIH grant support is required while a competing continuation application is under review, or
• The extension is necessary to permit an orderly phase-out of a project that will not receive continued support.

The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds. No single extension may exceed 12 months. When a budget period is extended, a subsequent award will not be made effective until the termination of the extended budget period. (This may necessitate an amended NGA to adjust the budget/project period end to one day prior to the start date of a Type 2.)

On November 5, 1990, Public Law 101-510 limited the availability and use of prior year funds to the current fiscal year and five subsequent years. To ensure that the grantee will utilize funds during this period, grants should

not be extended more than four fiscal years beyond the fiscal year used to fund the final budget period. For instance, if the final year was initially awarded in FY 2004 (budget period = 7/1/04 - 6/30/05), funds availability will lapse at the end of FY 2009 (9/30/2009). Therefore the grant should not be extended beyond FY 2008 (9/30/2009). The grantee must fully disburse the funds via the SF 272 Federal Cash Transaction Report and have their FSR received and accepted prior to the end of FY 2009 (9/30/2009). Any funds undisbursed in the Payment Management System as of 9/30/2009 will be deobligated on 10/1/2009. Please note that an extension approved beyond 9/30/2009 will not prevent the deobligation of funds.

The earlier limitation to extensions is strongly recommended to accommodate the delays inherent in the financial reporting requirement system. Therefore, to accommodate the additional time needed to fulfill the financial reporting, it is recommended that no award be extended for more than three years beyond the fiscal year used to fund the final budget period.

While P.L. 101-510 doesn't limit the IC's authority to provide further extensions, it does require that all claims beyond the period of fund availability will be paid with current year appropriations.

4. *Multiyear funding:* In September of 1996, the NIH Deputy Director for Extramural Research (DDER) gave blanket approval to multi-year fund Shannon (R55), Academic Research Enhancement Award (AREA) (R15), and Extramural Associate Research Development Award (EARDA) (G11) program awards. Shannon, AREA and EARDA program awards historically had received approval for multiyear funding because of characteristics unique to those mechanisms. Inasmuch as the rationale and justification to multiyear fund these awards recur annually, these

mechanisms may be "multiyear funded." However, no other grant may be multiyear funded unless the action receives prior approval of the NIH Deputy Director for Extramural Research (DDER).

5. ***Split-funding:*** No grant may be split funded under any circumstances.

D. References:

1. [HHS Grants Policy Directive 2.04](#), Awarding Grants

2. [OER Policy Announcement 1997-02](#): Single-Case Deviation from PHS/NIH Grants Policy

E. Definitions:

1. **Budget Period** – the intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.
2. **Competitive Segment** – the initial period of recommended support or each successive competing continuation period of a project period.
3. **Multiyear Funding** – a grant project that is funded for a period 12 months and one day, or longer, from a single annual appropriation. For the purposes of this policy, a no-cost extension of an existing grant does not constitute multi-year funding.
4. **Non-competing Continuation Grant** – a grant made in support of any budget period after the first budget period within an approved project period, except for the first budget period of a competing extension to a project period.
5. **Project Period** – The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and non-competing extensions.
6. **Project Period Extension** – the extension of a project period, with or without funds, which would otherwise terminate, in order to provide support for one or more additional budget periods.

7. **Split Funding** – a single award only partially funded from one annual appropriation with the intent to supplement the award from a new fiscal year appropriation to provide the remainder of the funding originally intended. Split Funding is not allowable (see "Policy").

8. **Supplemental Awards** – 1) competing supplement – an additional award of funds for an existing grant for the expansion of the project scope or research protocol, and 2) administrative supplement – an award of funds for an existing grant to meet increased costs that were unforeseen and not included in the last competing or noncompeting application, and is within the original project scope and research protocol.

F. Responsibilities:

Grants Management staff are responsible for assuring that NIH grants and cooperative agreements are funded according to the policies detailed in this NIH GAM. Scientific review staffs are responsible for assuring that applications for competing supplements do not exceed the project period of the parent grant.

G. Procedures:

1. *1. Application and Initial Grant Award:* An applicant requesting NIH support for a new or competing continuation project shall submit an Office of Management and Budget (OMB) -approved application (e.g., PHS 398, PHS 2590, PHS 416-1, OMB SF 424, grants.gov e-application, etc.). Unless otherwise stated in the Request For Applications (RFA), Program Announcement (PA), Broad Agency Announcement (BAA), the applicant may request no more than five years of support for each competitive segment. Project periods of more than five years are only considered with compelling programmatic justification and require the approval from the Director of OPERA (see "OER Policy Announcement 1997-02, Single –Case Deviation from PHS/NIH Grants Policy Statement.

2. *Non-competing Continuation:* To receive funding of each subsequent budget period within the approved project period, grantees are required to submit a

noncompeting continuation progress report directly to NIH. The progress report must be submitted in accordance with the PHS 2590 Progress Report or e-SNAP submission process. If progress is determined to be satisfactory and funds are available and needed for the project, a grant award will be made for the next budget period. The grant award will show any changes in the recommended level of future support. Additional noncompeting continuation grants will be made within an approved project period in accordance with the same procedure.

3. *Supplemental request:* Grantees may request an increase in support during a current budget period and/or for future years. To obtain such support competitively, the applicant must submit a supplemental PHS 398 application in accordance with the PHS 398 application instructions. Such an application is appropriate when:

   o A request for an increase in support for an expansion of project's scope or research protocol (competitive supplement), or

   o A request for an increase in support to meet increased costs that are within the scope of funded project or research protocol, but were unforeseen and not included in the last competing or non-competing application (Administrative Supplement).

   A supplemental application will not be accepted until after the original application has been awarded, and may not extend beyond the term of the current competitive segment. Applications for supplements are not appropriate when the single objective is to restore awards up to full scientific review group (SRG) recommended level if the SRG level was administratively reduced by the IC.

4. *Non-competing Project Period Extension:* Unless otherwise restricted by a term of award, a grantee may extend the final budget period of the competitive segment one time beyond the original expiration date that is reflected in the award notice without IC written prior approval. This may be done if no additional funds are required to be obligated by the NIH awarding office, there will be no change of the project's originally approved scope, and any one of the following applies:

- o Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project;
- o Continuity of NIH grant support is required while a competing continuation application is under review, or
- o The extension is necessary to permit an orderly phase-out of the project that will not receive continued support.

The grantee must notify the appropriate NIH awarding office, in via e-mail or correspondence, of the extension 10 days prior to the expiration date of the project period. Upon receiving the grantee's notification, the NIH awarding office will revise the project/budget period end dates in the appropriate systems and provide acknowledgment to the grantee by way of letter, e-mail, or in rare cases, a revised Notice of Grant Award. During the extension of the final budget period of the competitive segment, the grantee assures compliance with all required certifications, including human subjects and animal welfare, in accordance with applicable policies and regulations.

Grantees registered in the NIH eRA Commons may submit this initial extension notification through the Project Extensions feature. While HHS regulations (45 CFR Pt 74.25(d).(2). requires written notifications to be submitted at least 10 days prior to the expiration date, NIH received a policy deviation from DHHS for electronic notifications. As a result, grantees submitting this notification through the Commons have until the actual expiration date of the project period to enter the data. (Note: However, this electronic feature becomes unavailable once the actual expiration date of a grant has passed; i.e., retroactive notifications cannot be submitted electronically through the Commons.) Once the grantee has entered the new expiration date and an authorized official has submitted the notification to the NIH, the eRA system automatically updates the budget/project period end dates in the database and generates the appropriate e-mail notifications to the IC and the grantee institution.

Grantees that have utilized their automatic no-cost extension and are interested in requesting an additional no-cost extension of up to twelve months may submit a request to the Grants Management Specialist listed in the NGA. These requests may be submitted electronically in accordance with current NIHGPS. These requests must detail the benefits of NIH's approval to NIH and the project. Also, a special justification is required for an additional extension that would exceed the initial extension. In some cases (e.g., when a significant amount of funds appear to remain unexpended), it may be appropriate for the awarding office to request that the grantee provide the amount of funds available for expenditure and to explain how the remaining funds will be spent. In these cases, request for non-competing extensions should be submitted at least 30 days prior to the expiration date of the competitive segment. Approval of these additional extension requests will be processed through revised NGAs.

Although requests should be submitted at least 30 days prior to the expiration of the competitive segment, on rare occasions requests are submitted after the termination date. In these situations, it is within the awarding office purview to approve the extension retroactively. Retroactive approval should be dependent on adequate justification and an assurance from the institution that internal controls are in place to preclude similar situations from occurring.

5. *Multiyear Funded Projects:* Requests for multi-year funding must be routed from the EPMC member (or other IC designee) to the DDER and must be coordinated with and have input from the IC Budget Officer and Chief Grants Management Officer for considerations such as budgetary impact, grant work load, average grant costs etc. Requests for multiyear funding must clearly demonstrate that appropriate stewardship and programmatic management of the project(s) will be best served under a multiyear model rather than project period funding. Requests must be cleared through the IC director, the Director of the Office of Financial Management, (OFM) OD, and the Director of the Office of Policy for Extramural Research Administration (OPERA). For OD funded

programs, e.g., Office of Research on Women's Health and the Office of Behavioral and Social Sciences Research, OPERA and OFM staff will assist program staff with the procedural aspects of processing requests. To ensure timely review, multiyear funding requests should be forwarded to the DDER at least 30 days prior to the proposed grant award date.

After consideration and action by the DDER, requests will be returned directly to the IC EPMC member (or other IC designee) for inclusion in the official grant file. NIH must report multiyear awards to the Office of Management and Budget (OMB) within 10 days of the award date. Consequently ICs shall immediately notify the Chief, Division of Finance, OFM, upon issuing multiyear awards, including Shannon, AREA and EARDA awards, to enable OFM to comply with the OMB requirement. Information sent to OFM should include the grant number, the period and amount of multiyear funding and the rationale for multiyear funding.

Requests to the DDER must include the following information:
- o the complete grant number(s) or description of the program activity, e.g., an RFA;
- o the anticipated project period date(s);
- o the budget period date(s) if different from the project period dates;
- o the amount of the award(s) attributable to multiyear funding;
- o the total amount of the award(s) if different from the multiyear funding amount, and
- o the justification.

A suggested format is provided as Appendix 1.

The justification should specify: (a) the rationale for multiyear funding the proposed award(s) or program activity; (b) the impact on current and future fiscal year funding; (c) the effect(s) of the proposed action on the

objectives of the appropriation, e.g., mandated special initiatives, numbers of awards, average grant costs; and (d) the planned use of funds that would potentially be freed up in the succeeding fiscal year as a result of the multiyear funding action in the current year, if applicable.

As part of the justification, the rationale is the most important element in the request. Typically, for short term, low dollar, multiyear awards, the rationale often focuses on the opportunity for investigators to spend additional time directly on research by eliminating the administrative requirement to prepare a noncompeting application. For example, multiyear requests for awards for budget and project periods of two years or less with total project costs of $100,000 or less may be requested because NIH staff contemplate little need for progress reports in the context of two-year project periods. Rationales for higher dollar, longer term awards will be based on the specific aspects of each request.

6. ***Other Prior Approval Requests:*** Grantee requests for NIH prior approval must be made in writing (which includes e-mail) to the GMO no later than 30 days before the proposed change. The request to the awarding office must be signed by the Principal Investigator and the authorized organizational official. If the grantee does not obtain prior approval, when required, from the appropriate NIH awarding office it may result in the disallowance of costs, termination of the award, or other enforcement actions within NIH's authority.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, Item 4000, "Grants and Awards".)

NIH e-mail messages: NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered

Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

1. 1. **Office Responsible for Reviewing Management Controls Relative to this Chapter**: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).
2. **Frequency of Review**: The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.
3. **Method of Review**: OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this

issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

4. **Review Reports are sent to**: The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

Appendix 1: Sample Request for Multiyear Funding of Grants

Appropriation or CAN Number: _____

	Grant Number(s)	Project Period Date(s)	Budget Period Date(s)	Amt. of Award Attributable to MY$	Total Amt. of Award
1.	_____	_____	_____	_____	_____
2.	_____	_____	_____	_____	_____
3.	_____	_____	_____	_____	_____
4.	_____	_____	_____	_____	_____
5.	_____	_____	_____	_____	_____

Justification:

OER/DDER:

_____Approve _____Disapprove

_____   _____

_____   _____

Signature	Signature

NIH POLICY MANUAL

4301-201 - Facilities and Administrative Costs and Other Cost Policies

Issuing Office: OER/OPERA/DGP 301-435-0949

Release Date: 6/15/06

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1. **Explanation of Material Transmitted:** The purpose of this NIH Grants Administration Manual (NIH GAM) is to implement HHS Grants Policy Directive (HHS GPD) Part 3.01: "Post-Award - Indirect Cost and Other Cost Policies," and to rescind PHS GAM Part 609, Reimbursement of Indirect Costs and Part 610, Reimbursement of Indirect Costs on Training Grants. This NIH GAM outlines key policies including the roles and responsibilities of HHS and NIH staff, with respect to the award and administration of facilities and administrative (F&A, also known as indirect) costs under NIH grants and cooperative agreements. This NIH GAM also addresses research patient care costs. For purposes of this NIH GAM, the term "grants" includes cooperative agreements. This is the first issuance of this NIH GAM.

2. **Filing Instructions:** N/A, this is the first issuance of this NIH GAM.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.
- Online information, enter this URL:
  http://oma.od.nih.gov/manualchapters/

A. Purpose:

The purpose of this NIH Grants Administration Manual (NIH GAM) is to implement HHS Grants Policy Directive (HHS GPD) Part 3.01, "Post-Award - Indirect Cost and Other Cost Policies," and to rescind PHS GAM Part 609, "Reimbursement of Indirect Costs" and Part 610, "Reimbursement of Indirect Costs on Training Grants." This NIH GAM outlines key policies including the roles and responsibilities of HHS and NIH staff, with respect to the award and administration of facilities and administrative (F&A, also known as indirect) costs under NIH grants and cooperative agreements. This NIH GAM also addresses research patient care costs. For purposes of this NIH GAM, the term "grants" includes cooperative agreements. This is the first issuance of this NIH GAM.

B. Background:

Beginning October 1, 1996, NIH changed the terminology used in official documents (Notice of Grant Awards, correspondence, etc.) from indirect costs to facilities and administrative (F&A) costs. F&A costs are costs incurred by a grantee for common or joint objectives, which cannot be identified specifically with a particular project or program and are allocated to the project by the application of F&A rates.

C. Policy and Procedures:

Cost considerations are an integral part of NIH grants administration, both in contributing to a successful project outcome and in ensuring the stewardship of Federal funds. Grant awards provide direct cost amounts in relation to the project's scope and anticipated level of effort and an appropriate allowance for F&A costs. This is consistent with applicable statutes and regulations, Federal cost principles, the NIH Grants Policy

Statement (NIH GPS), and any limitations established by this GAM.

Cost reimbursement is limited to expenditures and amounts that comply with statutory, regulatory, cost principles, and policy requirements. For F&A costs, reimbursement must be consistent with the negotiated F&A rates and applicable federal cost principles; specifically OMB Circular A-21. [In this GAM, see section C.1.c.(1), Special Requirements for Colleges and Universities and OMB Circular A-21, "Cost Principles for Educational Institutions."]

No NIH grant, other than an award under the Small Business Innovation Research (SBIR) or the Small Business Technology Transfer (STTR) program, will include any increment above cost, whether termed "profit" or "fee". A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practices, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the grantee.

The total amount awarded (direct costs plus F&A costs and fee, when applicable), is the ceiling on the amount payable to a grantee. NIH is not obligated to make any additional awards or provide additional funding for changes in F&A rates or other purposes.

1. F&A Costs

a. Eligibility: Activities conducted by grantees that result in F&A costs are a necessary and appropriate part of NIH grants. Except for specific grant programs or an individual grant, which does not allow F&A costs, NIH Institutes and/or Centers (ICs) must provide F&A costs as either a fixed amount as specified in statute, regulation, or this NIH GAM; or an amount based upon a negotiated rate and reflected in a formal rate agreement.

(1) F&A costs are not provided if the award mechanism does not allow reimbursement of such costs. This includes the following award mechanisms:

• Fellowships
• Construction
• Conferences (R13, T36, U13)
• Equipment (S10, S15)
• Grants to individuals
• Grants to Federal institutions
• Resource Improvement Grants (G07)
• Resource Project Grants (G08)

The establishment of an F&A rate may not be necessary if the organization's total operations consist of a single grant-supported project, or the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such, and the Grants Management Office (GMO) is satisfied that the organization's accounting system can adequately identify and support all allowable costs as direct costs to the project. Such an accounting system must identify and segregate costs based on a process that assigns costs commensurate with the benefits provided to individual projects. At a minimum, these institutions must have established procedures for the distribution of the elements of cost that are normally treated as F&A costs.

(2) F&A costs are provided on a limited basis for the following classes of awards:

(a) Grants whose primary purpose is research training or education:

(i) Research Training Grants (Ts): F&A costs are limited to 8 percent of

total direct costs exclusive of tuition, fees, health insurance, consortiums in excess of $25,000, and equipment for Kirschstein Institutional National Research Service Awards (NRSA), unless the grantee is a state government, local government, or Indian tribal government which are reimbursed on the basis of their negotiated F&A rates. In those unique circumstances where a consortium arrangement is part of the approved research training program and consortium costs are separately awarded, the first $25,000 is included in the F&A base while costs greater than $25,000 are excluded from the base. F&A costs for consortium arrangements are also limited to 8 percent of total direct costs exclusive of tuition, fees, health insurance, and equipment.

(ii) Career Development Awards (Ks): F&A costs are limited to 8 percent of total direct costs exclusive of tuition, fees, and equipment. In those unique circumstances where a consortium arrangement is part of the approved research plan, and consortium costs are separately awarded, the first $25,000 is included in the F&A base while costs greater than $25,000 are excluded from the base. F&A costs for consortium arrangements are limited to 8 percent of total direct costs exclusive of tuition, fees, and equipment.

(iii) Education Projects (R25): F&A costs are limited to 8 percent of total direct costs exclusive of tuition, fees, and equipment. In those unique circumstances where a consortium arrangement is part of the approved research plan, and consortium costs are separately awarded, is included in the F&A base while costs greater than $25,000 are excluded from the base. F&A costs for consortium arrangements are limited to 8 percent of total direct costs exclusive of tuition, fees, and equipment.

(b) Shannon Awards (R55): Shannon Awards provide F&A at a rate of 25% of total direct costs.

(c) Grants to Foreign Organizations & Foreign Consortium Agreements: In 2001, NIH authorized limited F&A costs to foreign and international organizations. The F&A costs may not exceed 8 percent of total direct costs less equipment. Foreign grants and consortium agreements issued in prior fiscal years contained no provision for F&A costs (see NIH Guide 03/29/01, NOT-OD-01-028).

b. *Funding of F&A Costs:* The NIH established total cost commitments for future years on all grant and cooperative agreement awards with budget periods beginning after October 1, 1995 (see NIH Guide 10/27/95, NOT 95-249).

c. *Basic Considerations:* The rates in effect at the beginning of a competitive segment will be used to determine F&A cost funding levels for the entire segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. See section C.1.c.(1) for special requirements for grantees subject to OMB Circular A-21.

Grants management staff or other HHS staff must also make any necessary adjustments to rates negotiated by other Federal agencies to reflect HHS policy on independent research and development costs (IR&D) [see 45 CFR 74.27(b)(2)], and/or reductions as a result of the grantee's matching or cost sharing in direct or F&A costs.

Grants management staff shall determine the dollar amount of F&A costs applicable to a supported project by multiplying the appropriate F&A rate(s) by the authorized F&A cost base of the project.

Grants management staff should contact the Division of Cost Allocation

(DCA), HHS, and/or the Division of Financial Advisory Service (DFAS), NIH, (via telephone or e-mail) of any new, very large awards, or other changes that might significantly impact a grantee's previously established rate(s) to determine if a revised rate(s) is necessary.

(1) Special Requirements for Colleges and Universities and OMB Circular A-21, "Cost Principles for Educational Institutions":

Section G.7. of OMB Circular A-21 states, "Federal agencies shall use the negotiated rates for F&A costs in effect at the time of the initial award throughout the life of the sponsored agreement. 'Life' for the purpose of this subsection means each competitive segment of a project." This section goes on to state, "If negotiated rate agreements do not extend through the life of the sponsored agreement at the time of the initial award, then the negotiated rate for the last year of the sponsored agreement shall be extended through the end of the life of the sponsored agreement."

Further, the term "negotiated rate" in Section G.7. of OMB Circular A-21 does not apply to provisional rates. OMB stated this in the preamble of a proposed revision to OMB Circular A-21 published in the Federal Register, September 10, 1997, (page 47722).

The only exception to this policy is a very rare situation where, at the time of the initial award of a competitive segment, the only rate available is a provisional rate. This would occur when the period covered by a predetermined or fixed rate ends before a new predetermined or fixed rate is negotiated.

Example: Issuing an award to a university with a project period of 7/1/2004 to 6/30/2008:

Current F&A Agreement has the following negotiated rates:

TYPE	FROM	TO	RATE
			(%)
PREDETERMINED	7/1/02	6/30/05	57.0
PROVISIONAL	7/1/05	until amended	56.0

The commitments from July 1, 2004 to the end of the project period are to be awarded by extending the predetermined rate of 57% (this rate would also be used for reimbursement on the project).

Should the rates not be re-negotiated and a competitive award is issued with a project period starting July 1, 2005 or later, the provisional rate would be used for funding the project. Once 'permanent' rates are negotiated the grantee should use the permanent rate for reimbursement. Awards will not be revised to reflect the permanent rates. This unusual situation is the only case where the provisional rate is used in determining award levels for a grantee covered by OMB Circular A-21 (educational institutions).

When a grant budget period does not coincide with the grantee's fiscal year, it will be necessary to prorate applicable rates in computing the amount of F&A costs applicable to the grant.

Consortium/contractual F&A rates in effect at the time of the competing award are incorporated into the parent grantee's total cost commitment. If a consortium or subcontractor does not have a negotiated rate, see section C.1.d.(1), Establishment of F&A Cost Rates - General Policy.

(2) Special Situations: There are some situations that require the negotiation of project costs annually. The determinations to negotiate costs annually are typically programmatic. Examples of grants that are negotiated annually include some clinical trials, Primate Centers and General Clinical Research Centers.

d. Establishment of F&A Cost Rates

(1) General Policy: A claim for the reimbursement of F&A costs on NIH grants subject to this policy must be supported by the grantee's submission of an F&A cost proposal. Exceptions to this general policy are:

• Award mechanisms that limit F&A costs [see C.1.a.(1) for these mechanisms]
• SBIR/STTR awards [see C.1.d.(2), Establishment of F&A Cost Rates: SBIR/STTR Policy]
• Grantees that have never had an established rate [see C.1.d.(3), Grantees That Have Never Had an Established Rate]

NIH grantees that fail to submit a timely F&A cost proposal in support of their claim for F&A costs will be deemed by DCA or DFAS as not having a currently effective F&A rate. If this is the case, it will be noted in the rate file and subsequent rate agreements. In the absence of a rate, future awards to the grantee will not provide for the reimbursement of F&A costs. Failure to submit a timely proposal may also result in the disallowance of F&A costs previously reimbursed.

F&A cost proposals will be prepared in accordance with applicable cost principles and will conform to the other cost policies referenced in this NIH GAM or provided by the offices responsible for negotiating F&A rates.

If an organization has a rate with another government agency, it can be used after adjustment for the HHS treatment of independent research and development (IR&D) costs (i.e., excluded from the F&A pool and included in the F&A base) and any other adjustment that may be required. DFAS or DCA should be consulted either to perform this adjustment or to advise the GMO how to make the adjustment.

Except as otherwise provided for below, grantees are responsible for negotiating appropriate F&A rates with consortium and/or contractual participants that receive awarded funds under NIH grants. Such negotiations will be based on the federal cost principles applicable to the consortium/contractual participant. The procedures followed by the grantee in conducting the negotiations will be subject to review and audit by, or on behalf of HHS. If the grantee requires assistance with the negotiations, it should request such assistance from the appropriate GMO, who will coordinate requests with the DCA and/or DFAS.

Grantees will not be required to negotiate F&A rates with NIH consortium/contractual participants if any one of the following conditions exists:

• The NGA does not provide for F&A costs or the consortium/contractual participant has waived reimbursement of F&A costs. (Such waivers must be wholly voluntary and cannot be initiated or required by grantees or NIH officials.)

• The consortium/subcontract is for training purposes and is awarded to an institution of higher education, a hospital, or a nonprofit institution. In these cases, the consortium/subcontract will be subject to the policies and procedures set forth in section C.1.a.(2)(a)(i), Research Training Grants.

• The consortium/contractual participant is also a direct recipient of Federal grants or contracts and has negotiated F&A rates with DCA or DFAS or another cognizant agency. Although the grantee will not be primarily responsible for these negotiations, it may participate in the negotiations if the cognizant Federal officials consider such participation necessary or desirable.

• The consortium/contractual participant is a foreign organization. The foreign organization will be subject to policies and procedures set forth in section C.1.a.(2)(c), Grants to Foreign Organizations & Foreign Consortium Agreements.

(2) SBIR/STTR Policy: If the applicant has a currently effective F&A rate(s) with a Federal agency, the rate(s) should be used when calculating F&A costs. However, the rate(s) must be adjusted for IR&D expenses (see C.1.c., Basic Considerations).

(a) Phase I Grants: If the applicant does not have a currently effective negotiated F&A rate with a Federal agency, the applicant should propose estimated F&A costs at a rate not to exceed 40 percent of the total direct costs (no base exclusions). However, only actual allowable F&A costs are to be charged to the projects. If the awarded rate is not based on a negotiated rate, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate even if the grantee subsequently negotiates a higher F&A rate(s) applicable to the period of the grant award with a Federal agency.

(b) Phase II Grants: If the applicant does not have a currently effective negotiated F&A rate with a Federal agency, the applicant should propose estimated F&A costs. If the small business concern is being considered for an award, it will be asked to submit detailed documentation if the

requested rate is in excess of 25 percent of total direct costs (no base exclusions). If the requested F&A cost rate is 25 percent or less, no further justification is required, and F&A costs will be awarded at the requested rate. However, only actual F&A costs may be charged to projects. If awarded *rate is not based on a negotiated rate*, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate even if the small business concern **subsequently** negotiates a higher F&A rate(s) applicable to the period of the award with a Federal agency.

The SBIR and STTR solicitations provide a comprehensive presentation on the treatment of F&A costs on these programs.

(3) Grantees That Have Never Had an Established Rate: If a currently effective F&A rate is not available at the time of an award because the grantee has never established a rate and is unable to establish its initial rate prior to the date of the award, the following procedure will be followed:

(a) The GMO shall notify the grantee of the requirement to submit an F&A cost proposal to DCA (for all except for-profit organizations) or DFAS (for for-profit organizations), as soon as possible, but not later than three months from the effective date of the grant award. The GMO shall also advise the DCA or DFAS of this action.

(b) The GMO will contact the DCA or DFAS, as necessary, to advise the rate negotiator of any relevant matters concerning the establishment of the F&A rate.

(c) The GMO may contact the DCA or DFAS to obtain information on F&A rate(s) that are in the process of being established. This information can be used by the GMO in making the award in lieu of waiting for the normal distribution of the F&A rate agreement.

(4) Special F&A Cost Rates (Including Off-Site Rates): Some conditions may indicate the need for establishment of a special F&A rate. Grants management staff should consult with DCA/DFAS about the use of a special rate(s) if: 1) an activity will be conducted within a physical or administrative environment which will generate a significantly different level of F&A costs than other activities of the organization; 2) the special rate would be substantially lower or higher than the rate applicable to the other activities; and, 3) the rate would apply to a material (significant) amount of federally supported direct costs.

DCA/DFAS will be responsible for obtaining necessary information and supporting documentation from the applicant and/or grantee, which justifies the use and/or non-use of a special rate(s).

The GMO will advise the negotiators of any circumstances that might warrant establishment of special or off-site rates. The GMO will consult with DCA/DFAS or other cognizant negotiators concerning rates to be used when a grantee begins work on a very large, new or significantly expanded grant that is likely to have a significant impact on the rate.

The negotiators will evaluate the information provided by the GMO and will determine whether a special rate is necessary.

(5) Use of a Temporary Rate: If any of the above actions do not result in the establishment of a rate prior to the issuance of the award, the GMO may provide and authorize reimbursement at a temporary amount equaling one-half of the F&A costs requested by the grantee, up to a maximum of 10 percent of direct salaries and wages (exclusive of fringe benefits).

If the grantee subsequently submits a timely F&A cost proposal and establishes a rate, the GMO shall revise the award to provide additional funds for the difference between the amount initially awarded and the amount based on the approved rate *subject to the availability of funds.*

The GMO should assume that the grantee's F&A cost proposal was submitted on time unless a statement to the contrary is included in the F&A rate agreement. If the grantee does not establish the F&A rate before the submission of the Financial Status Report, any claims for F&A reimbursement shall be disallowed.

Grants management staff are responsible for adjusting awards to reflect: 1) the initial establishment of a rate if one has not been previously established, 2) the late submission of an F&A cost proposal for a subsequent fiscal year, or 3) other changed circumstances. Grants management staff must monitor the status of such situations via contact with the grantee and/or the cognizant Federal negotiators.

e. Rebudgeting and Post Award Management: Grantees are allowed latitude to rebudget within and between direct cost budget categories to meet unanticipated needs and to make other types of post award changes. Such changes may be made by the grantee within limits established by the NIH. Other changes require NIH prior written approval before modifying the budget or undertaking the activity in question. In using this authority, grantees are required to ensure that they exercise proper stewardship over Federal funds and that all costs charged to awards are allowable, allocable, and reasonable. Please see the NIH GPS for the sections titled, "Changes in Project and Budget" and "Expanded Authorities."

Consideration of changes in total costs to reflect F&A rate changes will not

be made routinely. NIH will not engage in budget negotiations for most noncompeting awards.

(1) Grantees Subject to OMB Circular A-21, (i.e., Colleges and Universities): F&A cost reimbursement on grants subject to OMB Circular A-21 is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding [see C.1.c.(1), Special Requirements for Colleges and Universities and OMB Circular A-21, "Cost Principles for Educational Institutions"]. Those grantees subject to OMB Circular A-21 may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (fixed or predetermined) rates rather than provisional rates (defined as not "negotiated" for the application of the OMB Circular A-21 requirement).

(2) Grantees Other Than Colleges and Universities: F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost was incurred, except if F&A costs were limited or not provided, SBIR/STTR awardees, and other grantees that have never established a rate. Grantees other than those subject to OMB Circular A-21 may be reimbursed at a higher rate than the rate used in calculating the award if a permanent rate is established subsequent to award. Such grantees may also rebudget between direct and F&A costs (in either direction) to accommodate an increase or decrease in F&A costs and are not required to obtain prior approval for the rebudgeting, unless it represents a change in the scope of the project.

For these grantees, award amounts will not be adjusted downward on the basis of a lower permanent F&A rate than that used in calculating the award unless the F&A rate proposal that served as the basis for the negotiation included unallowable costs.

f. Adjustment of Total Cost Commitment (due to F&A Issues): The amount awarded for F&A costs can be adjusted if one of the following conditions applies:

(1) An error was made in computing F&A costs;

(2) A negotiated rate(s) which differs from the rate(s) used in the grant award becomes effective (date of the rate agreement) more than one calendar month before the beginning date of the initial grant budget period. Future year F&A levels will only be revised when the competing award is adjusted;

(3) Supplemental awards and revised awards providing additional funding will reflect current F&A rates, even if different from those used to calculate F&A costs for the parent award. The parent award amounts will not be adjusted. Changes to future year commitments will reflect the same practice;

(4) A previously restricted unobligated balance from a prior period has been approved for expenditure in the current budget period;

(5) The award was made to a new grantee using a provisional amount for F&A costs and a negotiated rate is established subsequent to award;

(6) Change in Grantee Institution. The F&A rate of the new institution will be used to calculate the award. If the transfer occurs during a budget period and the F&A rate at the new institution is higher, funds may be added to accommodate the increased total costs if they are available. If funds are not added, the allocation between direct and F&A costs must be adjusted. Future year total cost commitments must be adjusted to reflect

the new institution's F&A rate. *If the direct costs available to the grantee are significantly reduced by this adjustment (>25%), the impact of the reduction on the approved scope of the project should be addressed*; and,

(7) The award contained no F&A costs because the grantee was delinquent in submitting its F&A cost proposal and a rate was established after award. F&A costs may not be awarded or reimbursement provided for any period prior to the date the F&A cost proposal was submitted. (The calculation of F&A costs will be consistent with the terms of the F&A Rate Agreement.)

g. Procedures For Settlement of F&A Costs

(1) Grantees with Currently Effective F&A Rates: Each Financial Status Report and Federal Cash Transaction Report submitted by the grantee shall reflect the proper amount of F&A costs applicable to the grant period. If a provisional or an earlier period's permanent rate is used in the report, a subsequent adjustment to the FSR is necessary if a lower permanent rate(s) applicable to the grant is established, except for educational institutions subject to OMB Circular A-21.

Educational institutions subject to OMB Circular A-21 with competitive segments awarded after May 8, 1996, must be reimbursed using the negotiated rates at the time of award if F&A costs were awarded based on a negotiated (fixed or predetermined) rate(s). In this circumstance, rebudgeting from direct costs to accommodate a subsequent rate increase(s) is not allowable. However, should the awarded F&A costs be based on provisional rates, the reimbursement will be based on the negotiated permanent rate(s) per the F&A rate agreement(s). In this circumstance rebudgeting from direct costs to accommodate a rate increase is allowable.

(2) Delinquent Grantees: If a currently effective F&A rate is not available at the time of an award because the grantee was delinquent in the submission of its F&A cost proposal, GMOs shall ensure that the award does not include funds for the reimbursement of F&A costs. GMOs shall also take action to recover any funds contained in a current award for F&A costs of the delinquent period. If the grantee subsequently establishes a currently effective rate, the GMO may exercise discretion to amend or revise the award to provide an appropriate amount for F&A costs if the amendment can be made within the same Federal fiscal year in which the initial award was made. However, GMOs will limit this amount, as specified in the rate agreement, to the F&A costs applicable to the period after the date of the grantee's proposal.

When a grant is awarded or revised without funds for the reimbursement of F&A costs, claims for those costs will not be accepted on the Financial Status Report or Federal Cash Transaction Report submitted under the grant. If the revised award provides funds for F&A cost reimbursement, the F&A costs allowed on the Financial Status Report shall be computed on the same basis as was provided to the grantee in the revised award.

2. Research Patient Care Costs

Research Patient Care Costs are the costs of routine and ancillary services provided by hospitals to patients participating in research programs. The costs of these services are normally assigned to individual research projects through the development and application of research patient care rates.

For the NIH policy on the determination and reimbursement of research patient care costs under grants and cooperative agreements, see the

"Research Patient Care Costs" section of the NIH Grants Policy Statement (rev. 12/2003) , and NIH Manual Chapter 6352-2, "Research Patient Care Costs Supported By NIH Sponsored Agreements."

D. References:

1. Federal Register, September 10, 1997, (page 47722).
2. Government Audit Standards (GAO Yellow Book)
3. 45 CFR 74.27(b) (2)
4. OMB Circular A-21, Cost Principles for Educational Institutions
5. OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations
6. NIH Grants Policy Statement (NIH GPS, rev.12/2003)
7. NIH GAM Chapter 4102-202 Definitions (pending release)
8. NIH Manual Chapter 54104 – NIH Research Grants Involving Foreign Institutions and International Organizations
9. NIH Manual Chapter 6352-2 - Research Patient Care Costs Supported By NIH Sponsored Agreements
10. NIH Manual Chapter 7610 - Establishment of Indirect Cost Rates for Use in the Award and Administration of Contracts and Grants with Commercial Organizations

E. Definitions:

Total Cost Commitment: The committed funding level established for each year of the project period when the competing grant or cooperative agreement is awarded.

For other definitions see NIH GAM 4102-202 (pending release in the NIH Manual System) or the NIH GPS (rev. 12/2003), "Glossary."

F. Responsibilities:

1. **Grants Management Responsibilities:** Grants management staff, as necessary, consults with the Office of Grants Management and Policy (OGMP), HHS; the Office of Audit Resolution and Cost Policy (OARCP), HHS; the Division of Cost Allocation (DCA), HHS; the Division of Financial Advisory Services (DFAS), Office of Acquisition Management and Policy, Office of Administration, Office of Management), NIH; and the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH. This consultation is to ensure that application instructions, program guidelines, program regulations, or other guidance provided to applicants/grantees contain appropriate coverage of F&A cost and other cost and fee policies, including those referenced or included in this GAM.

   Grants management staff are responsible for monitoring grantee compliance with cost policies and requirements. This is accomplished by reviewing grantee reports and other available information, participating in site visits, and by serving as a primary resource to the grantee community. Audits conducted by independent auditors, as required by the Office of Management and Budget (OMB) Circular A-133, will assess organizational compliance with the direct and F&A cost provisions of the cost principles through sampling and other tests. The audit may highlight areas of concern and should be used by grants management staff as a supplemental monitoring tool. It should be noted that commercial, for-profit organizations might have an independent audit performed that meets the requirements in OMB Circular A-133 or a financial related audit performed in accordance with [Government Audit Standards (GAO Yellow Book)](#).

In carrying out their responsibilities under this GAM, Grants Management staff utilizes the [NIH Grants Policy Statement](), applicable cost principles and information available from DCA or DFAS, which includes negotiated F&A and research patient care rate agreements. DCA negotiated rates are stored in a database maintained by HHS and are accessible via an on-line search feature accessible from the NIH Grants Management Infonet.

If F&A costs may be included in an award and are not otherwise specified in rate or amount, grants management staff are responsible for determining if the applicant/grantee has a negotiated F&A rate that will cover the period of the anticipated award, either in whole or in part.

If negotiated rates are not in effect, grants management staff will advise the applicant and/or grantee to establish a rate by submitting its initial rate proposal to DCA (or NIH's DFAS, if the applicant is a commercial, for-profit organization), and may not include any allowance in the award or provide F&A costs except as indicated below.

Grants management staff is also responsible for consulting with the cognizant office on special situations (as described in a grant application or as defined by DCA or other cognizant office) and for ensuring that the provisions of negotiated rate agreements are properly applied.

2. **Division of Cost Allocation (DCA), HHS:** When HHS is the cognizant agency, DCA is responsible for negotiating F&A rates and, as applicable, approving cost allocation plans (both central services cost allocation plans and public assistance cost allocation

plans) with applicants and/or grantees. These include State governments, local governments, Indian tribal governments, educational institutions, hospitals, and other non-profit organizations. DCA rate agreements are available online at http://rates.psc.gov/.

3. **Division of Financial Advisory Services, (DFAS), OAMP, NIH:** DFAS is the central organizational component at HHS authorized to negotiate F&A cost rates with commercial and for-profit organizations. DFAS rate agreements are available online at https://c-rads.od.nih.gov to all HHS employees who are approved and registered to use the Commercial Rate Agreement Distribution Services (C-RADS) system.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this NIH GAM must be retained and disposed of under the authority of NIH Manual Chapter 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, Item 4000, "Grants and Awards".

NIH E-Mail Messages: NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contract your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a Government legitimate purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided

to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

H. Management Controls:

The purpose of this NIH GAM is to outline key policies including the roles and responsibilities of HHS and NIH staff, with respect to the award and administration of facilities and administrative (indirect) costs under NIH grants and cooperative agreements. This NIH GAM also addresses research patient care costs.

1. **Office Responsible for Reviewing Management Controls Relative to this NIH GAM:** The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

2. **Frequency of Review:** The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. NIH GAMs with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

3. **Method of Review:** OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a

customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

4. **Review Reports are sent to:** The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officer(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

NIH POLICY MANUAL

4302-202 - Post Award: Matching and Cost Sharing

Issuing Office: OER/OPERA (301)-435-0949

Release Date: 9/10/2008

1. **Explanation of Material Transmitted:** This new NIH Grants Administration Manual (GAM) specifies the criteria, requirements and policies for matching and cost sharing under NIH grants and cooperative agreements (hereafter referred to as "grants"). Further, it implements Grants Policy Directive (GPD) 3.02, "Post-Award - Matching and Cost Sharing," and rescinds PHS Grants Administration Manual Part 123, "Matching." This NIH GAM supplements the provisions of 45 CFR 74.23, 45 CFR 92.24, and 42 CFR 52b on matching and cost sharing. This is the first issuance of this NIH GAM.

2. **Filing Instructions:**

   Insert:NIH Manual 4302-202 dated 9/10/2008.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.
- Online information, enter this URL:
  http://oma.od.nih.gov/manualchapters

A. Purpose:

This NIH Grants Administration Manual (GAM) specifies the criteria,

requirements and policies for matching and cost sharing under NIH grants and cooperative agreements (hereafter referred to as "grants"). Further, it implements Grants Policy Directive (GPD) 3.02, "Post-Award - Matching and Cost Sharing," and rescinds PHS Grants Administration Manual Part 123, "Matching." This NIH GAM supplements the provisions of 45 CFR 74.23, 45 CFR 92.24, and 42 CFR 52b on matching and cost sharing. This is the first issuance of this NIH GAM.

B. Background:

The general requirement for cost sharing under NIH research grants was eliminated in FY1986 when Congress removed the cost sharing requirement for Public Health Service research grants from the annual appropriations act for the Department of Health and Human Services (HHS). The change applied to budget periods funded after February 6, 1986. However, matching or cost sharing can occur on NIH grants when specific program legislation or applicable regulations provide for such matching or cost sharing (e.g., the matching requirement imposed under all NIH construction grants at 42 CFR 52b.6).

The individual terms "matching" and "cost sharing" have different historical derivations:

- In the Department regulations found at 45 CFR 74.23 and 45 CFR 92.24, "matching" refers to a statutorily required percentage of program or project costs that must be contributed by a recipient in order to be eligible for Federal funding or reimbursement of costs. A matching requirement may be stated either as a specified or minimum non-Federal percentage of total actual, allowable project costs or as a maximum percentage of Federal participation in such costs.
- As noted above, before Fiscal Year 1986, there was a statutory

requirement for HHS recipients to share in the costs of grant-supported research. "Cost sharing" now refers to any situation in which the recipient shares in the costs of a project other than as statutorily required by "matching".

For the purposes of this NIH GAM, the terms "matching" and "cost sharing" will be used as a single term ("matching or cost sharing") unless the context indicates a unique handling of either term.

C. Policy:

1. General
2. Pre-Award Considerations
3. Post-Award Considerations
4. Direct vs. Facilities & Administrative (F&A) Costs
5. Source of Matching or Cost Sharing
6. Deviations

1. General

Matching or cost sharing may only be required by NIH under one of the following conditions:

1. The requirement is based in statute; i.e., the program's authorizing statute may require matching or cost sharing or may determine the amount of matching or cost sharing.

2. The requirement is based in program regulations (whether or not they directly implement statutory language on matching or cost sharing).

   When the requirement is included in program regulations and not in statute, the requirement may be treated similar to a matching

requirement, e.g., it may be stated as a percentage of actual, allowable costs, but should be referred to as "cost sharing" because, by definition, "matching" refers to a requirement specified in statute.

NIH may not require matching or cost sharing on any other basis; e.g., inclusion of a requirement in a funding opportunity announcement without a statutory or regulatory basis is not permitted.

Consistent with HHS Grants Policy Directive 2.03 (revised 8/22/2006), any requirement for matching or cost sharing must be included in the Funding Opportunity Announcement (FOA) and in all Notices of Award (NoAs). If applicable, the announcement must state the manner in which proposed matching or cost sharing will be evaluated in the funding competition. If not applicable, the announcement must so state. The FOA must include a requirement for applicants to fully identify and document in the grant application the specific costs or contributions proposed to meet a matching or cost sharing requirement, the source of the funding and how the valuation was determined.

The costs borne by matching or cost sharing (including in-kind contributions) are subject to the rules governing allowability in 45 CFR 74.23 or 45 CFR 92.24, as applicable. These rules include allowability under the applicable cost principles and other terms and conditions of the award, including any prior-approval requirements. These rules also specify that in general, Federal funds may not be used as matching or cost sharing for other Federal funds except as expressly provided in Federal statute. Note, however, that recipients may use program income as a source of matching or cost sharing when explicitly authorized in the NoA.

Unless restricted by statute or regulation, matching or cost sharing may be provided as direct and/or F&A costs, consistent with the recipient's

accounting system and its usual method of charging for similar items, as well as any restrictions or limitations in the applicable cost principles.

Under NIH grant programs, all matching or cost sharing--whether required by statute or regulation--must be included as part of the total approved budget in the NoA, both as an amount and as a percentage. Therefore, unless there is a maximum recipient matching or cost-sharing amount set forth in statute or regulation, if the applicant proposes cost sharing at a level in excess of a cost sharing requirement, and NIH accepts the proposed cost sharing as part of the approved budget and project, it becomes an award requirement enforceable through the NoA. Note the award requirement is already covered in the standard term of award which references that "This award is based on the application submitted to, and as approved by, the NIH…". Any other special term of award is not required. The NoA should also stipulate that the amount of matching or cost sharing is subject to adjustment based on total allowable costs incurred.

When the program requires cost sharing, the NoA should be issued showing both Federal and non-Federal shares. This will in turn require the formal reporting of both Federal and non-Federal shares on the appropriate financial report (currently the Financial Status Report [FSR], [SF269 Financial Status Report (Long Form)](#) or [SF269A Financial Status Report (Short Form)](#)).

If matching or cost sharing is offered by the applicant in the form of unrecovered F&A costs through lower than negotiated rates, these rates should be reflected and formally noted in the NoA. Accordingly, when costs are claimed, the institution should reflect the agreed upon rate in the appropriate financial report. Because such reductions of F&A costs in financial reports might appear to be inadvertent, the recipient should be instructed in the terms of award to include an explanation, in the

"Remarks" section of the FSR indicating that the claim for less than full allowable F&A costs is intentional. See also section C.4. Direct vs. Facilities and Administrative (F&A) Charges.

All costs and contributions used to satisfy a matching or cost sharing requirement must be documented by the recipient and are subject to audit.

2. Pre-Award Considerations

Under NIH grant programs, the following considerations must be addressed as part of program planning:

The FOA's description of the matching or cost share requirement must indicate:

- Whether it is a fixed percentage/amount, a minimum percentage/amount, or a graduated percentage/amount;
- Whether it applies to each budget period or to the project period as a whole;
- Whether the requirement is negotiable;
- The manner in which proposed matching or cost sharing will be evaluated in the peer review and whether applications that do not propose matching or cost sharing as specified will be returned without review;
- If the level or type of matching or cost sharing proposed will be considered in the peer review process and how that information will be used in the evaluation, e.g., a scored evaluation criterion, assignment of extra points, or a preference factor. If matching or cost sharing will not be considered as part of the evaluation (apart from the grants management office's cost or budget analysis), the announcement must so state. If matching or cost sharing will be used as a peer review criterion, the funding opportunity

announcement must state the exact nature of the criterion, e.g., presence of matching or cost sharing, matching or cost sharing at a particular level or of a particular type;

- If there are any restrictions or limitations on the applicant/recipient meeting the required share through cash and/or in-kind contributions (if authorized); and,
- Any special application requirements related to matching or cost sharing, e.g., whether there is a need for any pre-award documentation to establish the applicant's ability to provide the proposed matching or cost sharing.

3. Post-Award Considerations

Consistent with other aspects of post-award administration, NIH must administer matching or cost sharing on the same basis as the funding provided, that is, on an annual basis for those awards made under the project period system. Unless otherwise required by statute or regulation, the final calculation of the amount of matching or cost sharing and the assessment of recipient compliance with the matching or cost sharing shown on the NoA must be based on the approved budget and the actual, allowable costs and in-kind contributions (if authorized) for each budget period.

In accordance with good business practices, a recipient should provide required matching or cost sharing in proportion to its expenditure of the Federal share of the total project costs. Recipients are not required to provide matching or cost sharing before drawing down Federal funds.

In determining if a recipient met a matching or cost-sharing requirement, the percentage will be applied to the overall amount of actual, allowable costs regardless of the individual category(ies) in which the

costs/contributions occur.

If an award includes matching proposed by the recipient that exceeds the statutory requirement (or regulatory requirement implementing the statute) and the recipient is unable to meet the amount in excess of the required level, the Grants Management Officer may, where justified, reduce the matching to no less than the statutory or regulatory requirement. The GMO or other designated official may take similar action based on a regulatory cost-sharing requirement if permitted by the regulations.

If a recipient provides matching or cost sharing that exceeds that required by the NoA, the excess amount is not subject to the requirements of 45 CFR Part 74 or 92 or this NIH GAM unless the amount is used to offset otherwise unallowable matching or cost-sharing amounts.

The grantee should reflect the total Federal and Non-Federal share of outlays on the Financial Status Report (SF 269).

4. Direct vs. Facilities and Administrative (F&A) Charges

The classification of costs and contributions as either direct or F&A must be consistent with the classification of similar items which the grantee charges to grant accounts. Thus, if items such as rent, utilities, executive salaries, etc., are treated as F&A in developing the grantee's F&A rate, then contributions in these categories may not be regarded as direct cost contributions to the grant-supported activity. Similarly, the use of facilities and equipment already owned by the grantee may not be counted as a direct cost contribution where the cost or value of such use is reflected in the applicable F&A rate as depreciation or use charges.

If a recipient has established special or multiple F&A cost rates (e.g., off-site), the requirement for consistent classification of costs applies to the

activities covered by each rate.

Unrecovered F&A costs, i.e., the difference between the amount awarded for F&A costs and the amount that could have been awarded under the negotiated F&A cost rate is an appropriate source of matching or cost sharing. In this case, the recipient reduces its charge to the award for the F&A costs to which it would otherwise be entitled and the amount of the reduction qualifies as matching or cost sharing.

A grantee may not use unrecovered F&A costs as matching or cost sharing for those programs that award a limited F&A rate (e.g., career and training awards) because costs borne by matching or cost sharing must be allowable under the terms and conditions of the award.

5. Source of Matching or Cost Sharing

a. The allowable sources of matching or cost sharing are:
    i. Non-Federal source (e.g., State or local government, private non-profit foundation, private individual);
    ii. Program income if the NoA expressly cites the matching alternative as a term of award;
    iii. Federal funds awarded under other grants or contracts if the recipient is not required to account to the Federal government for their expenditure;
    iv. Unrecovered F&A as noted above in C.1. General.

    Exceptions may be specified by statute or regulation. (The Office of Policy for Extramural Research Administration [OPERA] and/or Office of General Counsel [OGC] may be consulted concerning the allowability of a source for matching or cost sharing.)

b. Generally, matching or cost sharing requirements may not be met from the following sources:

    i.   Costs paid by another Federal award or subaward unless the authorizing Federal statute permits those costs to be used as matching or cost sharing. However, this limitation does not apply to fee or profit earned by a recipient or subrecipient from a contract/subcontract awarded under another Federal assistance award;

    ii.   Costs or contributions used to satisfy a matching or cost sharing requirement on another Federal grant or procurement contract;

    iii.   Costs or contributions of services or property financed by program income earned by contractors under a contract from the recipient or a subrecipient (apart from any fee or profit the contractor earns as a result of the contract), unless expressly authorized by the terms and conditions of the NoA.

6. Deviations

For construction programs, the Director of the Institute/Center (IC) has the authority to waive the actual rate of matching or cost sharing. This authority can be exercised in both the pre- and post-award setting. For non-construction programs, the statutory or regulatory authority for matching or cost sharing should be reviewed to determine if deviations are addressed. The CGMO should consult with OPERA and/or OGC, as appropriate, regarding applicable deviation authorities. See also NIH Delegations of Authority, Program: Grants and Awards #8.

D. References:

1. 42 CFR 52b, "National Institutes of Health Construction Grants"
2. 45 CFR 74.23, "Cost Sharing or Matching" from "Uniform

Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations"

3. [45 CFR 92.24](#), "Cost Sharing or Matching" from "Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments"

4. [HHS GPD Part 3.02: Post-Award – Matching and Cost Sharing](#)

5. [HHS GPD Part 3.03: Post Award - Program Income](#)

6. [NIH GAM 4301-201](#) , Facilities & Administrative Costs & Other Cost Policies

7. [NIH GAM 4303-203](#), Post-Award: Program Income

8. [NIH GAM 4304-204A](#), Post Award: Construction, Alterations & Renovations, and Real Property Construction

9. [NIH Manual Chapter 55807](#), Submission and Receipt of Financial Status Reports

10. [NIH Manual Chapter 1743](#), Keeping and Destroying Records

E. Definitions:

1. **Matching or Cost Sharing:** The value of third party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal government. Matching or cost sharing may be required by law or regulation. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

2. **Recipient Contributions:** Contributions the recipient bears for program or project purposes through cash outlay, including cash contributed to the recipient (or subrecipient or cost-type contractor under a grant) by third parties, or the provision of services.

F. Responsibilities:

1. Grants Management Officers are responsible for the following:

1. Reviewing draft FOAs and proposed program or other regulations to determine compliance with the requirements of the relevant HHS Action Transmittal and this GAM (see "**C. POLICY, 1. General**").

2. As participants in the review of applications and the negotiation of grant budgets, ensuring that if matching or cost sharing is not included in the FOA it is not introduced during review/negotiations as a means of reducing the potential Federal funding for individual awards.

3. Reviewing costs and contributions that applicants propose to meet a matching or cost sharing requirement and obtaining any necessary documentation from the applicant to ensure that the costs/contributions are appropriate and available to the applicant. The proposed costs/in-kind contributions must receive the same level of review and scrutiny as costs to be borne by Federal funds.

4. Preparing NoAs that conform to the requirements of this NIH GAM and 45 CFR 74.23 and 45 CFR 92.24.

5. Performing post-award administration activities ("**C. POLICY, 3. Post-Award Considerations**") to ensure compliance with a matching or cost sharing requirement including:

    1. Reviewing the FSR and other documentation to determine whether matching or cost sharing is being provided and whether the rate of expenditure is appropriate.

    2. Adjusting award amounts or taking an enforcement action, as necessary, if a recipient fails to meet a matching or cost sharing requirement.

    3. Determining if another program's/agency's funds proposed as matching or cost sharing may be used to match or cost

share funds in the program(s) under their cognizance.

2. Program Officials are responsible for the following:

1. Ensuring that the program office has an adequate statutory or regulatory basis for including a matching or cost-sharing requirement in an FOA.

2. Preparing FOAs and including the appropriate cost sharing/matching requirements as applicable (see "**C. POLICY, 1. General**").

3. Reviewing applications and monitoring the peer review process ensuring that if matching or cost sharing is not included in the FOA it is not introduced during review/negotiations as a means of reducing the potential Federal funding for individual awards.

4. Working in partnership with the Grants Management Official to review costs and contributions that applicants propose to meet a matching or cost sharing requirement; obtaining any necessary documentation from the applicant to ensure that the costs/contributions are appropriate and available to the applicant. The proposed costs/in-kind contributions must receive the same level of review and scrutiny as costs to be borne by Federal funds.

5. Performing post-award programmatic activities ("**C. POLICY, 3. Post-Award Considerations**") to ensure compliance with a matching or cost sharing requirement.

G. Procedures:

1. **Application Process**: The source and amount of funds proposed by an applicant to meet a matching or cost sharing requirement must be identified in the application. The applicant will be required to demonstrate that the funds are committed or available prior to NoA.

2. **Award Process**: The NoA will reflect the NIH (Federal share) and the grantee's share (non-Federal share) of the total approved budget. Prior approval and other dollar thresholds are determined on the basis of the total approved budget unless otherwise specified. The terms of award should stipulate the matching requirements as a percentage (i.e. 50%) and a dollar amount. This is based on the total allowable costs incurred.

3. **Post-Award**: All costs used to satisfy matching requirements must be documented by the grantee and shall be subject to audit. The grantee should provide matching in proportion to its expenditure of the NIH dollars awarded. However, grantees are not required to provide their matching prior to drawing down NIH funds.

   If a grantee is not providing matching or cost sharing at an acceptable rate or is unable to provide required matching or cost sharing the Institute/Center (IC) should assess the reasons, review statements and assurances contained in the application, and determine the flexibility it has, if any, in modifying the requirement and the extent to which special conditions or sanctions should be applied.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this NIH GAM must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Section 1100--General Administration, item G. Committee Management: Charted Federal Advisory Committees (and all other items that apply), and Section 4000--Grants and Awards (all items that apply).

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted

over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

The purpose of this NIH GAM is to present the policies, procedures and responsibilities for the management of matching and cost sharing requirements for NIH grants.

Office Responsible for Reviewing Management Controls Relative to the NIH GAM: The Office of Policy for Extramural Research administration (OPERA), Office of Extramural Research (OER).

Frequency of Review: The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a

more frequent and/or detailed review and will receive the highest priority in the review schedule. A management control review of this issuance will be conducted no less than every 4 years.

Method of Review: OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the [GMAC Policy and Procedure Announcement 2000-01](#). This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

Review Reports are sent to: The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

NIH POLICY MANUAL

4303-203 - Post Award: Program Income

Issuing Office: OER/OPERA (301)-435-0949

Release Date: 9/10/2008

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1. **Explanation of Material Transmitted:** This new NIH Grants Administration Manual (NIH GAM) sets forth the requirements for program income earned under NIH grants and cooperative agreements (hereinafter referred to as "grants"). This NIH GAM implements HHS Grants Policy Directive (GPD) Part 3.03, "Post Award – Program Income," supplements the program income provisions located in 45 CFR Part 74 and rescinds PHS Grants Administration Manual Part 149, "Program Income." In addition, this NIH GAM implements the responsibilities of NIH staff and grantees in monitoring and reporting program income. This is the first issuance of this NIH GAM.

2. **Filing Instructions:**

   Insert: Insert NIH Manual 4303-203 dated 9/10/2008..

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL: http://oma.od.nih.gov/manualchapters

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A. Purpose:

This NIH Grants Administration Manual (NIH GAM) sets forth the

requirements for program income earned under NIH grants and cooperative agreements (hereinafter referred to as "grants"). This NIH GAM implements HHS Grants Policy Directive (GPD) Part 3.03, "Post Award – Program Income," supplements the program income provisions located in 45 CFR Part 74 and rescinds PHS Grants Administration Manual Part 149, "Program Income." In addition, this NIH GAM implements the responsibilities of NIH staff and grantees in monitoring and reporting program income. This is the first issuance of this NIH GAM.

B. Background:

Until 1994, the administrative regulations (45 CFR Part 74) that govern NIH grants allowed grantees to use program income for costs which were in addition to the allowable costs of the project or program and which furthered the objective of the Federal statute under which the grant was made. This allowance was for those awards issued under the additive alternative. In 1994, 45 CFR Part 74 was revised to require grantees to use program income earned during the project period in accordance with the terms and conditions of award (59 Fed. Reg. 43754 (August 25, 1994) codified at 45 CFR Part 74). In 2001, NIH placed all grants and cooperative agreements under expanded authorities (NIH Guide for Grants and Contracts, "Revised Terms and Conditions For NIH Awards," 9/28/2001). With this change in terms of award, all grants were given the additive alternative for program income unless there is a concern with the recipient or activity, and the Institute/Center (IC) uses special terms and conditions, or the grant program requires a different program income alternative. (see "C. Policy, Exhibit 1" and "C. Policy, 5. Special Terms and Conditions").

C. Policy:

1. General

2. Accountability - Usage and Reporting
3. Licensing Fees and Royalties on Patents, Copyrights and Inventions
4. Sale of Equipment, Supplies and Real Property
5. Special Terms and Conditions (45 CFR 74.14)

1. General

Program income is gross income earned by a grantee, a consortium participant, or a contractor under a grant that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed, charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; and license fees and royalties on patents and copyrights. (Note: Program income from license fees and royalties from copyrighted material, patents, patent applications, trademarks, and inventions is exempt from financial reporting requirements; see **C. POLICY, 3. Licensing Fees and Royalties on Patents, Copyrights and Inventions□.**)

NIH grantees are encouraged to generate program income and to maximize such income, consistent with the purpose and nature of the grant or activities carried out under the grant. In addition, NIH grantees are required to:

1. monitor all gross program income;
2. use program income in a manner that is consistent with the terms of award; and,
3. report net program income on the [Financial Status Report (FSR) - SF 269- Long Form](#).

Generally all awards issued by NIH ICs reflect the additive alternative for

all grantees, including for-profit entities, unless there is a concern with the recipient or activity, and the IC uses special terms and conditions, or the grant program requires a different program income alternative.

Consortium agreements and contracts under grants are subject to the terms of the consortium agreement or contract with regard to the program income generated by the activities, but the terms specified by the grantee must be consistent with the requirements of the grant award.

2. Accountability - Usage and Reporting

Accountability refers to specifying how the income is to be used, whether the income needs to be reported to NIH, and for what length of time. Alternatives are described in the Exhibit 1 chart below.

Program income earned during the period of grant support shall be retained by the grantee according to the alternative applied and must be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award.

Unless otherwise specified in the terms and conditions of the award, NIH grantees are not accountable for program income accrued after the period of grant support.

Exhibit 1. Use and Applicability of Program Income Alternatives		
Program income alternative Use of program income	**Applicability**	
Additive Alternative	Added to funds	**Applies to all NIH**

	committed to the project or program and used to further eligible project or program objectives.	**awards** unless there is a concern with the recipient or activity or the grant program requires a different alternative.
Deductive Alternative	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based.	Available for use by NIH programs on an exception basis.
Combination Alternative*	Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.	Available for use by NIH programs on an exception basis.
Matching Alternative	Used to satisfy all or part of the non-Federal share of a project or program.	Available for use by NIH programs that require matching.
*The Combination Alternative (combining the Additive & Deductive Alternatives) is available for research projects where a significant		

> **amount of program income is anticipated. It allows an appropriate level of monitoring when deemed necessary.**

With the exception of income earned from licensing fees and royalties for copyrighted material, patents, patent applications, trademarks and inventions made under an award, grantee institutions are required to report the amount of net program income earned and the amount expended on the Financial Status Report ([FSR SF 269 Long Form](#)). Any allowable costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported. Grantees are responsible for the monitoring and reporting requirements detailed in the [NIH Grants Policy Statement](#)(NIH GPS), the reporting requirements included in the [PHS 398](#), Public Health Service Grant Application☐, the [SF424 Research and Related (R&R) Application for Federal Assistance](#)☐, and the [PHS 2590](#), Noncompeting Continuation Progress Report for a Public Health Service Grant.☐ In addition, the grantee shall disburse funds made available from program income before requesting additional cash payments unless the terms and conditions of the grant/program indicate an alternate use of the program income.

The amount of program income earned and the amount expended must be reported on the FSR (SF 269 Long Form). Program income subject to the additive alternative must be reported on lines 10r and 10s, as appropriate, of the FSR; program income subject to the deductive alternative must be reported on lines 10c and 10q of the FSR; and program income subject to the matching alternative must be reported on lines 10g and 10q of the FSR.

Program income resulting from license fees and royalties from copyrighted

material, patents, patent applications, trademarks, and inventions is exempt from these reporting requirements (see **C. POLICY, 3. Licensing Fees and Royalties on Patents, Copyrights and Inventions**☐).

3. Licensing Fees and Royalties on Patents, Copyrights and Inventions

NIH grantees do not have to report program income earned from licensing fees and royalties or for copyrighted material, patents, patent applications, trademarks, and inventions made under an award unless specific terms and conditions of the NoA provide otherwise. For example, the NoA may include special terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

However, the regulations implementing the Bayh-Dole Act (37 CFR §§ 401(8) and 401.14(h)) require reporting on utilization of subject inventions, including the reporting of income resulting from NIH-funded inventions. Specifically, as part of the annual invention utilization report, grantees must report income generated by all subject inventions to which title has been elected and by inventions that have been licensed but not patented (see NIHGPS [rev. 12/2003] and iEdison.gov).

4. Sale of Equipment, Supplies, and Real Property

Equipment and supplies purchased by non-profit institutions of higher education or non-profit organizations (whose principal purpose is the conduct of scientific research) which receive NIH grants for basic or applied research are exempt from any requirement to account for the proceeds from the sale of the equipment or supplies purchased under these grants. However, NIH has certain rights with respect to such property as specified in the NIHGPS (rev. 12/2003), at Administrative Requirements"Management Systems and Procedures"Property

[Management System Standards](#).☐

All other types of grants and grantees are subject to the requirements in 45 CFR 74.34 or 45 CFR 92.32, as applicable, if title to the equipment vests in the grantee rather than in NIH. If the grant-supported project or program for which equipment was acquired is still receiving NIH funding at the time of sale, the grantee must credit the NIH share of the proceeds to the grant and use that amount under the deductive alternative for program income. If the grantee is no longer receiving NIH grant support, the amount due should be paid in accordance with instructions from NIH. These grants and grantees may also be subject to the requirements in 45 CFR 74.35 or 45 CRF 92.33, as applicable with respect to the use or sale of unused supplies.

The requirements that apply to the sale of real property are addressed in [NIH GAM 4304-204A](#), "Post Award" Construction, Alteration and Renovations, and Real Property.

5. Special Award Conditions (45 CFR 74.14)

If NIH imposes special terms and conditions under the provisions of 45 CFR 74.14, then the deductive alternative must be used as a term and condition of NIH grant awards.

D. References :

1. Patent and Trademark Laws Amendments, [35 USC 200-212](#)
2. Citations from 45 CFR Part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations,☐ including (but not limited to): 45 CFR 74.22, Payment; 45 CFR 74.24, Program Income; 45 CFR 74.34,

Equipment; and, 45 CFR 74.35, Supplies. (www.gpoaccess.gov/ecfr/)

3. Citations from 45 CFR Part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments,☐ including (but not limited to): 45 CFR 92.21, Payment; 45 CFR 92.25, Program Income; 42 CFR 92.32, Equipment; and 42 CFR 92.33, Supplies. (www.gpoaccess.gov/ecfr/).

4. [HHS GPD 3.03, Post Award "Program Income"](#)☐

5. [HHS GPD 3.07, Post-Award " Termination and Enforcement"](#)☐

6. [NIH Grants Policy Statement (rev. 12/2003)](#)

7. [PHS 398, Public Health Service Grant Application](#)

8. [SF424 Research and Related (R&R) Application](#)

9. [PHS 2590, Noncompeting Continuation Progress Report](#)

10. [NIH GAM 4304-204A](#), Post Award: Construction, Alterations and Renovations, and Real Property☐

11. [NIH GAM 4304-204B](#), Post-Award: Equipment, Supplies, Inventions and Patents, and Debt Instruments☐

12. NIH GAM 4307-307A, Termination and Enforcement☐ (pending release)

13. [NIH Manual Chapter 1743](#), Keeping and Destroying Records

E. Definitions :

1. **Program Income:** Gross income earned by a grantee that is directly generated by the grant-supported project or activity or earned as a result of the award.

2. **Accountability:** Whether NIH will specify how the income is to be used and whether the income needs to be reported to NIH and for what length of time.

F. Responsibilities:

1. Grants Management Officer (GMO)

GMOs are required to indicate the appropriate use of program income on each Notice of Award (NoA), be aware of the types of grant mechanisms and research activities that have the potential to generate program income, and to assure the appropriate monitoring for these mechanisms and activities. Appropriate monitoring includes, as applicable, review of information provided in annual progress reports and financial reports, consulting with Program Officials as necessary to determine if there has been any impact on the approved scope and budget, and if any change in award terms is necessary. Program income earned during the period of grant support shall be retained by the grantee and used in accordance with the alternative specified by NIH in the NoA.

2. Program Official

In consultation with the GMO as necessary to determine if there has been any impact on the approved scope and budget, and if any change in award terms is necessary.

G. Procedures:

Grantees must have accounting systems and procedures in place to identify program income with the specific grant that generated it. If program income had not been anticipated in the grant application or is different from the amount anticipated, the grantee shall indicate, as applicable, the source of the program income and the reason for the change from the estimate under â€œRemarks (FSR, SF 269-Long Form). Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported.

The amount of program income earned and the amount expended must be reported, by the grantee, on the FSR (SF 269 Long Form). Program income subject to the additive alternative must be reported on lines 10r and 10s, as appropriate, of the FSR; program income subject to the deductive alternative must be reported on lines 10c and 10q of the FSR; and program income subject to the matching alternative must be reported on lines 10g and 10q of the FSR. In addition, grantees must report program income according to the instructions in the PHS 2590, â€œNoncompeting Progress Report for a Public Health Service Grant.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this NIH GAM must be retained and disposed of under the authority of NIH [Manual 1743, Keeping and Destroying Records], Appendix 1, NIH Records Control Schedule, Section 4000--Grants and Awards (all that apply), Section 1100--General Administration, Item L. Patents, Inventions, and Licensing (and any other items that apply), and Section 2600--Procurement, Property and Supply Management (all that apply).

NIH e-mail messages: NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees, supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided

to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

The purpose of this NIH GAM is to present the policies, procedures and responsibilities for the management of program income earned under NIH grants.

Office Responsible for Reviewing Management Controls relative to this NIH GAM: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

Frequency of Review: The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. NIH GAMs with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

Method of Review: OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The MCCM Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order

to determine NIH-wide compliance.

Review Reports are sent to: The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officer(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

NIH POLICY MANUAL

4304-204A- Post Award: Construction, Modernization, or Alteration
and Renovations of Research Facilities

Issuing Office: OER/OPERA (301) 435-0949

Release Date: 9/10/2008

1. **Explanation of Material Transmitted:**

This new NIH Grants Administration Manual (NIH GAM) provides guidance to NIH program and grants management staff on the administration of NIH construction (funded under the C06 or UC6 activity code) and modernization (generally funded under the C06 and G20 activity codes) grants and cooperative agreements (hereafter referred to as "grants"). It also applies to major alteration and renovation (A&R), which are individual projects exceeding $500,000 in direct costs funded under a research project or other grant mechanism. A&R funded under a center grant is not subject to the requirements of this NIH GAM, regardless of the direct cost total. In addition, individual A&R projects costing $500,000 or less in direct costs generally are not subject to the requirements of this NIH GAM unless the A&R activity is considered "construction" or "modernization" (see E. Definitions). Policies governing the administration of minor A&R projects are located in their entirety in the NIH Grants Policy Statement (NIHGPS), "Selected Items of Cost." However, all NIH grant-related activities, whether or not they include construction or major A&R activities, are subject to the Federal historic preservation law as described in Section 106 of the National Historic Preservation Act of 1966 [see G. 2. e. (iii) below]. The topics of equipment, supplies, inventions and patents and debt instruments, also included in HHS GPD 3.04 are addressed in NIH GAM 4304-204B, "Post Award:

Equipment, Supplies, Inventions and Patents and Debt Instruments."

This NIH GAM implements Health and Human Services (HHS) and NIH regulations and those portions of HHS Grants Policy Directive (GPD) 3.04, "Property" that apply to construction and modernization grants and A&R. In addition, this NIH GAM is a supplement to the NIHGPS. This NIH GAM rescinds PHS Grants Administration Manual (PHS GAM) Parts 111, "Alteration and Renovation of Facilities with PHS Grant Funds Appropriated Under Discretionary Grant Programs Without Construction Authority;" 140, "Protecting the Federal Interest in Real Property Acquired with PHS Grant Support;" and 401-410, "Construction Grants."

2. **Filing Instructions:**

   Insert: NIH Manual 4304-204A dated 9/10/2008. .

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL: http://oma.od.nih.gov/manualchapters

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A. Purpose:

This NIH Grants Administration Manual (NIH GAM) provides guidance to NIH program and grants management staff on the administration of NIH construction (funded under the C06 or UC6 activity code) and modernization (generally funded under the C06 and G20 activity codes) grants and cooperative agreements (hereafter referred to as "grants"). It also applies to major alteration and renovation (A&R), which are individual projects exceeding $500,000 in direct costs funded under a research project or other

grant mechanism. A&R funded under a center grant is not subject to the requirements of this NIH GAM, regardless of the direct cost total. In addition, individual A&R projects costing $500,000 or less in direct costs generally are not subject to the requirements of this NIH GAM unless the A&R activity is considered "construction" or "modernization" (see E. Definitions). Policies governing the administration of minor A&R projects are located in their entirety in the NIH Grants Policy Statement (NIHGPS), "Selected Items of Cost." However, all NIH grant-related activities, whether or not they include construction or major A&R activities, are subject to the Federal historic preservation law as described in Section 106 of the National Historic Preservation Act of 1966 [see G. 2. e. (iii) below]. The topics of equipment, supplies, inventions and patents and debt instruments, also included in HHS GPD 3.04 are addressed in NIH GAM 4304-204B, "Post Award: Equipment, Supplies, Inventions and Patents and Debt Instruments."

This NIH GAM implements Health and Human Services (HHS) and NIH regulations and those portions of HHS Grants Policy Directive (GPD) 3.04, "Property" that apply to construction and modernization grants and A&R. In addition, this NIH GAM is a supplement to the NIHGPS. This NIH GAM rescinds PHS Grants Administration Manual (PHS GAM) Parts 111, "Alteration and Renovation of Facilities with PHS Grant Funds Appropriated Under Discretionary Grant Programs Without Construction Authority;" 140, "Protecting the Federal Interest in Real Property Acquired with PHS Grant Support;" and 401-410, "Construction Grants."

B. Background:

Over the last several years, NIH has experienced a significant expansion of its construction and modernization programs. The NIHGPS includes guidance and the award terms and conditions for construction and modernization grants and A&R activities funded as part of a grant. General extramural policies are adequately covered under the NIHGPS and are not repeated in this NIH GAM, although in several sections there are references to the NIHGPS, specifically the sections entitled "Construction, Modernization or Major Alteration and Renovation of Research Facilities," and "Selected Items of Cost, Alteration and Renovation" as a source for additional information.

However, NIH has determined that additional internal guidance is necessary for program and grants management staff responsible for the solicitation, award, and management of grants involving construction, modernization, and major A&R projects. This NIH GAM should be used in conjunction with the NIHGPS for a complete understanding of the requirements.

C. Policy:

1. Institutes and Centers (ICs) program and grants management staff are required to comply with the policies and procedures contained in this NIH GAM unless a deviation has been approved in accordance with the OER Policy Announcement 1997-02 dated January 30, 1997.
2. Individual programs are permitted to supplement both the extramural and internal guidance as long as that supplemental guidance is consistent with and does not deviate from the requirements of the NIHGPS and this NIH GAM.
3. An IC may fund minor A&R costs when allowed based on the type of grant or recipient. An IC must have statutory authority to fund construction or modernization grants or major A&R projects. If authorized by statute, NIH ICs may make awards for or fund costs associated with the following:
   o Grants for construction of a new building,
   o Grants for modernization of existing research facilities,
   o Major A&R projects under a grant if the type of grant/mechanism allows such activity.

D. References:

1. National Center for Research Resources authorizing legislation – Sections 481A and 481B of the Public Health Service Act, as amended by Sections 303 and 304 of Public Law 106-505 (42 U.S.C. 287a-2 and 287a-3)
2. Sections 301 and 405 of the Public Health Service Act, as amended (42 U.S.C. 241 and 284)
3. [42 CFR Part 52a, National Institutes of Health Center Grants](#)

4. [42 CFR Part 52b, National Institutes of Health Construction Grants](#)
5. [45 CFR Part 74,](#) Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations
6. [45 CFR Part 92](#), Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments
7. [Executive Order 11514](#), Protection and Enhancement of Environmental Quality, March 5, 1970
8. [Executive Order 12372](#), Intergovernmental Review of Federal Programs, July 14, 1982
9. [Executive Order 13287](#), Preserve America, March 3, 2003
10. [Office of Management and Budget (OMB), Intergovernmental Review (State Single Point of Contact (SPOC) List](#))
11. [NIH Grants Policy Statement](#) (2003 version or its successor)
12. [NIH Delegation of Authority 1130,](#) Program: Grants and Awards 01 Grants-in-Aid
13. [NIH Manual Chapter 1743](#), "Keeping and Destroying Records"
14. [HHS GPD Part 2.03](#), Information for Potential Applicants Competing for Grants
15. [HHS GPD Part 3.02](#), Matching and Cost Sharing
16. [HHS GPD Part 3.04](#), Property
17. [NIH Design Policy Guidelines](#) (issued by the Office of Research Facilities Development and Operations)
18. [OER Policy Announcement 1997-02, Single-Case Deviation from PHS/NIH Grants Policy, January 30, 1997](#)

E. Definitions:

This NIH GAM uses the following definitions:

1. Construction: Construction of a new building or the modernization of, or completion of shell space in, an existing building (including the installation of fixed equipment, but excluding the cost of land and off-site improvements). The construction of "shell" space is not allowable as a construction activity since that

space does not provide usable space for research activities.

2. Modernization: Alteration, renovation, remodeling, improvement, expansion, and/or repair of an existing building and the provision of equipment necessary to make the building suitable for use by a particular program.

3. Major A&R: An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving modernization, improvement or remodeling, exceeding $500,000 in direct costs. Major A&R is an unallowable activity or cost under foreign grants and domestic grants with foreign components.

4. Minor A&R: An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving improvement or remodeling, which does not exceed $500,000 in direct costs. Minor A&R is not an allowable activity or cost under grants to individuals or grants for limited purposes, such as grants in support of scientific meetings (conference grants). Routine maintenance and repair of the organization's physical plant or its equipment is not considered A&R; these types of costs are typically treated as facilities and administrative (F&A) costs. If the A&R activity will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in G. 2. e. (3) below must be followed. Policies for individual A&R projects that are treated as direct costs and that will not exceed $500,000 are located in their entirety in the NIHGPS, "[Selected Items of Cost](#)" and the section entitled "[Construction Grants, Administrative Requirements, Prior-Approval Requirements, Alteration and Renovation Projects under Nonconstruction Grants](#)."

F. Responsibilities:

The following NIH officials/offices/functions have responsibilities for construction and modernization grants and major and minor A&R projects as specified.

1. Grants Management Officer (GMO):

The GMO is the NIH official responsible for the business management and other non-programmatic aspects of grants. Specific responsibilities associated with the award of construction or modernization grants or grants involving major A&R projects include review of the funding opportunity announcement and program guidelines; administrative review of applications for compliance with statutes, regulations, policies, and guidelines; and ensuring post-award and post-grant (post-closeout) compliance, including monitoring facility usage requirements and timely receipt of documents and reports required of grantees. The GMO also ensures that systems are in place to monitor any required post-performance compliance, e.g., reporting of income received after the period of support, continued use of the facility for purposes consistent with those of the award, and recoupment of the Federal share of sales proceeds or amortized value. When minor A&R funds are involved, the GMO ensures the allowability of costs and ensures that the A&R activity meets the criteria outlined in the NIH GPS. The GMO is the NIH official with authority to obligate/release grant funds and remove restrictions imposed by NIH following the approval of the grantee's working drawings and specifications.

2. Grants Management Specialist (GMS):

The GMS is an agent of the GMO and is assigned responsibility for the day-to-day management of grants. The GMS is responsible for completing the grants management checklist (see Appendix III) prior to preparing a Notice of Award (NoA) for a construction or modernization grant or another type of grant that includes funding for major A&R. When minor A&R costs are involved, the GMS is responsible for ensuring the allowability of A&R costs and that the A&R is consistent with the criteria and documentation requirements outlined in the NIHGPS, "Selected Items of Cost" and the section entitled "Construction Grants, Administrative Requirements, Prior-Approval Requirements, Alteration and Renovation Projects under Nonconstruction Grants." The GMS is responsible for obtaining architectural/engineering advice from the responsible IC program official or utilizing the services of expert consultants, including those located in the Office of Research Facilities Development and Operations (ORF), to review minor

A&R documentation submitted by applicants/grantees, as needed.

3. Program Official (PO):

The PO is the NIH official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. Specific responsibilities associated with the award of construction or modernization grants or grants involving major A&R projects include the development of the funding opportunity announcement and program guidelines; coordination with the Scientific Review Administrator in the review of applications; addressing the questions outlined in the Program checklist (see Appendix IV) prior to the issuance of an award; post-award monitoring of the progress of the construction, modernization, or major A&R activity and review of documents submitted by grantees, including working drawings and specifications, prior-approval requests, and reports; and post-grant (post-closeout) activities, such as reviewing alternate usage requests during the period for which the grantee remains accountable for usage. Where needed expertise is not available within the IC, the PO may elect to use the services of expert consultants, including those located in the ORF or an outside architectural and engineering (A&E) firm, to review construction-related documents submitted by applicants/grantees.

4. Scientific Review Officer (SRO):

SROs are health science administrators who manage the activities of Scientific Review Groups (SRGs). For the SRG for which he or she is responsible, the SRO reviews applications for completeness and conformity to NIH requirements; ensures that adequate numbers of reviewers with appropriate expertise are available for application review; assigns applications to individual reviewers as discussion leaders and for preparation of written critiques; and serves as the overall point of contact with applicants during the initial phase of the peer review process, i.e., until the conclusion of the SRG meeting. Construction and modernization grant applications generally are reviewed by an IC SRG rather than by a Center for Scientific Review (CSR) SRG.

5. Office of Research Facilities Development and Operations:

ORF is the NIH office responsible for all aspects of facility planning, construction, renovation, and maintenance of NIH facilities. ORF is responsible for development and maintenance of the NIH Design Policy and Guidelines. The NIH Design and Policy Guidelines are being revised and are expected to be published no later than September 2008 under the new name, " NIH Design Requirements Manual." The PO may ask ORF to conduct the review of working drawings and specifications for NIH-funded construction, modernization, or major A&R projects. ORF, in consultation with the PO, may work directly with the grantee in preparing and submitting acceptable required working drawings and specifications for NIH approval. In addition, ORF is required to return the working drawings and specifications to the IC GMO for filing in the official grant file (See Section I. Records Retention and Disposal).

G. Procedures:

1. **Pre-Award Activities**
   a. **Program Planning:** In planning a construction or modernization grant program, the PO, in consultation with the GMO and SRO, shall ensure the following:
      i. That the program is implemented consistent with the authorizing statute and other applicable statutes, regulations, and policies, including seeking advice from the Office of the General Counsel (OGC) as necessary;
      ii. Adequate consideration is given to the appropriate award instrument (see discussion below regarding "Support Mechanism");
      iii. Funding opportunity announcements and application instructions are compliant with statutory, regulatory, and policy requirements and are complete and clear;
      iv. Maximum feasible opportunity is provided to applicants to prepare and submit high-quality applications;
      v. Adequate time is available for peer review; and

vi.   Sufficient time is available to complete any required environmental and historic preservation reviews and prepare a NoA protecting the Federal government's interests in the property.

b. **Funding Opportunity Announcement (FOA):** In developing the FOA (Request for Applications [RFA] or program announcement [PA]) for a construction or modernization program, the PO, in consultation with the GMO, must consider the following and address each consideration in the FOA, as appropriate. Consideration of these issues in advance of developing the FOA will expedite its issuance. This section also addresses applicable requirements for major A&R projects.

   i.   *Type of Funding Opportunity Announcement:* Construction and modernization grants may be awarded in response to an RFA or PA. However, because funding for construction and modernization programs is typically limited to availability in the current fiscal year (FY), an RFA generally should be used to solicit construction or modernization grant applications.

   ii.   *Authorizing Legislation, Appropriations Act, and Regulatory Requirements*, including funds availability, program objectives, matching requirement (see below), and eligibility.

   iii.   *Support Mechanism*—grant or cooperative agreement: If substantial programmatic involvement by NIH staff in the construction or modernization activity is anticipated, the IC should use a cooperative agreement. Review and approval of working drawings and specifications and routine monitoring of construction or modernization activity are not considered substantial programmatic involvement and, therefore, do not of themselves require use of a cooperative agreement.

   iv.   *Eligibility:*

        (a). Unless limited by the authorizing statute, public and private nonprofit organizations located in the United States or in U.S.

territories or possessions generally are eligible for construction and modernization grants. If a program chooses to limit eligibility beyond that specified in the statute, a justification for limited competition is required. For-profit organizations, foreign organizations and Federal institutions are not eligible for construction or modernization grants.

(b). Because IC review and approval of final architectural drawings and specifications is required, applicants may not submit applications for construction or modernization grants that were advertised or put out for bid or where construction or modernization is underway at the time of application. For major A&R projects, if these activities occur before award or approval of the project, the associated costs will not be allowable.

(c). Generally, projects should not be advertised or put out for bid before the expected start date of the award; however, in exceptional cases, NIH may approve the start of the activity after submission of the application but before the date of the award (see G.2.a., "Award Activities —Construction/Modernization/A&R Status" below).

v.   *Unallowable Activities:* A&R (major or minor) is not an allowable activity under grants to Federal institutions. Major A&R is not an allowable activity under foreign grants or domestic grants with foreign components.

vi.   *Use of SF 424 R&R:* Applicants will be instructed in the FOA whether to use the SF 424 (R&R) for NIH construction or modernization projects as well as for requests for support of major A&R projects. The applicant must download the application package and instruction for a specific FOA through the NIH Guide for Grants and Contracts or the Grants.gov APPLY web site. The

SF424 "family" of forms can be found at:
http://apply07.grants.gov/apply/FormLinks?family=15.

vii. *Intergovernmental Review under Executive Order (EO) 12372*:
FOAs that announce the availability of construction or
modernization grants or funding for major A&R support must
include language specifying that applications submitted under that
FOA are subject to EO 12372 as implemented by the State in which
the applicant is located. The IC should consider the time associated
with the State Single Point of Contact (SPOC) review of
applications (60 days from the established deadline date for receipt
of applications) when determining the schedule for application
receipt, review, and award. Applicants must transmit any comments
resulting from the State's review to the IC. Comments should be
submitted with the application or as soon as they are received if the
application has already been submitted.

States may choose not to participate in the intergovernmental
review process and, in those cases, will not have a SPOC. In other
cases, States with SPOCs may choose to exclude applications
under particular programs from SPOC review. The list of SPOCS
can be found at http://www.whitehouse.gov/omb/grants/spoc.html.
For guidance on responding to comments or accommodating
intergovernmental concerns, IC staff should refer to 45 CFR Part
100, Intergovernmental Review of Department of Health and
Human Services Programs and Activities. Note: This Executive
Order (EO) is applicable to the G20 program only if the FOA invites
applications that involve major A&R.

viii. *Matching:*

(a). The FOA must explicitly state if matching will be required under
a construction or modernization grant. If matching is required, the

announcement must state the manner in which proposed matching or cost sharing will be evaluated in the peer review process.

(b). The FOA also must specify whether any required matching must be in the form of allowable costs incurred by the grantee or a contractor under the grant or the value of third-party in-kind contributions to meet a matching requirement (if authorized). Third-party in-kind contributions are the value of goods and/or services third parties donate for program or project purposes without charge to a recipient (or subrecipient or cost-type contractor under a grant). NIH generally does not allow grantees to use the value of third-party in-kind contributions to meet a matching requirement.

(c). Applicants must be instructed to identify the source and amount of funds proposed to meet the matching requirement in the application. The authorized organizational representative must assure that the identified matching is or will be available for the grant should it be awarded. To be allowable as matching, costs and in-kind contributions (if authorized) must meet the allowability and documentation requirements of 45 CFR 74.23 or 45 CFR 92.24, as applicable.

(d). Examples of allowable matching include institutional reserves, donations, bonds, or pledges. If the matching is in the form of pledges, a statement from the bank or lending institution as to the discounted value should be submitted along with a statement that there are sufficient institutional funds available should the pledges not materialize. If the matching funds are contingent, a description of the contingency should be included. If appropriations from State or local governments are available or will be available as part of the match, the amount and date of availability should be

included. Other sources of matching, such as bonds or mortgages, should be described.

(e). Federal funds received by the applicant/recipient under another Federal assistance award may not be used to meet any part of the matching share unless the authorizing legislation for such funds permits such usage.

(f). GPD Part 3.02 and NIH GAM 4302.202 provide additional guidance on matching.

ix. *Operation of Facility:* The applicant must be instructed to address in the application the availability of funds for operation of the facility throughout the usage period to ensure the effective use of the facility for the intended purposes.

x. Special requirements include, but are not limited to, the following:

(a). NIHGPS: Indication that the NIHGPS section, Construction, Modernization or Major Alteration and Renovation of Research Facilities, is applicable and will be included as a term and condition of award.

(b). *National Environmental Policy Act of 1969* (NEPA), including Public Disclosure, Section 102 of NEPA and EOs 11514 and 13287: It is the IC's responsibility to determine the applicability of NEPA. Applicants may use the "Review of Environmental and Other Impacts" document (see Appendix 1) to assess the environmental impact associated with the proposed project. The following language shall be included in FOAs for construction or modernization grants or that may provide funding for major A&R projects:

"NIH must comply with the National Environmental Policy Act of 1969 (NEPA) for any actions using NIH funds or property that may affect the environment. Because projects for construction, modernization, or major A&R activities have the potential to affect the environment, NIH requires that applicants for this type of support provide information on anticipated environmental impact as part of their applications. Applicants may use the "Review of Environmental and Other Impacts" document that is available at (http://www.ncrr.nih.gov/research_infrastructure/environmental_analysis_suggested_checklist.pdf) as part of the application package to supply this information. An alternate format can be used as long as equivalent environmental and other impacts information accompanies the application."

NIH will review the information on anticipated environmental impacts contained in the application to assess the level of environmental impact of the proposed project. It is the responsibility of NIH to determine which of the following will apply to the proposed project:

- Environmental Impact Statement (EIS): a document required of federal agencies by NEPA for major projects or legislative proposals significantly affecting the environment. A tool for decision making, it describes the positive and negative effects of the undertaking and analyzes reasonable alternative actions and mitigation measures.

- Environmental Assessment (EA) An environmental

analysis prepared pursuant to the NEPA to determine whether a federal action would significantly affect the environment and thus require a more detailed environmental impact statement.

- No Further Action is Required.

If NIH determines that an EIS or EA is required, the applicant (recipient) must conduct the appropriate environmental review and provide the necessary documentation to NIH for review, approval, and further processing. NIH will provide advice and assistance to the applicant (recipient), as necessary, concerning review procedures; evaluate the results of the review; and make the final decision on environmental impact as required by NEPA.

Applicants also must (1) provide a current listing and copies, as applicable, of all relevant licenses, permits, and/or other approvals required (these would include, but would not be limited to, the state and local air, water quality, and zoning board reports), and (2) indicate the state, local, and regional planning authorities contacted or consulted regarding the application and briefly discuss the proposed facility with respect to regional development plans. >

Applicants are not required to incur costs for extensive consultant services at the application stage; therefore, hiring of consultants to develop detailed data and elaborate presentations is discouraged and such costs generally will not be allowable as pre-award costs."

(c). *National Historic Preservation Act, Archaeological and Historic Preservation Act of 1960, and EO 13287*: Under the provisions of the National Historic Preservation Act, as amended (16 U.S.C. 470

et seq.), the Archaeological and Historic Preservation Act of 1960, as amended (16 U.S.C. 469a-1 et seq.), and EO 13287, the Secretary of the Interior has compiled a National Register of Historic Places—sites and buildings of significant importance to U.S. history[1]. These statutes require that, before approval of a grant related activity, NIH take into account the effect on these sites of the proposed activity. NIH is primarily responsible for determining whether activities will affect a property listed in the National Register or one that meets the eligibility criteria for inclusion, even if not included in the National Register at the time the application is submitted (see NIHGPS).

(d). *Individuals Eligible to Serve as the Project Director/Principal Investigator (PD/PI) on Construction or Modernization Grant Applications:* The FOA shall include any special eligibility criteria for individuals to serve as the PD/PI. Generally, the individual who serves as the PD/PI should be a senior institutional official (e.g., Dean or Vice President of Research) who has responsibility for the oversight of institutional research as well as the authority to commit institutional funds and resources.

(e). *Program-specific Design Requirements:* The IC shall consider the need for inclusion of special design requirements to ensure that the facility will support the intended research activity. For example, bio-containment facilities and research support laboratories must be designed to maximize safety in the work space and surroundings. Thus, stringent security and access control may need to be provided for the building. If so, these requirements must be communicated in the FOA so that the applicant can include the necessary costs in the application budget and describe in the application narrative how it plans to meet the required measures.

(f). *Insurance Requirements:* Information about the title and physical insurance requirements that will be required as a condition of the award (see NIHGPS and paragraphs 2.o. "Title Insurance" and q. "Physical Destruction Insurance" of this NIH GAM).

xi. *Review Criteria*: The FOA must clearly state the criteria by which applications will be evaluated. 42 CFR 52b.5 sets forth the criteria pursuant to which NIH must evaluate applications for construction grants. NIH review criteria and selection factors generally include:

- The priority score assigned to the application by an NIH peer review group;
- Scientific merit of the research activities that will be carried out in the proposed facility.
- The administrative and leadership capabilities of the applicant's officers and staff.
- The relevance of the project for which construction is proposed to the objectives and priorities of the particular program authorized by the Public Health Service Act.
- Research and financial need for the project and the need for appropriate geographic distribution of similar facilities.
- Scientific or professional standing or reputation of the applicant and of its existing or proposed PD/PI, officers and research staff.
- Relationship to the applicant's overall research programs and impact on relevant research programs and facilities in the geographic area and nationwide.
- Availability, by affiliation or other association, of other scientific or health personnel and facilities to the extent necessary to carry out the proposed research

program for the facility, including, when warranted, the adequacy of a biohazard control and containment program.

- Project cost and design.

  Because the construction grant regulations found at 42 CFR 52b do not apply to minor A&R funded under a research project grant, the standard peer review criteria (significance, approach, innovation, investigator, and environment) should be applied to such grants. Similarly, the construction grant regulations do not apply to A&R funded under an NIH center grant. Thus, a major A&R project requested as part of a center grant would be reviewed using the published review criteria for the center grant program, which may or may not include specific criteria for the review of a major A&R project.

xii. *Review Process - Peer Review:* Construction and modernization grant applications are subject to the NIH peer review process. Major A&R projects under grant applications also are subject to peer review because they are part of an overall application (or subsequent change in scope) that is subject to peer review. The review of these latter applications will follow normal CSR/IC procedures, as applicable. However, in these cases, the SRO should involve individuals with expertise necessary to evaluate the proposed A&R activity.

xiii. *Documentation Requirements*: The FOA must clearly specify documents required for submission with the application as well as those that will be required as a condition of the award (see Section I. Records and Retention and Disposal). Construction or

modernization applications typically require the following:

- Working drawings and specifications.
- Narrative description of proposed utilization of space.
- Detailed description of floor plan.
- Detailed cost estimate.
- Identification of special design problems.
- Description of existing utility systems and those proposed for new or modified space.
- Plans for handicapped accessibility.
- Description of safety criteria accommodated in the existing building and in the facility as modified.
- If property is leased, statement and documentation of length of lease.
- If the space represents a portion of the building, a description of the precise location of the grant-supported space.
- Time schedule for each major activity in the project

xiv. *Title to Site*: The FOA must instruct the applicant to include with the application a legal opinion describing the interest the applicant has in the performance site. The legal opinion should describe any mortgages or other foreclosable liens on the property, including the principal amount of the mortgage (and rate of interest); the dates of the mortgage; the terms and conditions of repayment; the appraised value of the property; and any provisions designed to protect the Federal interest in the property.

xv. *Post-construction Activities and Closeout*: The FOA should include information on close-out requirements and post-grant activities, i.e., facility usage requirements and monitoring facility usage compliance, if they differ from those contained in the NIHGPS.

c. **Program Guidelines:** If an IC issues program guidelines to supplement the FOA with detailed policy or procedural information for a construction or

modernization grant program, these guidelines must be referenced in the FOA and the NoA.

2. **Award Activities** (see sample PO and GMS checklists in Appendixes 3 and 4)

    a. **Construction/Modernization/A&R Status:** Prior to issuing an award, IC staff shall assess the status of the proposed construction, modernization, or major A&R activity to ensure the project's continued eligibility, i.e., the project should not normally have started nor should the project be advertised or put out for bid before issuance of the NoA until the grantee receives NIH approval of required design documents. On an exceptional basis, and with single-case deviation approval from the Chief GMO, the IC may approve the start of a construction, modernization, or major A&R activity prior to issuance of award. However, all terms and conditions of award that would otherwise apply to the award apply even in the absence of an award, e.g., the applicant must submit final working drawings and specifications for IC approval. Also, if this approval is granted, the applicant must use matching funds to cover all costs for construction, modernization, or major A&R that are incurred in advance of the effective date of award.

    b. **Single Point of Contact Comments** (SPOC): The SPOC approval letter must be in the official file for applications subject to EO 12372.

    c. **Title to Site:** The GMO is responsible for reviewing the legal opinion submitted with the application describing the interest the applicant has in the performance site. If the applicant has fee simple title (absolute ownership of real property in which the owner has the right to control, use and transfer the property at will) to the site, the legal or title opinion may simply state that the applicant holds fee simple title to the site free of all mortgages or other foreclosable liens to all land, rights-of-way, and easements necessary for the project. However if the applicant does not have a fee simple or other estate or interest in the site, the applicant must be able to ensure that the grant-supported space will be used for its intended purpose for the period of Federal interest (e.g., usually 20 years).

In those cases where the site and/or building is leased, the legal opinion should show that an undisturbed lease agreement exists that would extend for the period of Federal interest and that the terms of the lease do not preclude construction or post-occupancy activities proposed in the application.

d. **Budget:** The IC must review the estimated project costs to verify that all proposed budget items are allowable, reasonable, allocable, and necessary as specified in the NIHGPS and applicable cost principles.

e. **Special Requirements**

   i. *NEPA:* If NIH determines that NEPA applies to the grant-supported activities, the environmental aspects of the activity must be reviewed and evaluated by NIH before final action on the application. As provided in the FOA, the application must be accompanied by the "Review of Environmental and Other Impacts" document or equivalent information to facilitate review and evaluation for environmental concerns before approval or other action on the application. This review also includes determinations concerning floodplain management pursuant to EO 11988, Floodplain Management (May 24, 1977) (3 CFR, 1977 Comp., p. 117) and EO 11990, Protection of Wetlands (May 24, 1977) (3 CFR, 1977 Comp., p. 121).

   If, on the basis of the information provided by the applicant, NIH determines that there may be an environmental impact, the following activities should occur:

   (a). The applicant/recipient should be directed to prepare (or engage a contractor to prepare) an Environmental Assessment (EA) and submit the first draft to the NIH PO. The draft EA is normally circulated within the NIH, including ORF, for review and comment. Public notification may be required by the individual

State's requirements. The NIH may also direct an applicant/recipient to skip the EA preparation and proceed directly to preparing an Environmental Impact Statement (EIS) (see h).

(b). The PO will coordinate the review of the draft and provide consolidated comments to the applicant/recipient.

(c). Taking the NIH's comments into account, the applicant/recipient submits an electronic copy of the final draft EA to the PO, who ensures that all comments have been addressed.

(d). When the PO advises the applicant/recipient of the acceptability of the final draft EA, he or she will provide further instructions, e.g. required number of copies to submit to the PO.

(e). The NIH office/official responsible for environmental matters shall forward copies of the final draft EA to the State and any other stakeholders that need to review and comment on the draft EA and will be the focal point for receipt of comments.

(f). Once those comments are shared with the applicant/recipient, the applicant/recipient will be expected to incorporate them, responding to them appropriately.

(g). The applicant/recipient must submit final copies of the EA to the PO, who will provide them to the NIH environmental office/official.

(h). The NIH environmental office/official will prepare the Finding of No Significant Impact (FONSI) or memo of decision to prepare an EIS and provide the IC with the final letter of acceptance, which is then forwarded to the applicant/recipient.

ii. *Public Disclosure Requirement:* The GMO is responsible for

ensuring that the applicant has publicly disclosed the project and described its environmental impact in a newspaper or other publicly available medium prior to the issuance of an award pursuant to EO 11514.

iii. *National Historic Preservation:* If NIH determines that a grant related activity may affect an historic property or a potentially eligible historic property, NIH must follow the procedures indicated in Section 106 of the National Historic Preservation Act of 1966 and must consult with the NIH Federal Preservation Coordinator as well as the cognizant State or Tribal Historic Preservation Officer and obtain public input as required by this statute (see NIHGPS). If a designated historic property will be affected, the applicant must be instructed to obtain clearance from both the appropriate State Historic Preservation Office and Tribal Historic Preservation Office before submitting the application. The State Historic Preservation Liaison Officer or the National Trust for Historic Preservation may be contacted for additional details. If it is determined that the proposed project will have an adverse effect on the site, NIH must negotiate an appropriate mitigation plan before it may fund the project.

iv. *Applicant/recipient compliance with other applicable public policy requirements* as contained in the NIHGPS, e.g., civil rights, debarment, and lobbying.

f. **Operation of Facility:** The GMO, in consultation with the PO, shall review the adequacy of the applicant's response regarding the availability of funds for operating the facility for the duration of the required usage period.

g. **Overlap:** The GMO, in consultation with the PO, must determine if the application overlaps with any other Federal or non-Federal effort and/or support. In the event they determine there is overlap, based on the application or additional information requested from the applicant, NIH

shall negotiate with the recipient to restructure the project, if possible. NIH may not fund a grant or project where there is (or there is the potential for) duplication of funding.

h. **Certificate of Need:** The PO must determine if Certificate of Need (CON) requirements apply in the State in which the facility is located and, if so, whether the applicant has received a CON. A CON is issued as the result of a regulatory process that requires certain health care providers to obtain state approval before offering certain new or expanded services. The CON process is intended to help ensure that new services proposed by health care providers are needed for quality patient care within a particular region or community. Health providers requiring a CON for certain types of projects include hospitals that may receive NIH grants for construction or modernization. CON review covers not only new facility construction but also initiation of specialized hospital services, bed conversions, increases in the number of inpatient beds, and a variety of other projects which could significantly affect services or costs. Renovations to existing health care facilities that do not involve the addition of beds or services are not subject to a CON process.

i. **Matching:** The GMO, in consultation with the PO, reviews application submissions to verify compliance with the matching requirement as specified in the FOA. This includes determining that Federal funds under another Federal assistance award will not be used to meet any part of the matching share unless the authorizing legislation for such funds permits this usage. If it is determined that the applicant's assurance of the availability of matching is insufficient and more certainty is required, the GMO shall contact the applicant to request updated matching documentation.

If the applicant is requesting support for only a portion of the total construction project (for example, the renovation of two floors out of six), the GMO must obtain assurance that funds for the other portion of the

project are available. Lack of funds for non-NIH supported space might delay the completion of the NIH portion of the facility.

j. **Expanded Authorities:** Construction, Modernization or Alteration and Renovation awards generally do not permit the awardee to extend the final budget period of a project period without NIH prior approval. NIH retains this authority to consider extension requests due to the limitations imposed on the use of obligated Federal funds under Title 31 USC, Subtitle II, Chapter 15, Subchapter IV, Section 1552. Therefore, the terms and conditions of the award, must communicate this prior approval requirement as noted below.

k. **Notice of Award:** The budget period and project period dates will be the same for a C06, UC6, and G20 award because these are not funded under the project period system, i.e., they do not involve continuation awards. The budget period/project period dates for a construction or modernization grant can extend beyond a one year period. Major A&R projects funded as part of a grant mechanism are subject to the traditional budget and/or project period system of funding. The NoA must reflect both the Federal and any non-Federal (matching) share of the total allowable costs.

Terms and Conditions: The GMO, in consultation with the PO, must ensure that each award includes appropriate terms and conditions (see sample terms and conditions in Appendix 5). Because the NIHGPS is a term and condition of the award, the requirements it contains generally need not be repeated in the award unless there is a program-specific or award-specific need to include additional or clarifying information. For example, the requirements for filing the Notice of Federal Interest (NFI) and for physical destruction and title insurance are detailed in the NIHGPS and need not be repeated in the award unless the GMO determines that repeating the information is necessary to assure protection of NIH's

interests. The duration of the required usage period (usually 20 years), which is not specified in the NIHGPS, needs to be addressed in each award.

The terms and conditions of award shall include, but are not limited to, the following:

i. The estimated date the construction contract will be signed;
ii. The estimated date of construction completion;
iii. Estimated cost of the proposed construction, modernization, or major A&R project and how/when funds will be released for expenditure;
iv. Amount of space (net square feet/meters) affected by construction, modernization, or major A&R;
v. Description of the program areas to be supported under the award;
vi. Matching requirement, if any;
vii. Information on the release of funds based on milestones and/or the reimbursement of allowable costs incurred prior to approval of working drawings and specifications;
viii. Usage requirement;
ix. Prior approval requirement to seek an extension without additional funds or if an extension would not be permitted due to the five-year limitation on the use of obligated funds, the NoA should include an informational term to advise the awardee to fully expend awarded funds by June 30 of the last year of support.
x. Use and disposition of any grant-related program income;
xi. Record retention requirements; and
xii. The requirement for the recipient to sign the award to accept it and its terms and conditions.

I. **Usage Requirement:** While some authorizing statutes do establish an end point beyond which further accountability is not required, the provisions of 45 CFR Part 74 do not themselves establish a specific end

point for accountability. However, if, pursuant to 45 CFR 74.32(b), a recipient no longer needs the real property for the purpose of the original project, and use in other Federally sponsored projects and programs or sale is not a feasible alternative or is not in the best interests of the program, the IC Chief GMO may issue a revised NoA to authorize the recipient to use the property for alternative activities. The Chief GMO's written determination should be supported by facts and supporting rationale specific to that grant. While this approval may indicate that the IC will no longer monitor the recipient's use of the property, the NFI in the property must remain (see below). See the sections under "5. POST-GRANT ACTIVITIES" found at "a. Monitoring Facility Usage Compliance" and "b. Alternate Usage" for additional information related to an alternate use of the facility and prior approval requirements.

m. **Notice of Federal Interest**

    i.   Immediately after the grantee signs the contract to begin construction, modernization, or major A&R activity or formalizes in writing the determination to use force account labor (the grantee's own personnel and equipment), the grantee must file the NFI. While the requirement to file an NFI has been required by Public Health Service and NIH grants policies since the 1980s, it became a regulatory requirement in 45 CFR 74.37 for those organizations subject to 45 CFR Part 74 in 1994 (59 Fed. Reg. 43754-01 (August 25, 1994) (codified at 45 CFR Part 74)). For all other grantees, it remains a policy requirement. Associated fees for filing the NFI are allowable costs.

    ii.   The NFI is a document filed in the local land records in the jurisdiction in which the property is located to place a lien on the property to ensure compliance with the facility usage requirement. The principal intent of the NFI is to ensure that the Federal interests in the property are not subordinated to those of non-Federal parties. The NFI must accurately indicate that the property was

constructed, modernized, acquired, or improved with NIH funds and that, during its useful life as defined in the NFI, NIH's use and disposition requirements apply. See samples in Appendix 5, Terms and Conditions of Award, and Appendix 6, Notice of Federal Interest Letter.

      iii.   The NFI protects NIH's interest in the grant-supported property should the grantee want to sell, lease, or mortgage the property during the period of Federal interest. The Federal interest in real property may not be conveyed, transferred, assigned, mortgaged, leased, or otherwise be encumbered or subordinated by a recipient unless a deviation is approved by the IC Director or designee.

n. **Leased Property**

      i.   Construction, modernization, or major A&R may be performed on leased property only in exceptional circumstances and must be approved in advance by the IC Chief GMO. If approved, the grantee must be advised through the NoA of both its responsibilities and liabilities for that property under the grant and how they relate to the interests of others with a financial interest in the property.

      ii.   The general requirement is that the holder of each existing lien on the property must agree to subordinate its interests to the Federal government. If this is not feasible, the lessor must agree to include, in the lease, clauses that indicate (a) the continued rights of the grantee and NIH in the event that the lessor of record changes, whether by sale, foreclosure, or otherwise, as in effect before such a change, and (b) if the Chief GMO agrees, at lease initiation, that if NIH's interests are subordinated (whether based on present or future conditions), the lessor and all lienholders must warrant that the grantee's full use of and access to the premises during the term of the lease (and under the conditions provided therein) shall not be infringed as a result. If the grantee cannot obtain such agreements or the lessor does not agree to these lease provisions, a deviation

must be obtained from the Chief GMO.

iii. The NFI (or equivalent language) shall be a part of the lease, whether a provision of a new lease or an amendment to an existing lease and be agreed to by both the grantee and the lessor. The NFI language must be submitted to the Chief GMO for approval as part of the documentation required to obtain prior approval for leasing, or, in the event that timing is not practical, before the recipient can draw down funds from the Payment Management System or be reimbursed, as applicable. The NFI/lease language shall provide that: (a) the grantee agrees not to sublease, assign, or otherwise transfer the leased property, or use the property for a non-grant-related purpose(s) without the written approval of the Chief GMO (at any time during the term of the lease, whether or not grant support has ended); (b) the lessor will inform the awarding office of any default by the grantee under the lease; (c) the NIH IC shall have 60 days from the date of receipt of the lessor's notice of default in which to attempt to eliminate the default, and that the lessor will delay exercising remedies until the end of the 60-day period; (d) the NIH IC may intervene to ensure that the default is eliminated by the grantee or another grantee named by the awarding office; (e) the lessor shall accept payment of money or performance of any other obligation by the awarding office's designee, for the grantee, as if such payment of money or performance had been made by the grantee; (f) in the event that the grantee defaults, the grant is terminated, or the grantee vacates the leasehold before the end of the lease term, the NIH IC shall have the right to designate a replacement for the grantee for the balance of the lease term, subject to approval by the lessor, which will not be withheld except for good reason; and (g) the lease and any amendment to it shall be recorded in the land records.

o. **Title Insurance:** Title insurance is required to insure the fee interest in the

real property for an amount not less than the full appraised value of the property (not just the Federal portion). The IC may waive the title insurance requirement if the recipient can demonstrate, to the satisfaction of the GMO, that it has fee simple title to the site free and clear of all liens, easements, rights-of-way, and any other adverse interests which would encumber the project, or that the institution is self-insured (e.g., the recipient has sufficient funds available to satisfy any liens placed against the facility or land).

p. **Builder's Risk Insurance:** Builder's risk insurance, which is an allowable cost either for the grantee or the construction contractor, is usual practice and recommended to cover potential losses after initiation, but before completion of construction, caused by theft, fire, vandalism, and other types of accidental loss or damage to the structure. Builder risk insurance generally covers the structure under construction or portion of the structure being modernized, including fixtures designed to be a permanent part of the completed construction or modernization project, which is the minimum coverage required by NIH. Depending on the policy, it may cover the materials, supplies, machinery or equipment used (or to be used) in the project while at, or in transit to, the project site, or at a temporary location.

q. **Physical Destruction Insurance**

    i.   Physical destruction insurance is required to cover the replacement or repair of any damage that may occur to the facility after completion of construction. The physical destruction insurance policy must insure the full-appraised value of the building from risk of partial or total physical destruction. When Federal participation in the construction or modernization of a building covers only a portion of the cost, the insurance must cover the total cost of the facility because damage to the building could make it unusable and, thereby, affect the Federal interest. The insurance policy must be maintained for the duration of the recipient's ownership of the

property unless there is a limitation on the Federal interest (e.g., 20 years).

ii. The IC may waive the insurance requirement if the recipient can demonstrate, to the satisfaction of the GMO, that it is effectively self-insured, i.e., the recipient has sufficient funds to pay for any damage to the facility, including total replacement. This generally is the case for units of government with taxing authority. It also may be the case for a unit of government or non-governmental entity that is sufficiently bonded or insured to cover potential losses. If the recipient is not a unit of government, it must demonstrate that it has sufficient funds to replace or repair the facility or to satisfy any liens, and the source of the funds (e.g., an endowment or special fund set aside specifically for this purpose). The IC shall ensure that the recipient includes in the insurance policies a requirement for the insurance company to notify the IC GMO of any changes in the policy or coverage.

r. **Unresolved Issues Prior to Award:** The IC should make every attempt to resolve all issues prior to making the award. However, under exceptional circumstances (i.e., it is necessary to issue an award before the end of the fiscal year), an award may be made as long as it contains the necessary terms and conditions to address the unresolved issues.

3. **Post-Award Activities**

a. **Prior Approval Requirements:** All requests for prior approval must be responded to in writing by the GMO, after consultation with the PO and, when applicable, ORF. In response to a grantee's request, the IC may need to consider the following:

i. *Deviations from Design Requirements:* When it is in the best interest of NIH and the project, the GMO, in consultation with program staff, may, if appropriate, allow deviations from the applicable *NIH Design and Policy Guidelines or the NIH Design Requirements Manual.* For example, this may be the case if NIH

funding is only a small percentage of the overall construction, modernization, or major A&R activity. Consideration must include whether or not NIH has authority to deviate from certain requirements, the cost associated with requirement, and the impact on the construction, modernization, or major A&R activity if the requirement is eliminated or modified.

ii. *Plans and Specifications:* Obtain NIH awarding office approval of plans and specifications both before soliciting bids or proposals and before awarding a prime construction contract.

iii. *Alternate Contracting Methods:* Requests may involve use of the following alternative contracting methods in lieu of formal advertising resulting in lump-sum, fixed-price contracts as specified in 45 CFR Part 74. In determining whether to approve a request for use of an alternate contracting/bidding process, NIH should make certain that the grantee assures that there is adequate competition and that the work is to be awarded to a qualified contractor whose costs are competitive. To be approvable, there must be an overall cost and time savings to NIH.

(a). *Construction Management Agreement:* A management services contract under which a grantee contracts for technical consultation during the design stage of a project and for organization and general project oversight of construction activities during the construction phase. In this situation, a construction manager becomes the construction manager at risk and assumes the role of the construction contractor. The construction manager is responsible for the procurement of all construction work under a guaranteed maximum price (GMP) contract (see "Guaranteed Maximum Price Contracts" below).

(b). *Design-Construct Services*: Where design-construct services

are contracted, construction firms respond to a request for proposals by submitting building designs that meet the grantee's performance requirements within a GMP covering all architectural, engineering, and construction services required. This alternative contracting method is used rarely.

(c). *Guaranteed Maximum Price Contracts:* A contract under which a firm assumes total financial responsibility to complete construction of the project at or below a GMP. This is the most common alternative contracting method requested. NIH may generally approve this request when the grantee is at the level of 70 percent of design documents.

iv. *Contingency Fund:* When it is in the interest of the IC and under limited circumstances, the Director, OPERA, may grant a single-case deviation to the 2 percent limit on the contingency fund (see NIH GPS). However, this limit must never exceed 5 percent of estimated construction costs.

v. *Change in Scope:* Approval of a request involving a change in scope needs to consider how the change may affect the cost of the project, research purpose (i.e., consistency with program intent), or construction schedule.

vi. *Request for Increase in Funds:* If additional funds are not available, the IC may need to consider working with the grantee to modify the proposed construction, modernization, or major A&R activity.

vii. *Extensions:* Review of extension requests must take into account the 5-year limitation of the expenditure of appropriated funds (see "Appropriation limit on expenditure of funds" below).

viii. *Change in Facility Usage/Transfer of Remaining Facility Usage:* See "Post-Grant" below for considerations related to approving an alternate use of the facility or transferring the remaining years of a usage obligation to another facility.

b. **Project Monitoring**

   i. **When monitoring construction, modernization, or major A&R activity, the IC GMO and PO shall consider:**

   (a). *Progress* based on the proposed schedule to ensure that the grantee is not falling significantly behind schedule.

   (b). *Disbursements Reported through the HHS Payment Management System (PMS)* to assess whether the disbursement of funds is consistent with grantee-reported progress.

   (c). *Appropriation Limitation on Expenditure of Funds*—the 5-year limitation on the use of obligated funds as specified in 31 U.S.C. 1552. In accordance with this limitation, grant funds must be expended by the grantee by the end of the 5th fiscal year following the fiscal year that the NoA is issued. When awards are issued in September of a given fiscal year, this further constrains the availability of the funds since, due to the PMS requirement that funds be reported as fully disbursed before September 30 of the 5th fiscal year after the NoA is issued, the grantee then only has 4 years and 9 months available to expend the funds before the end of the 5th fiscal year. While the grantee technically can expend funds during the additional 3 months comprising the 5-year period, the Office of Financial Management, NIH, must take an exceptional action to allow this. Therefore, NIH ICs should be advising grantees that the NIH policy is that, in these circumstances, the funds are available for 4 years and 9 months.

   Due to the limitation of the use of obligated funds as discussed in the "Award Activities" section above, NIH retains authority to review and consider requests for extensions without additional funds. NIH

retains this authority to avoid an awardee's extension of a project period beyond the five-year period. The NIH prior approval requirement is communicated to the awardee in the terms and conditions of award.

For example, if a construction project is awarded on September 30, 2005, using FY 2005 funds, the funds generally will be available for expenditure only through June 30, 2010. In this example, if the grantee claims allowable costs that equal or exceed the amount awarded, in order to use 100 percent of the awarded funds, the grantee must report the funds as fully disbursed on the PSC 272, Federal Cash Transactions Report, and have its Financial Status Report, showing all funds obligated and no unliquidated obligations, received and accepted prior to the end of FY 2010 (September 30, 2010). Any funds undisbursed in PMS as of September 30, 2010, will be deobligated on October 1, 2010. The extension of the project period end date beyond September 30, 2010 (in this example) will not prevent the automatic deobligation of funds. Thus, NIH may not approve such extensions. Further, this limitation on the availability of appropriations may limit the grantee's ability to submit a revised FSR within the 15-month period usually authorized. If the appropriation has expired, NIH may not accept a revised FSR with increased obligations and/or outlays, regardless of when it is submitted.

ii. The GMO must ensure that systems are in place to monitor award and post award activity and any required post-performance compliance, e.g., reporting of income received after the period of support, continued use of facility for purposes consistent with those of the award, and recoupment of the Federal share of sales proceeds or amortized value.

c. **Final Inspection and Cost Review**

    i. After construction, modernization, or major A&R is completed, a final inspection normally is performed to ensure that the project was constructed, modernized, or altered in accordance with the approved design documents. An inspection may be conducted as a site visit, recipient-submitted photographs of space, or other appropriate means, as determined by the IC.

    ii. A construction project is considered complete at the point in which the builder turns over to the grantee a facility constructed with NIH grant support, or portion of a facility modernized or modified under a major A&R project, that conforms to the design and specifications approved by the NIH and is available for occupancy. The period of Federal financial interest (usually 20 years) will begin either when the builder turns the facility over to the grantee institution (e.g., the date of the final acceptance of the building) or at the point of beneficial occupancy, whichever comes first.

    iii. In addition, a cost analysis of the project is performed to compare actual costs against project estimates to determine if the grantee is entitled to 100 percent of the award amount. For example, when a project is funded, the costs relating to the project are estimated since a construction contract has not been signed, construction has not begun, and the project is not complete. Depending on the bidding climate, the cost of the project may be more or less than anticipated. Therefore, to determine the actual cost of the project, the IC shall request from the grantee a report detailing the actual allowable costs of construction, modernization, or A&R per net square foot/meter and also the actual allowable costs of the entire grant-supported project (administrative costs, architectural and engineering costs, surveys, demolition, fixed equipment, filing of the NFI, and other allowable costs) calculated to net square foot/meter (see "Closeout" below). These amounts must be multiplied by the

amount of net square feet/meter of space actually supported under the award.

    iv. If the amount of allowable costs equals or exceeds the amount awarded, the grantee is entitled to 100 percent of the awarded amount and the grant can be closed out with a zero unobligated balance. If the amount of allowable costs is less than the amount awarded, the grantee is not entitled to 100 percent of the awarded amount. If the grantee is not entitled to 100 percent of the amount awarded, then the grantee shall report the excess funds as an unobligated balance on the FSR.

d. **Date of Beneficial Occupancy:** The actual date of beneficial occupancy of the facility must be ascertained. This date is important as it establishes the beginning date for the facility usage requirement.

4. **Closeout**

a. The GMO shall send a closeout letter in advance of the project period end date to notify the grantee of the following documents and information required for closeout: (see sample closeout letter provided in Appendix 7).

    i. A final tabulation of net assignable space supported under the award for each program activity.

    ii. The actual cost of construction, modernization, or A&R[2] per gross and net square foot/meter.

    iii. Date of beneficial occupancy of the completed facility.

    iv. A simplified floor plan or space assignment drawing.

    v. A copy of the final Financial Status Report reflecting the Federal and non-Federal share of outlays.

    vi. A written assurance signed by an authorized organizational representative stating that the grantee has obtained title insurance and/or physical destruction insurance (if required), and agrees to maintain that insurance in accordance with NIH requirements and comply with the usage requirement for the duration of the Federal interest in the property (e.g., 20 years). If the organization is self-

insured against the risks involved, the written assurance must state that the grantee has sufficient funds available to satisfy any liens or to replace and/or repair the facility. This assurance shall state the source of the funds, such as the institution's endowment or other special funds set-aside specifically for this purpose.

b. Once the closeout information is obtained, the GMO shall revise the award to reflect the actual location of the grant-supported space, cost and amount of net square feet/meters supported under the award. This information shall be used when monitoring the use of space during the usage period. (See sample Post Closeout Acceptance letter provided in Appendix 8).

5. **Post-Grant Activities**

   a. **Monitoring Facility Usage Compliance**

      i. The IC is required to monitor grantee compliance with the facility usage obligation through periodic facility and use certifications or reports, site visits, and other appropriate means for the duration of the required usage. NIH has established a self-certification process for monitoring the use of grant-supported space. A letter or other form of communication should be sent to the grantee at least biennially by the GMO to inquire about the use of space (see sample monitoring and follow-up monitoring letters in Appendixes 9 and 10). The grantee is asked to review the activities conducted in the grant-supported space and then certify that the space is still being used for its intended purpose. In addition, the grantee shall provide (a) a list of the PD/PIs occupying the grant-supported space and (b) an indication of their research interests and updated photographs of the grant-supported areas that were provided at time of grant closeout.

      The letter also reminds the grantee to seek prior approval if a change is planned and requests that the grantee assure the IC that

it continues to provide the required insurance requirements.

ii. The IC will review any request for a change in the planned use of space to determine if the alternate use of space is acceptable or not acceptable and will send a written response to the grantee. If during the required usage period, the facility is no longer used for the original intended purpose and the IC did not provide prior approval for an alternate use, the IC shall advise the grantee and begin activity to recover its share of the investment in the construction, modernization, or major A&R of the real property (see below). Unless alternate requirements have been specified in the governing statute, construction grants and modernization grants and major A&R under research grants are subject to the requirements of 42 CFR Part 52b and the provisions of 45 CFR 74.30 through 74.32 and 45 CFR 74.37 or 45 CFR 92.31, as applicable, concerning real property management, use, and disposition. Major A&R under center or other grants/mechanisms are subject to the provisions of 45 CFR 74.30 through 74.32 and 45 CFR 74.37 or 45 CFR 92.31, as applicable, concerning real property management, use, and disposition. After the required usage period, NIH will no longer monitor the use of the space. (See sample letter provided in Appendix 11.)

iii. A site visit should be performed prior to the end of the usage period (e.g. during the 17th - 20 th years if the usage period is 20 years) to ensure the grantee's compliance with the usage obligation. NIH staff should also note the use and condition of the facility and to ensure that the grant-supported space is fully operational.

iv. IC staff planning a monitoring site visit shall coordinate their visit with other ICs to determine if a review of the other IC's grant-supported space should be performed during the same site visit.

b. **Alternate Usage:** In determining whether to approve an alternate use of the facility, the IC should take into consideration the extent to which the

facility will be used for:

- Other health-related purposes consistent with the authorizing legislation of the program;
- Other health-related activities that are consistent with the mission of the IC; or
- Training and instruction in health fields for health professionals or health-related information programs for the public.

c. **Transfer of the Usage Obligation**

. The grantee also may propose to transfer the usage obligation from the original grant-supported facility to a facility of substantially comparable or greater value or utility to carry out the original purpose for which the grant was awarded. The IC may consider the approval of this type of request if all the following provisions are met by the grantee:

(a). The grantee is transferring its obligation to another facility that is found to be equally suitable for the grant purposes and would support the programs originally provided for in the original facility.

(b). The new facility conforms to the minimum standards of construction and equipment as set forth in 42 CFR 52b.12.

(c). The facility to which the usage obligation will be transferred constitutes a bona fide sale involving actual cost to the grantee and results in additional or improved facilities for purposes of the program (42 CFR 52b.11).

(d). The facility to which the usage obligation will be transferred (exclusive of the land) has a cost or value equal to or greater than the original.

(e). The grantee assures that it will continue to use the facility to which the usage obligation will be transferred for the originally authorized purpose throughout the duration of the remaining usage obligation.

    i.   If the above provisions are met, the remaining usage obligation may be released from the original facility constructed with grant funds and transferred to the new facility. The original NFI shall be amended and a new NFI shall be recorded in the local land records in the jurisdiction in which the property is located. In addition, the grantee shall be reminded that it continues to be subject to all other requirements of the award.

    ii.   If alternate usage is approved, the GMO must revise the NoA to reflect the approval of the transfer in the usage obligation and the allocation of programs to occupy the space. The IC must continue to monitor the grantee's compliance with the usage obligation at the alternate facility.

d. **Monitor Post-Performance Compliance**: Ensuring that systems are in place to monitor any required post-performance compliance, e.g., reporting of income received after the period of support, continued use of facility for purposes consistent with those of the award, and recoupment of the Federal share of sales proceeds or amortized value.

e. **Recovery of Federal Share:** If during the required usage period the facility is no longer used for the originally intended purpose and the IC does not provide prior approval for an alternate use, the grantee will be required to reimburse NIH for its share of the facility. The Federal share will be calculated as provided in 45 CFR 74.32 or 45 CFR 92.31, as applicable, and the NIHGPS. NIH staff should consult with the Office of Financial Management and the OGC when seeking recovery of the Federal share of costs.

H. Official Grant File:

The official grant file should be maintained by the IC Grants Management Office until the facility usage requirement has been satisfied. Grant files may then be retired in accordance with the NIH record retention policy ([NIH Manual Chapter 1743, "Keeping and Destroying Records"](#)). The IC may also elect to create a working "monitoring" file folder during the required usage period. This file must also be maintained and retired in accordance with the NIH record retention policy.

I. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Section 1100 – General Administration (all that apply), Section 2600 Procurement, Property and Supply Management (all that apply) and Section 4000 - Grants and Awards (all that apply).

NIH *e-mail messages.* NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after

they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

J. Management Controls:

The purpose of this NIH GAM is to present the policies, procedures and responsibilities for the management of matching and cost sharing requirements for NIH grants. Office Responsible for Reviewing Management Controls Relative to the NIH GAM: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

Frequency of Review: The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule. A management control review of this issuance will be conducted no less than every 4 years.

Method of Review: OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

Review Reports are sent to: The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as

appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

K. Appendices:

The following appendices are all sample documents that may be modified, as needed, as long as the changes are consistent with the requirements of this NIH GAM and the NIHGPS.

[Appendix 1 Review of Environmental and Other Impacts Document](#)

[Appendix 2 Environmental Impact Statement Process](#)

[Appendix 3 Grants Management Specialist Checklist](#)

[Appendix 4 Program Official Checklist](#)

[Appendix 5 Sample Terms and Conditions of Award](#)

[Appendix 6 Notice of Federal Interest Letter](#)

[Appendix 7 Pre-Closeout Letter](#)

[Appendix 8 Post-Closeout Letter](#)

[Appendix 9 Post-Grant Monitoring Letter](#)

[Appendix 10 Post-Grant Follow-Up Monitoring Letter](#)

[Appendix 11 Final Letter at End of Facility Usage Requirement](#)

[1] This list may be obtained from the State Liaison Officers designated by their respective states to administer this program or from the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue NW, Washington, DC 20004 (telephone: 202-606-8503; website: http://www.achp.gov/). The National Trust for Historic Preservation

is located at 1785 Massachusetts Avenue NW, Washington, DC 20036 (telephone: 202-588-6000; website: http://www.nationaltrust.org/).

[2] For major A&R, this type of activity should take place at the end of the A&R project rather than at closeout of the overall award.

NIH POLICY MANUAL

4304-204B - Post Award: Equipment, Supplies, Inventions and Patents and Debt Instruments

Issuing Office: OER/OPERA (301) 435-0949

Release Date: 9/10/2008

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1. **Explanation of Material Transmitted:** This new NIH Grants Administration Manual (NIH GAM) sets forth the requirements for the following types of property that may be present under NIH grants and cooperative agreements (hereinafter referred to as "grants"): equipment, supplies, inventions and patents, and debt instruments. It may be used as guidance for such costs that are part of a grantee's Facilities and Administrative (F&A) costs in conjunction with any applicable cost principle requirements and negotiated F&A rate agreement(s). Further, this NIH GAM supplements the requirements located in 45 CFR Part 74, 45 CFR Part 92, and 37 CFR Part 401, and implements those segments of HHS Grants Policy Directive (GPD) 3.04, "Post-Award – Property" that apply to equipment, supplies, inventions and patents, and debt instruments. In addition, this NIH GAM **rescinds**: 1) PHS Grants Administration Manual (PHS GAM) Part 713, "Personal Property Available to Grantees"; 2) **NIH Manual Chapter 55602, "Management of and Accountability for Equipment Acquired Under NIH Grants"**; and, 3) OER Policy Announcement 2000-01 "NIH Compliance Policy for Extramural Invention Reporting." This is the first issuance of this NIH GAM. The topics of construction, real property, major alteration and renovation

and minor alteration and renovation, also included in HHS GPD 3.04 are addressed in [NIH GAM 4304-204A](#), "Post Award: Construction, Modernization or Major Alteration and Renovations of Research Facilities."

2. **Filing Instructions:**

   Insert: NIH Manual 4304-204B dated 9/10/2008

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- Online information, enter this URL:
  http://oma.od.nih.gov/manualchapters

A. Purpose:

This NIH Grants Administration Manual (NIH GAM) sets forth the requirements for the following types of property that may be present under NIH grants and cooperative agreements (hereinafter referred to as "grants"): equipment, supplies, inventions and patents, and debt instruments. It may be used as guidance for such costs that are part of a grantee's Facilities and Administrative (F&A) costs in conjunction with any applicable cost principle requirements and negotiated F&A rate agreement(s). Further, this NIH GAM supplements the requirements located in 45 CFR Part 74, 45 CFR Part 92, and 37 CFR Part 401, and implements those segments of HHS Grants Policy Directive (GPD) 3.04, "Post-Award – Property" that apply to equipment, supplies, inventions and patents, and debt instruments. In addition, this NIH GAM rescinds: 1) PHS Grants Administration Manual

(PHS GAM) Part 713, "Personal Property Available to Grantees"; 2) NIH Manual Chapter 55602, "Management of and Accountability for Equipment Acquired Under NIH Grants"; and, 3) OER Policy Announcement 2000-01 "NIH Compliance Policy for Extramural Invention Reporting." This is the first issuance of this NIH GAM. The topics of construction, real property, major alteration and renovation and minor alteration and renovation, also included in HHS GPD 3.04 are addressed in [NIH GAM 4304-204A](), "Post Award: Construction, Modernization or Major Alteration and Renovations of Research Facilities."

B. Background:

The various property management and accountability requirements for equipment, supplies, inventions and patents, and debt instruments that apply to NIH grants reside in statutes, regulations, and HHS and NIH policies (see "D. References"). In general, this NIH GAM neither repeats nor restates the existing regulatory and policy requirements. Rather, the intent of this chapter is to organize the topic in a manner that reflects the NIH perspective and to provide, in a single document, appropriate references to the many separate regulations and policies that collectively represent the formal guidance on the subject.

C. Policy:

1. General
2. Equipment
3. Supplies
4. Inventions and Patents
5. Debt Intruments

1. **1. General**

Requirements applied to property covered by this NIH GAM shall be consistent with applicable administrative requirements (45 CFR Parts 74 or 92 as applicable) in terms of both the classification of property and the type and duration of accountability. Absent authority provided in those administrative requirements, property management requirements may not be more liberal or more restrictive unless allowed by an approved deviation or in the case of more restrictive conditions, a designation of the grantee as "high risk/special award conditions" (see 45 CFR 74.14).

The allowability of costs for particular types of property and related expenditures will be based on the governing statute; regulations; applicable cost principles; this NIH GAM; and, the terms and conditions of each Notice of Award (NoA).

2. **Equipment**

Under the authority of the Public Health Service (PHS) Act, NIH makes assistance awards for the support of a variety of research and research training activities. Funds provided under these awards may be used, among other purposes, for the purchase of equipment necessary to the approved goals of the research.

Allowability: The cost principles provide definitions for "special purpose equipment" and "general purpose equipment" as well as rules on allowability. Usually, general purpose equipment is not allowable as a direct charge except when approved in advance by the awarding agency. Special purpose equipment is generally allowable as a direct charge provided it meets the institution's definition of equipment. See also "E. Definitions" for distinctions between special and general purpose equipment.

In accordance with the NIH Grants Policy Statement, grantees may rebudget to purchase allowable items of equipment. However, purchases of a unit of equipment exceeding $25,000 may require NIH prior approval as a change of scope.

Accountability: For purposes of the property management requirements of 45 CFR Parts 74 and 92, equipment is generally defined by its acquisition cost ($5,000 or more per unit) and its useful life (greater than one year). In general, unless otherwise specified by statute or regulation, title to equipment acquired by a grantee (domestic and foreign), including commercial organizations, vests with the grantee upon acquisition, subject to the property management requirements of 45 CFR 74.31, 74.34, and 74.37, or 45 CFR 92.32 as applicable.

The vast majority of funds awarded by NIH are for the conduct of research at nonprofit institutions of higher education or at nonprofit organizations whose primary purpose is the conduct of scientific research. Under the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301 et.seq. (P.L. 95-224), NIH may permit these grantee organizations (e.g., universities and research foundations) to obtain title to equipment acquired with research grant funds without further obligation to the Federal Government (see 31 U.S.C. 6306). Such equipment is "exempt" property. Exempt property is not subject to the requirements of 45 CFR 74.34, except for those obligations set forth in 45 CFR 74.34(h)(1), (2), and (4). 45 CFR 74.34(h) provides NIH the right to require transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding office.

With regards to a grant awarded to a Federal institution, NIH will consider all nonexpendable personal property acquired as "exempt"

(see 45 CFR 74.33) for purposes of determining the accountability requirements of 45 CFR 74.34.

For-profit organizations and other organizations not considered "exempt" generally are subject to the administrative requirements of 45 CRF 74.34.

All equipment not considered "exempt" property is generally subject to the acquisition, use, and disposition requirements of 45 CFR 74.34 or 45 CFR 92.32 as applicable.

Since the provisions of exempt or non-exempt property are outlined in the NIH Grants Policy Statement (GPS), and the GPS is incorporated by reference in all Notices of Award, the applicable provision regarding equipment accountability is included by reference and does not need a separate term of award.

Federally owned equipment that has not been declared excess or surplus pursuant to the Federal Management Regulations (41 CFR 102-36 & 102-37) may be provided for grantee use under a revocable use license agreement. Historically, these situations have been limited to ones in which a grantee is also an HHS contractor and it has utilized equipment that is titled to the Federal Government; however, use of this authority is not limited to these circumstances. HHS retains title to such equipment and it is subject to use and disposition as provided in the revocable use license agreement. For further information contact: Director, Property Management Branch, Office of Logistics and Acquisition Operations, Office of the Director, NIH, 301-402-6279.

Day-to-day post-award property management under NIH grants is

generally the responsibility of the grantee organization, whether title is vested in the grantee or remains with NIH.

Limitations or controls on the acquisition or management of equipment by grantees should be based only on:

1. Limitations imposed by a program's authorizing statute or program regulations;
2. Programmatic concerns expressed by independent reviewers, e.g., the property is not of a type suitable for the project;
3. Any applicable regulatory requirements in 45 CFR Parts 74 or 92; or
4. Property management system concerns based on documented findings in audit reports, site visits, or other assessment or monitoring information.

For purposes of 45 CFR 74.34(f)(3) and 45 CFR 92.32(d)(2), statistical sampling is an acceptable basis for conducting the physical inventory of equipment and reconciliation, provided the sampling is reliable, appropriate, and makes common sense.

When a grantee requests a change of institution, the current grantee shall include a list of equipment costing $5,000 or more transfering with the project on the "[Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant" (PHS 3734)]." Generally, title to equipment acquired by a grantee with NIH funds vests in the grantee. However, in the case of a change of institution, NIH has authority to require the transfer of equipment purchased with grant funds to the new institution (see 45 CFR 74.34(h)(2)).

3. **Supplies**

NIH Institutes/Centers (ICs) may not place special management or disposition requirements (beyond those of 45 CFR 74.35 and 45 CFR 92.33, as applicable) on supplies that are appropriately chargeable as direct costs to NIH grants. This is consistent with the policy that grantees have title to supplies, are responsible for managing that category of property, and may, as they determine necessary, establish organizational requirements more restrictive than those imposed by NIH and 45 CFR Parts 74 & 92.

4. **Inventions and Patents**

Extramural funding from NIH supports biomedical research in an effort to gain new knowledge that will lead to better health for everyone, and this knowledge often manifests itself as intellectual property, i.e., unique findings that are research resources and/or result in new products, materials, and processes. In the past, ownership of these inventions and associated patents vested with the Federal Government. However, the Bayh-Dole Act of 1980 (Pub. L. No. 96-517; 35 U.S.C. 200-212), its implementing regulations (37 CFR 401), and the related Executive Order 12591 (April 10, 1987) provide incentives for the practical application of research supported through Federal funding agreements. To be able to retain principal rights and title to inventions made with Federal funds, so-called "subject inventions," the grantee must comply with a series of regulations that ensure the timely transfer of the technology to the private sector, while protecting limited rights of the Federal government. These laws and implementing regulations define terms, parties, and responsibilities; prescribe the order of disposition of rights; prescribe a chronology of reporting requirements; and, delineate the basis for and extent of government actions to retain rights.

NIH has a major responsibility in protecting, promoting, and monitoring inventions that result from the extramural research programs it funds.

The laws and regulations apply to any subject invention (see definitions) and to all types of grantees of Federal funding. This currently includes non-profit and for-profit (both small and large businesses) institutions, Federal, state and local units of government, and foreign grantees that receive funding through grants, cooperative agreements, or contracts as direct recipients of funds, or as consortium participants or subcontractors under those awards. Note however that fellowships and training grants, which are made by NIH primarily for educational purposes, do not contain provisions regarding the various Bayh-Dole rights to invention. However, trainees are often associated with a research project and when the project is a federally funded research grant, an invention stemming from this research is normally subject to invention reporting requirements.

NIH grantees may retain intellectual property rights to subject inventions provided they do (without limiting the requirements of 37 CFR 401 and the Bayh-Dole Act) the following:

> timely report all subject inventions to NIH;

> make efforts to disseminate or otherwise commercialize the subject invention through patent or licensing;

> formally acknowledge the Federal government's support in any patent applications and patents that arise from the subject invention; and

formally grant the Federal government a nonexclusive, non-transferable, irrevocable, paid-up license to the subject invention, for or on behalf of the U.S. throughout the world.

See the NIH Grants Policy Statement (rev. 12/2003), "Inventions and Patents," Exhibit 5, which summarizes grantee responsibilities for invention reporting as specified in the regulations in 37 CFR Part 401. NIH staff and grantees should refer to 37 CFR Part 401 (available on iEdison at http://iEdison.gov) for a complete discussion of the regulations. Terms and definitions relating to extramural inventions are also published in the *NIH Guide for Grants and Contracts*, dated September 22, 1995, as a "*20-20 View of Invention Reporting to the NIH*".

When there is a change of grantee organization, if an inventor moves to a new organization, the rights to existing inventions and patents usually remain with the former organization. Sharing of any royalties with the inventors and assignment of ownership from the organization must be consistent with applicable law (e.g., 35 U.S.C. 202(c)(7)). More information on this can be obtained by emailing OPERA at Edison@nih.gov.

iEdison and Edison Report–Lite (ERL): To facilitate NIH and grantee compliance with invention reporting requirements, NIH developed two internet-based systems. iEdison is the interagency system providing a single interface for grantees to comply with the Bayh-Dole regulations for invention reporting. Edison Report-Lite (ERL) provides NIH extramural staff (Program and Grants Management) a system for querying inventions information housed in the iEdison system. iEdison includes links to Invention Reporting resources including a

timeline for invention reporting compliance as part of "Invention Reporting Tips" and "Frequently asked Questions."

5. **Debt Instruments**

The following describes the major types of debt instruments:

1. Grantee as a Debtor: when an NIH IC assists in financing the acquisition or construction of real property (or major A&R), the awarding office must require that any mortgage agreement entered into by the grantee specifically provides that, in the event of default, the awarding office may, at its option and in lieu of repayment based on sales proceeds, assume the role of mortgagor and continue to make payments on the mortgage. The IC should consult the Office of the General Counsel (OGC) before assuming the role of mortgagor. Amounts owed by the grantee to NIH will be determined and collected pursuant to the Department's debt collection process and requirements. Note, NIH grants rarely, if ever, provide actual assistance for "financing" the acquisition, construction, or major alteration and renovation of real property. However, in the event such assistance is provided, the IC must require that in the event of default on the mortgage by the grantee, the grantee must immediately notify the GMO.

2. Grantee as a Creditor: for programs that allow or require the grantee to enter into financing arrangements with third parties, the following applies to the management and disposition of the resulting debt instruments:

    1. the terms and conditions of the NoA must be consistent with any governing programmatic statutory or regulatory provisions;

    2. the terms and conditions of the NoA must address the

grantee role and the NIH role, if any, with respect to those third parties, and any required provisions for those third-party agreements. At a minimum, the award must address grantee responsibilities and liabilities in the event of non-payment or late payment by the third party, grantee accountability both during and after the end of the grant, and the NIH role, if any, in the event of early termination of the grant; and

3. for accountability purposes, debt instruments (other than mortgages on real property acquisition or construction financed with Federal funds) shall be treated in accordance with 45 CFR 74.36 (e).

Consistent with 45 CFR Pt 74.37, real property, equipment, intangible property, and debt instruments that are acquired or improved with Federal funds shall not be encumbered without the approval of the NIH.

D. References:

1. [45 CFR Part 74,](#) "Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations"
2. [45 CFR Part 92,](#) "Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments"
3. [37 CFR 401](#), "Rights to Inventions Made By Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements"
4. [Federal Grant and Cooperative Agreement Act of 1977](#), 31 U.S.C. 6301 et seq
5. [NIH Grants Policy Statement (NIHGPS, rev, 12/2003](#) or its

successor)

6. [HHS Grants Policy Directive 3.04: Post-Award – Property](#)
7. [NIH Manual Chapter 54104, "NIH Research Grants Involving Foreign Institutions and International Organizations"](#)
8. [NIH Manual Chapter 54805, "Research Grants Awarded to Non-Affiliated Individuals"](#)
9. [NIH Manual Chapter 55201, "Change of Grantee Institution"](#)
10. [Commonly Asked Questions About Equipment Under Grants, NIH Guide, Volume 24, Number 15, April 28, 1995](#)
11. [Property Management Branch, Office of Logisitics and Acquisition Operations, NIH](#)
12. [A "20-20" View of Invention Reporting to the NIH](#), NIH Guide, Volume, 24, No. 33, September 22, 1995
13. [NIH Manual Chapter 1743](#), Keeping and Destroying Records

E. Definitions:

1. **Debt Instrument:** A document, such as a promissory note, used to record a legal obligation of one party to pay a financial obligation to another in accordance with predetermined terms and conditions.
2. **Equipment:** An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.
   1. **Special purpose equipment:** Equipment which is used for research, medical, scientific or other technical activities. Examples include microscopes, x-ray machines, surgical instruments, and spectrometers.
   2. **General purpose equipment:** equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular

offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. Note that unless specifically justified for a special research purpose, laptops are a general use business item and so are treated as an administrative cost. Costs of laptops would be considered general purpose equipment or supplies, depending upon the price and the organization's capitalization threshold. Direct charging of a normally administrative cost must be consistent with the applicable cost principles.

3. **Invention:** A discovery, device or process which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

4. **Patent:** A government-issued document granting the exclusive right to exclude others from making, using, offering for sale, selling or importing the invention for a specific geographic territory for a specific number of years.

5. **Supplies:** All tangible property other than equipment.

6. **Subject Invention:** Any invention of a grantee/contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(a)(9) of the Plant Variety Protection Act, 7 U.S.C. 2401(a)(9) must also occur during the period of grant/contract performance.

F. Responsibilities:

1. **Director, Office of Policy for Extramural Research Administration (OPERA):**

Director, Office of Policy for Extramural Research Administration (OPERA): OPERA is responsible for developing and disseminating general policy guidance for the material covered by this NIH GAM. This includes:

1. developing policies and procedures, conducting training for extramural staff, performing outreach to the extramural research community, and issuing policy and informational announcements for the NIH Guide for Grants and Contracts and other NIH publications.
2. serving as the primary point of contact for extramural invention reports, disclosures, confirmatory licenses, waivers, and other documentation required by the Bayh-Dole Act; coordinating with other Office of Extramural Research (OER) offices as appropriate;maintaining and enhancing iEdison and Edison Report-Lite; providing user support for compliance tools; and providing oversight and compliance of Bayh-Dole requirements by performing random compliance checks and conducting site visits with grantee/contractor organizations.

2. **Institute/Center (IC) Chief Grants Management Officers (CGMOs) and/or Program Officials (POs):** IC Chief GMOs and/or POs share responsibility for implementing NIH grants policy through IC-specific policies and procedures. Of special note are the following:
   1. **Equipment & Supplies:** Both Program and Grants Management staff share in the responsibility to determine allowability of requested costs as part of any cost analysis performed prior to issuing an award. Special care should be taken to review any requests for computer equipment such as laptops since that would require special consideration as an allowable direct cost. Both Program and Grants Management staff share in the responsibility to coordinate with NIH property

management staff on matters involving federally?owned property and consult with them, as appropriate, on other property management considerations under grants.

2. **Inventions and Patents:** Although the primary responsibility for oversight and monitoring extramural invention activities resides with the NIH Office of Policy for Extramural Research Administration, extramural staff who administer grant programs are responsible for understanding the laws and policies governing invention reporting and for ensuring that grantee/contractor organizations are in compliance with the Bayh-Dole Act. In addition, extramural staff should coordinate with the Division of Extramural Inventions & Technology Resources (DEITR), OPERA, and OGC, as necessary, on invention and patent matters. Specific responsibilities for Grants Management and Program Officials are noted below.

    1. **Grant Management Staff:** Should remind grantees of their invention reporting obligations, particularly those with limited grant funding experience (i.e., commercial organizations and small business entities). Determine if an informational letter that details invention reporting requirements is appropriate at the time of award. (Such a letter is now routinely included with the Notice of Award for SBIRs and STTRs and is available internally from the Grants Management Infonet at: http://odoerdb2.od.nih.gov/gmac/topics/patents_main.html.) Determine if there are circumstances where special terms of award are warranted to ensure that any resulting invention will be made available for public use. Before implementing special terms and conditions of award, ICs should consult with OER.

    2. **Program Officials (POs):** Review of a grant/contract

application, including the scientific progress report, may reveal information that relates to the development of intellectual property (i.e., direct, indirect, or tangential references to the creation of an invention, a biological material, a unique research resource, and similar matters.). A PO may need to make a determination whether an invention is related to the research project and should be cognizant that references to commercialization, manufacturing, or marketing may be a result of NIH funding. In such cases, the PO must either inform grants management staff of this research outcome and grants management will take responsibility for seeing that the grantee fully compiles with all reporting requirements, or the PO will fulfill this function by conducting a search of the ERL system to establish whether or not this research outcome has been reported to NIH. If necessary, the PO will obtain additional information from the grantee and see that an invention report is filed, if appropriate, and properly document the official file. (See Section H. for record retention and disposal.) POs must avoid any actual, apparent, or perceived conflict of interest with regard to their role as scientific advisor to grants. POs who provide expert advice to grantees or become co-inventors must be aware of ethical issues and avoid impropriety. Recusal of any funding decision or program responsibility would normally be appropriate.

3. **Debt Instruments:** In those rare occasions where an IC provides assistance that involves debt instruments, NIH IC staff are responsible for determining the allowability of such an agreement and for using the appropriate terms and conditions

on the NoA. If an IC actually considers assuming the role of mortgagor, the IC must consult with OGC before considering assuming that responsibility. Should any debt recovery be needed, IC grants management staff will coordinate with OFM officials in accordance with established debt recovery procedures.

G. Procedures:

1. **Equipment & Supplies:** NIH IC staff should review applications that include proposed costs for equipment or supplies to assure that requested costs are allowable. Particular attention should be given to requests for computer equipment such as laptops since that would require special consideration as an allowable direct cost. In addition, IC staff should assure that the applicant has adequate systems in place to manage the property, the property is necessary for the successful performance of the grant, and there are not any potential issues, e.g., procurement issues, less?than?arms' length leases, or generation of program income that should be addressed either in pre-award negotiations or the terms and conditions of award.

2. **Inventions and Patents:** NIH ICs should review applications and progress reports for compliance with Invention reporting requirements. If an invention report is included in a competing or non-competing grant application or on the Final Invention Statement and Certification (HHS 568), a search of the iEdison database should be conducted to verify whether or not any inventions have been reported under the specific grant number. Using the ERL interface (https://s-edison.info.nih.gov/erl/), if the search shows any reported inventions, it will be assumed the grantee institution is reporting inventions and no further action will be required. If information regarding inventions as reported in the application is not consistent with iEdison records,

OPERA must be notified via the ERL interface. The IC will send an email to the Authorized Organizational Representative prior to award to inform them about invention reporting requirements that should be done through iEdison (for a sample e-mail see the GM Infonet, Topic = Inventions and Patents). OPERA will work with the IC to take any additional steps necessary to reconcile the discrepancy with the grantee organization.

All actions taken by grants management must be documented and made part of the official file. A copy of an invention report from ERL or other information sent to OPERA is acceptable documentation for the official grant file. (See Section H. for record retention and disposal.) All invention related documentation (i.e., correspondence, disclosures, and similar documentation) directed by the grantee to IC staff must be forwarded to OPERA for inclusion in the iEdison record system. The only exception is the HHS 568, which should be filed in the official grant file. However, if a copy of the HHS 568 reflects any inventions, a copy must be forwarded to OPERA for inclusion in the iEdison system of records. (See Section H. for record retention and disposal.)

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this NIH GAM must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Section 4000 Grants and Awards (all that apply), Section 1100-General Administration, Item L. Patents Inventions and Licensing (and any other items that apply), and Section 2600 Procurement, Property and Supply Management (all that apply). Refer to the NIH Manual for specific instructions.

NIH e-mail messages: NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

The purpose of this NIH GAM is to present the policies, procedures, and responsibilities for the management of equipment, supplies, inventions and patents, and debt instruments that may be present under NIH grants.

Office Responsible for Reviewing Management Controls Relative to this Chapter: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

Frequency of Review: The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance.

NIH manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

Method of Review: OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the [GMAC Policy and Procedure Announcement 2000-01](). This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

Review Reports are sent to: The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

NIH POLICY MANUAL

54101/4101/6304-2 - Establishment of New Activities and Activity Codes

Issuing Office: OER 435-0949

Release Date: 1/15/01

1. **Explanation of Material Transmitted:** This chapter has been revised to update the process (and makes it fully electronic) for the development, clearance, and authorization of new activities and activity codes used to formally identify various mechanisms of support (grant, cooperative agreement, and contract) used in the extramural programs of the NIH. Responsibility for this function is now with OER, OPERA.

2. **Filing Instructions:**

   Remove: NIH Manual 4101/6304-2 dated 12/28/92.
   Insert: NIH Manual Chapter 4101/6304-2 dated 01/15/0.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Office of Management Assessment, OA, on 496-2832.

- On-line information, enter this URL:
  http://oma.od.nih.gov/manualchapters/

A. Purpose:

This chapter describes the process to be followed for development, clearance, and authorization of new activities and activity codes used to formally identify various mechanisms of support/funding (grant, cooperative agreement, or contract) used in the extramural programs of the NIH.

B. Background:

There have been several changes in the process of establishing activities and activity codes.

- Elimination of the Center for Scientific Review (CSR) in the establishment process.

- Inclusion of the Director, OEP in clearance process.

- Notation that the second and third activity code character may be alpha or numeric.

- Implementation of an electronic process to establish activities and activity codes.

Traditionally the establishment of new Activities and Activity Codes process used the NIH Mail and a walk through delivery system. In response to increased technology, use of e-mail, the paper reduction act and reinventing government, the Activity Codes process is now facilitated electronically.

C. Policy:

An Information for Management, Planning, Analysis and Coordination (IMPAC) activity code is broad in nature and intended to transcend an IC's

scientific program or program initiative. A proposed new activity code should differ significantly from other activity codes in order to justify and require separate identification and accountability.

Generally, the following criteria are taken into consideration in establishing a new activity or activity code within the NIH:

1. Financial support/funding mechanism to be used (grant, cooperative agreement or contract).

2. Regulatory, legislative, administrative, or scientific requirements for special accountability and reporting.

3. Special budgetary consideration.

4. Special requirements for overall assignment, referral, or review of applications/proposals.

5. Special requirements for changing or mandating contract programs.

This issuance sets forth the establishment of new activities and activity codes process electronically. The clearance process is handled by using an electronic file copy memo. The memo includes a name/office/date box. The IMPAC activity code process is routed via e-mail.

D. Definitions:

1. **ACTIVITY -** A broad group or category applied to various NIH funding mechanisms for the purpose of tracking, special reporting, and accountability; for example, the "R" category covers several types of research projects (e.g., R01, R29, R37, R55, etc.), whereas, the "F" activity category covers various types of fellowship grants (e.g., F32, F35, etc.) and the "N" activity category covers

various types of contracts.

2. **ACTIVITY CODE -** A code assigned by the NIH to identify a generically similar group of support programs. An activity code consists of three characters. The first is alphabetic; the second and third may be alphabetic or numeric (e.g., R01 - Research Project [Traditional]; U01 - Research Project [Cooperative Agreement]; N01 - Research and Development Contracts [Contract]; RC1 - NIH Challenge Grants and Partnerships Program - Phase I [Research and Development Grant]). The activity code is an integral part of the NIH document numbering system.

3. **Electronic Dissemination -** Information that is sent throughout the NIH via e-mail. The official files to be used in the establishment of new Activities and Activity Codes process are managed electronically in the Office of Policy for Extramural Research Administration (OPERA) and in the IMPAC II database. Contract activity codes shall also be established and managed by OPERA.

E. Responsibilities:

1. The awarding components select the most appropriate activity code for any initiative, such as new Program Announcements (PAs), Requests for Applications (RFAs), or Requests for Proposals (RFPs). If existing activity codes seem inappropriate, an Office, Institute or Center (IC) may recommend the establishment of a new code. A concise, written definition and justification must accompany each recommendation for a new activity code.

2. To avoid use of the same code for different activities, the Office of Policy for Extramural Research Administration (OPERA), OER, OD receives all requests for new activities or activity codes

electronically, coordinates the internal electronic clearance of code assignments, and maintains them in an IMPAC database.

    a. Requests for a new NIH contract activity code should be sent via e-mail to the Director of the Office of Acquisition Management and Policy (OAMP), OA, OD. The Director, OAMP e-mails the request (along with a recommendation) to OPERA who coordinates code assignments in the IMPAC System. The OPERA forwards the request and a recommendation through the Director of the Office of Extramural Programs (OEP), OER, OD to the NIH Deputy Director for Extramural Research (DDER), OER, OD for a final decision. The e-mail system is used to send the request through the clearance process.

    b. Requests for a new NIH grant or cooperative agreement activity code should be e-mailed to the Director of the Office of Policy for Extramural Research Administration (OPERA), OER, OD for review, recommendation and is then routed through the Director of the Office of Extramural Programs (OEP), OER, OD to the NIH Deputy Director for Extramural Research (DDER), OER, OD for a final decision. The e-mail system is used to send the request through the clearance process.

3. The DDER shall establish all new NIH activity categories or activity codes and notifies the OPERA via e-mail. The DOPERA notifies the requester of the DDER's final decision to establish or not to establish the proposed activity or activity code.

F. Procedures:

If an IC determines that an initiative is sufficiently different from any existing activity code and that the initiative requires special reporting and

accountability, then the IC must prepare a memorandum to the Director Office of Acquisition Management and Policy (OAMP), OA, OD or the Director of the Office of Policy for Extramural Research Administration (OPERA), OER, OD.

The IC prepared memorandum for a new activity code should concisely justify the reason for the new activity code and provide its proposed title and definition along with the Administering Code. The memo must also include the Activity Budget Account Codes and Descriptions, and the Budget Research Grant Category *(Note: this last requirement does not apply to contract activity codes.)*

The memo is sent electronically to the Director of OAMP or of OPERA. OAMP forwards all contract activity and activity code requests along with recommendations to the OPERA. The OPERA will review the request and forward it and recommendations to the Director of OEP. The Director of OEP then forwards it and recommendations to the DDER for a final decision. OPERA will prepare a memorandum announcing the DDER's final decision. A copy of this memorandum shall be sent to the OAMP. All correspondence regarding the activity code request is sent by e-mail.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#),"Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule," Item 4000-A-2 (IMPAC), Item 1100-B-1 (Policy), and Item 1100-F-1 (NIH Directives).

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or

have informational value are considered Federal records. **These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose.**

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

H. Management Controls:

The purpose of this manual issuance is to describe the electronic process to be followed for development, clearance, and authorization of new activities and activity codes used to formally identify various mechanisms of support used in the extramural programs of the NIH.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter**: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), Office of the Director (OD), is accountable for the method used to ensure that management controls in activities and activity codes administration are implemented.

2. **Frequency of Review**: Ongoing reviews will occur as scheduled or on

an ad hoc basis.

3. **Method of Review:** OPERA will monitor this activity for grants and coordinate with OAMP with regard to contracts.

4. **Review Reports are sent to**: Deputy Director for Extramural Research (DDER)

I. Publications and Distribution:

The User Support Branch (USB), DEIS, OPERA, OER, OD, will maintain a manual entitled Activity Codes, Organization Codes, and Definitions Used in Extramural Programs on the web at
http://grants.nih.gov/grants/funding/ac.pdf .

Appendix 1 - ABBREVIATIONS, ACRONYMS, AND FORMS:

CSR-Center for Scientific Review

DDER-Deputy Director for Extramural Research

DEIS-Division of Extramural Information Systems

DOAMP - Director of the Office Acquisition Management and Policy

DOPERA - Director of the Office of Policy for Extramural Research Administration

IC- Office, Institute or Center

IMPAC-Information for Management, Planning, Analysis and Coordination

OAMP-Office of Acquisition Management and Policy

OD- Office of the Director

OEP-Office of Extramural Programs

OER-Office of Extramural Research

OPERA -Office of Policy for Extramural Research Administration

PA - Program Announcements

RFA-Request for Applications

RFP-Request for Proposals

USB-User Support Branch

Appendix 2 - DIRECTORY:

Deputy Director for Extramural Research

Building One, Room 144

496-1096

Director, Office of Extramural Research

Rockledge Two, Suite 6182

435-2768

Director, Office of Policy for Extramural Research Administration

Rockledge One, Suite 1190

435-0949

Director, Office of Acquisition Management and Policy

6100 Executive Blvd., Room 6D01

496-4422

User Support Branch

Rockledge One, Suite 1025

435-0996

NIH POLICY MANUAL

54104 NIH Research Grants Involving Foreign Institutions and International Organizations

Issuing Office: OPERA/OER 435-0949

Release Date: 01/22/02

Replaces: 09/01/01

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1. **Explanation of Material Transmitted:** This chapter was previously updated 09/01/01 to include information regarding the allowability of limited (8%) Facilities and Administrative costs for foreign institutions and international organizations (see Sections K and Terms and Conditions Applicable to Foreign Grants). This current update is to clarify that the 8% is strictly for Administrative costs and only equipment costs are excluded in computing the 8% allowance.

2. **Filing Instructions:**

   > **Remove:** NIH Manual 54104 dated 09/01/01 in its entirety.
   > **Insert:** NIH Manual 54104 da ted 01/22/02

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- On-line information, enter this URL:
  http://oma.od.nih.gov/manualchapters/

- To sign up for e-mail notification of future changes, please go to the

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A. Purpose:

This chapter states the NIH policies and procedures governing awards of biomedical or behavioral research grants to foreign institutions, international organizations, and to U.S. grantees for projects which have a substantial foreign component.

B. Revisions:

1. This chapter is being revised to update information regarding the allowability of limited (8%) Facilities and Administrative costs for foreign institutions and international organizations (see section K and Terms and Conditions Applicable to Foreign Grants).

2. There is also clarification that the addition of a foreign component requires prior approval for all recipients, regardless of the terms of award (see section G.)

3. In addition, Section N "Management Controls" has been updated to reflect implementation of the Grants Management Compliance Board.

C. Applicability:

The policy is applicable only to NIH grants and cooperative agreements for research projects. It is not applicable to *Special Foreign Currency Agreements* (P.L.-480 Programs).

D. Background:

The PHS Act Title III, Part A. Sec. 307 (a) states:

"For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, health care technology, and the health services research and statistical activities authorized by section 306 and Title IX."

Authority for carrying out these objectives has been delegated from the Secretary, DHHS, to the Assistant Secretary for Health and redelegated to the Director NIH. The Director, NIH, has redelegated this authority as specified in NIH Manual Chapter 1130, Delegations of Authority, [Program: Grants and Awards No. 1](). In pursuing this objective the NIH recognizes the special opportunities for furthering research programs through the use of unusual talents, resources, populations, and environmental conditions in other countries which are not readily available in the United States or which augment existing United States resources. At the same time, NIH recognizes that it can support research in other countries only when such research has important specific relevance to the objectives of the NIH authorized in the legislative and appropriation acts of the Congress. Any exercise of this authority will be carried out in harmony with U.S. foreign policy.

E. References:

1. PHS Grants Administration Manual Part 709, Research Grants to Foreign Institutions, International Organizations and to Certain U.S. Grantees for Support of Foreign Activities;

2. NIH Manual Chapter 54510, Referral and Initial Review of NIH Grant and Cooperative Agreement Applications;

3. NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in their Review of Extramural Activities

4. NIH Manual Chapter 55201, Change of Grantee Institution;

5. NIH Manual Chapter 1130, Delegations of Authority, Program: Grants and Awards No. 1, Grants in Aid;

6. NIH Manual 1895 - Coordination of International Activities;

7. Departmental Deviation providing for limited Facilities & Administrative costs to foreign and international grantees dated March 13, 2001 available by contacting OPERA, 435-0949.

F. Definitions:

1. **Foreign Grant**: A biomedical or behavioral research grant or cooperative agreement awarded to a foreign institution or international organization.

2. **A substantial foreign component** of a grant to a U.S. institution is defined as:

a. The use of grant funds to provide support to any significant scientific element or segment of the project which is to be performed outside the U.S. either by the grantee project staff or by a researcher employed by a foreign institution.

b. The use of grant funds in such a manner that it may impact on U.S. foreign policy through the involvement of grantee project staff in the affairs or environment of the foreign country.

c. Any activity as described above or including the involvement of human or animal subjects whether or not grant funds are expended.

3. **Foreign Institution**: A private or public nonprofit institution or for-profit organization located in a country other than the United States and its territories and subject to the laws of that country, irrespective of the citizenship of the proposed principal investigator.

Exception: *American University of Beirut* is considered a domestic institution for purposes of Facilities & Administrative costs and cost sharing and is exempt from the requirements of a review by the Department of State. It is considered foreign for all other purposes.

4. **International Organization:** An organization which identifies itself as international or intergovernmental with membership from and representing the interests of more than one country, without regard to whether the headquarters and the location of the proposed activity are inside or outside the United States.

If there is any doubt as to whether the grant involves a substantial foreign component, consult the Fogarty International Center (FIC) for an opinion.

G. **Policy:**

1. **Criteria.** The proposed foreign grant project must meet all of the following criteria in order to be awarded:

a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries which are not readily available in the United States or which provide augmentation of existing United States resources.

b. The project has specific relevance to the mission and objectives of the awarding Institute or Center **(**IC**)** and has the potential for significantly advancing the health sciences in the United States.

c. The application must be approved by the awarding IC Council/Board.

d. Grants may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, gender and minority requirements.

2. **Project Period.** The initial project period and each competitive segment thereafter may be awarded for up to five years.

3. **Exceptions.** Foreign institutions may not be awarded grants for program projects, centers, resources**,** or Institutional National Research Service Awards. Grants may not be made to individuals as grantees in a foreign country.

4. **Transfer of Support or Addition of a Foreign Component.** Grants may not be transferred *to* or *between* foreign institutions. Transfer *from* a foreign to a domestic institution may be approved administratively by the IC. The addition of a foreign component requires prior approval for all recipients, regardless of the terms of award.

5. **Department of State (DOS) Concurrence.** The DOS requires that

proposed Research and Development which is to be conducted in a foreign country, and proposed acquisition of human materials from sources in a foreign country, must be reviewed by the DOS to assure conformance with the international policies of the U.S. Government.

The NIH must obtain concurrence from the DOS before making any new or competing continuation awards to a foreign institution. For projects with a substantial foreign component, awards for the foreign components may not be made until DOS concurrence is obtained. Domestic components, however, may be made whenever the awarding IC deems it appropriate.

6. **Supplements and Changes in Mechanisms of Support or Principal Investigator.** If the parent grant previously received clearance from FIC/DOS, then new administrative or competitive supplements, and changes in mechanisms of support (grant/cooperative agreement/contract), or changes in the principal investigator, do not require additional review. Exceptions are: (1) if the supplement is to work in a new site or new foreign country; (2) if the supplement substantially changes the objectives of the research grant; and, (3) if both a new investigator and a new grantee are proposed.

7. **Conferences.** Conferences (R13s) supported by grants or cooperative agreements no longer require clearance by the FIC/DOS.

8. **Responsibility.** On behalf of the Director, NIH, the Fogarty International Center serves as the focal point at the NIH for the coordination of all grants to foreign institutions in terms of their relation to intergovernmental arrangements, overall DHHS policy, U.S. foreign policy interests, and NIH interagency agreements. The FIC makes all necessary contacts with the DOS.

9. Beginning with awards issued in FY2002, limited F&A costs (8% for Administrative costs, exclusive of equipment costs) may be provided on competing grants to foreign institutions and international organizations. This provision is to allow for the support of costs incurred to provide for compliance with DHHS and NIH requirements including but not limited to: the protection of human subjects, the welfare of animals, financial conflict of interest, and invention reporting. No funds are provided for Facility costs.

H. **Procedures for Review:**

Foreign research grant applications are received by the Center for Scientific Review (CSR), NIH, and assigned to an appropriate initial review group and to an awarding IC and its National Advisory Council or Board.

1. **Initial Review.** For applications from a foreign institution the summary statement will have a special section (heading in caps) which covers the criteria in Section G.1.a., such as the special resources or characteristics of the research project (e.g**.,** human subjects, animals, disease, equipment, techniques), whether similar research is being done in the United States, and whether there is a need for additional research in this area.

2. **Advisory Council or Board.** No application from a foreign institution may be awarded without it having been called to the attention of and having received the approval of a National Advisory Council or Board. In approving foreign applications the Council or Board will consider why the application is of special interest to the awarding IC.

3. **Program Staff.** Program staff must document in the official grant file why each application from a foreign institution has been selected for an

award. Information from the summary statement and the discussion of the Council or Board are included as part of the documentation, as well as the staff rationale for selection based on the criteria as specified in G.1.a.-d.

I. IC Procedures:

1. **General.** Following each Council or Board meeting, the NIH awarding IC determines which foreign research grants it proposes to award. In the interim between Council or Board recommendation and DOS concurrence, any inquiry from the applicant concerning the status of the application will be answered in terms of "not yet approved for funding."

2. **Advance Review.** Request for DOS concurrence may be made in advance of the Advisory Council or Board consideration if IC staff determines, on the basis of priority score and program relevance, that an application has the potential for funding.

3. **Substantial Foreign Component.** Proposed new and competing continuation awards to U.S. institutions for projects with a substantial foreign component must be reviewed by FIC to determine if the concurrence of the DOS is necessary prior to award. FIC will obtain DOS concurrence, if necessary.

4. **Review by Department of State.** No new or competing continuation foreign award may be made without the concurrence of the DOS. The FIC makes all contacts in matters requiring concurrence of the DOS. If an awarding IC expects to make a foreign award, the FIC sends the necessary documents to the DOS. Concurrence is based upon a determination by the DOS that the proposed award is consonant with U.S. foreign policy objectives.

5. **Procedure.** See [Appendix](#).

J. Fogarty International Center Procedures for Review and Coordination:

FIC Review. The Fogarty International Center, Division of International Relations (FIC/DIR) reviews the documents for conformance to the criteria cited in G.1.a.-d. Additionally, FIC/DIR will review each proposed award to determine adequacy for the DOS review for conformance of the project with U.S. foreign policy. If satisfactory, FIC/DIR will forward the necessary documents to DOS for review and concurrence as appropriate. After review, DOS notifies FIC of either concurrence or non-concurrence of proposed award. FIC keeps a copy of DOS notification and forwards the original to the awarding IC. Should a clearance be disapproved, the clearance documents will be returned to the IC with an explanation of the disapproval. If desired by the IC, FIC/DIR will arrange for appeal of clearance recommendation with DOS. Please note the FIC/DIR and DOS review may take up to six weeks.

K. Exceptions to Allowable Costs and Assurance Requirements:

1. **Unallowable Costs.** Costs for the following items are *not* allowable:

a. alterations and renovations;

b. custom and import duties; including consular fees, customs surtax, value-added taxes, and other related charges; and

c. F&A costs. Full F&A will not be allowed with the exception of the

American University of Beirut and the World Health Organization. However, limited F&A (8% for Administrative costs, minus equipment costs) will be provided to support compliance costs (e.g., human subjects, welfare of animals, financial conflict of interest, invention reporting, etc.). No Facility costs will be provided.

2. Civil Rights, Disabled, Sex and Age Discrimination Assurances are **not** required for grants to foreign institutions and international organizations. Assurances for Research Misconduct, Lobbying, Drug-Free Workplace, Delinquent Federal Debt, Financial Conflict of Interest and Debarment are required.

L. Payment Responsibilities and Procedures:

The Office of Financial Management, Government Accounting Section, has the responsibility for the payment (U.S. dollars only) for grants awarded to foreign grant recipients. Any questions regarding payments issued to foreign grantees may be addressed to the office below:

National Institutes of Health
Office of Financial Management
Financial Services Branch

Government Accounting Section
Building 31, Room B1B05, MSC 2050
9000 Rockville Pike
Bethesda, Maryland 20892-2050
Telephone: 301-402-9123
Fax: 301-402-4934

If the amount of the award is **$15,000 or less**, one advance payment in lump-sum is processed. If the amount of the award is **greater than $15,000**, an advance payment equal to one-fourth of the amount is processed at the beginning of the budget period with succeeding quarterly payments processed in advance.

If the amount of funds advanced to the institution on a quarterly basis is insufficient to meet the cash requirements of the grant, the institution must make a written request to the awarding IC for any additional funds needed in excess of those provided on a quarterly basis.

M. Records Retention and Disposal:

All records (**e-mail** and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule," Item 4000 which covers NIH Grants and Awards and item 1100-G which covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail messages: NIH e-mail messages (messages including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. **These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your I/C Records Officer for additional information.**

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have

back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

N. Accountability and Management Controls Citation:

The purpose of this manual issuance is to state NIH policies and procedures for grants to foreign organizations or to domestic organizations with substantial foreign components.

1. **The Office Responsible for Reviewing Management Controls Relative to this Chapter**: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), is accountable for the method used to ensure that management controls in grants administration are implemented.

2. **Frequency of Review**: Ongoing reviews will occur as scheduled or on an ad hoc basis.

3. **Method of Review**: Responsibility for accountability and management controls for this chapter reside with the OPERA, OER. The frequency of review will be no less often than every four years. The Method of Review will be Other Review.

OPERA will use the NIH internal grants management compliance model (GMCM) to assess compliance with the policies stated in this issuance. The GMCM contains a file review component to ensure that I/C grant files are properly maintained and processed with regard to policies associated with foreign and international grantees. Reports of findings and

recommendations resulting from GMCM reviews or other similar types of reviews will be provided to the Grants Management Compliance Board for appropriate action. Common issues will be brought to the Grants Management Advisory Committee for resolution and corrective action. Depending upon the nature and the extent of problems found, if any, the Director, OPERA, may recommend additional policy guidance or training for grants management staff.

4. **Review Reports are sent to**: The DDER and the Director, OPERA,OER.

Appendix

INTRODUCTION

The following information and procedures provide detailed instructions in the management of foreign research grants; policy matters are contained in the body of the manual chapter.

BACKGROUND

The Department of State (DOS) has the authority under the Foreign Relations Authorization Act, to examine all international U.S. Government activities for its impact on national security and foreign policy. To oversee activities related to NIH awards, FIC has established a formal notification and concurrence process whereby the FIC collects and forwards information to the Department of State regarding proposed NIH grants to foreign institutions, and transmits cables through Department of State to U.S. Embassies. Please note that grant content considered as sensitive include the following: vaccine-related research, HIV/AIDS research, drug abuse, involvement of pregnant women, children and primates in research,

and politically sensitive regions.

The foreign clearance process can be started at various times - post-IRG, pre-Council, post-Council - and each IC varies in when it is started. Most ICs initiate the clearance process in the grants management office. Regardless of when or where the process begins, ICs must be reasonably certain that a positive funding decision will be made at the time the clearance documents are forwarded to FIC.

WHAT CONSTITUTES FOREIGN INVOLVEMENT?

Any activity as described below including involvement of human and animal subjects (see "Completing Research Objectives" below) whether or not grant funds are expended.

Any significant element or segment of the project which is to be performed outside the U. S., either by the grantee or by a researcher employed by a foreign institution.

Any extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sample collection, etc. Foreign travel for consultation is not considered a substantial foreign component.

FIC will determine if foreign clearance is necessary on a case-by-case basis. All grants with foreign involvement should be evaluated for determination of State Department clearance.

CLEARANCE PROCESS

Include one copy of the following:

NIH Form 1820 (Rev.1/96) (a form for each foreign component)

Copy of summary statement
Copy of grant application
Related correspondence

On the clearance package, attach a memo or route slip with the following information: the name of the IC staff contact submitting the package with phone and fax numbers; address of where to return signed 1820 form; state if the foreign involvement is a new foreign activity. If the grant is a renewal of a previous foreign clearance, attach a copy of the previously cleared NIH Form 1820.

[NIH FORM 1820](#) - **NOTIFICATION OF PROPOSAL TO MAKE AN AWARD**

If *multiple foreign countries* are involved, complete an NIH Form 1820 for each country.

Indicate domestic PI's name and complete organizational address in area, "Domestic PI."

Indicate foreign collaborating investigator's name and complete organizational address in area, "Foreign PI." When there is no foreign principal or collaborating investigator, document the name and address of the domestic PI's local contact in the foreign country.

Date of birth, place of birth and residency are no longer necessary.

It is important that the area documenting estimated total dollar award be complete, with the top line reflecting the total annual domestic funding and the lower line reflecting the total annual foreign funding.

COMPLETING RESEARCH OBJECTIVES:

Research objectives need to be written in technical terms to the greatest extent possible.

Supply a brief description of overall grant objectives and research activity in the foreign country.

State where the research is being conducted, i.e., hospital, laboratory, outpatient clinic, and indicate the city or town where research will take place. In the case of "field work" describe where the work will be done.

On whom are the investigators conducting research? e.g., women, children, diabetics, control subjects, primates, rats, rabbits, etc.

Documentation of human subject involvement: Describe the number of study and control subjects enrolled in the project, the ratio of gender and ethnic origin. Include a description of the research being conducted on study subjects. For example, are the study and control subjects providing blood or urine samples, tissue specimens or are they involved in drug/placebo clinical trials? Indicate the duration of human subject involvement.

For the exportation of animals or plants from the foreign site, state if government permits have been obtained.

Investigators working abroad are encouraged to apply high standards of treatment and care in research involving animals, similar to the principles outlined in the PHS Animal Welfare Policy.

The Office of Laboratory Animal Welfare (OLAW) must have a "Statement of Compliance with Standards for Humane Care and Use of Laboratory Animals by Foreign Institutions" on file for all foreign institutions with activities involving animals.

If additional space is needed for research objectives, please attach an addendum.

FOR ACTIVITY INVOLVING HUMAN SUBJECTS AND/OR ANIMAL SUBJECTS

Check appropriate box to indicate status of negotiation of human or animal subject assurances with Office of Human Research Protection (OHRP) and OLAW, respectively, and give assurance identification numbers if applicable.

NOTE: The Grantee should not be referred to FIC for the status of the clearance process. The grants specialist serves as liaison between the Grantee and FIC. Attempts by the principal investigator to contact either the FIC or the DOS only creates delays in the clearance process. The grants specialist may instead inquire on behalf of the PI with the FIC.

TERMS AND CONDITIONS APPLICABLE TO FOREIGN GRANTS

In general, the policies and requirements applicable to domestic research grants are applicable to grants made to foreign institutions and international organizations. There are, however, certain exceptions and special conditions listed below:

Single-case Deviations. The awarding IC may make single-case deviations in instances involving NIH policy, e.g., to award an excepted grant mechanism (G.3.), to transfer to or between foreign institutions (G.4.) and to award patient care costs. In the case of transferring to or between foreign institutions, the awarding IC must ensure that the special criteria for making a foreign award are met. This authority for a single-case deviation includes transferring a domestic grant to a foreign entity, as this

requires prior approval.

Currency Exchange. All requests for funds, including the budget contained in the application, shall be stated in U.S. dollars. Once an award is made, the NIH will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards. Foreign grantee institutions are strongly urged to use U. S. banks to ensure that payments will arrive on time.

Unallowable Costs. Costs for the following items are **not** allowable:

1. Alterations and renovations;

2. Custom and import duties; including consular fees, customs surtax, value-added taxes and other related charges; and

3. F&A. Beginning with awards issued in FY2002, limited F&A (8% for Administrative costs, minus equipment costs) may be provided on competing awards as detailed in Section K. No Facility costs will be provided.

Patient Care Costs. Patient care costs are provided only in exceptional circumstances.

Equipment. Management and accountability requirements for equipment purchased with NIH grant funds are identical to those for domestic institutions as specified in CFR Title 45 Part 74.

Reports and Records. Foreign grantee institutions must submit reports in English and in terms of U.S. dollars. Record retention and audit requirements are the same as those for grants to domestic institutions.

Expanded Authorities. Foreign grantee institutions are included in

Expanded Authorities. Inclusion in the Streamlined Non-competing award process (SNAP) process is at the discretion of the awarding IC.

Assurances. Assurances for Civil Rights, Disabled, Sex and Age Discrimination are not required for grants to foreign institutions. Assurances for Research Misconduct, Lobbying, Drug-Free Workplace, Delinquent Federal Debt, Financial Conflict of Interest and Debarment (with the exception of foreign governments and international organizations) are required.

Audit. Foreign grantees are subject to the audit requirements as set forth in [OMB Circular A-133](). A-133 requires that any recipient or sub-recipient that expends $300,000 or more in a year in Federal awards shall have a single or program-specific audit conducted for that year.

Debarment/Suspension. If the awarding IC anticipates the pursuit of debarment or suspension, then contact with the FIC is crucial prior to initiating any other action.

Annual Reporting Requirements. FIC compiles a list annually of awards made to domestic organizations with foreign components. To ensure accuracy, FIC forwards the list of awards made during the previous fiscal year to IC Executive Officers and Grants Management Officers for their review and verification of accuracy. ICs are requested to verify the accuracy of these numbers in writing or, alternatively, ICs may provide a statement to the FIC Executive Officer that the Notification of Proposal to Make an Award (NIH Form 1820) is to be used by FIC to verify the data.

CLEARANCE PACKAGE SUBMISSION:

Forward the complete package of material to:

Division of International Relations, FIC

Building 31, Room B2C11, MSC 2220

Phone: 301-496-4784

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NIH POLICY MANUAL

54105 - NIH Support of Scientific Meetings & Conferences by Grants & Cooperative Agreements

Issuing Office: OER 301-435-2768

Release Date: 04/16/2008

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1. Explanation of Material Transmitted: NIH Manual 54105 has been updated to: (1) clarify guidance specific to the scientific peer review of conference grant applications (R13s and U13s), (2) define additional terms relevant to conference grants, (3) clarify the review criteria to be used for initial peer review of these mechanisms, (4) clarify Just-in-Time procedures for conference grants, (5) clarify the roles of NIH staff in the management and oversight of conference cooperative agreements, (6) provide guidance consistent with the electronic submission of conference grant applications, and (7) provide guidance consistent with the establishment of multiple Project Director/Principal Investigator (PD/PI) awards for the support of team science projects.

2. Filing Instructions:

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- Online information, enter this URL: http://oma.od.nih.gov/manualchapters.

A. Purpose:

This chapter states policy and procedures unique to supporting extramural scientific meetings and conferences using the R13 and U13 mechanisms. The primary purposes of this revised chapter are to: (1) clarify guidance specific to the scientific peer review of conference grant applications (R13s and U13s), (2) define additional terms relevant to conference grants, (3) clarify the review criteria to be used for initial peer review of these mechanisms, (4) clarify Just-in-Time procedures for conference grants, (5) clarify the roles of NIH staff in the management and oversight of conference cooperative agreements, (6) provide guidance consistent with the electronic submission of conference grant applications, and (7) provide guidance consistent with the establishment of multiple Project Director/Principal Investigator (PI/PD) awards for the support of team science projects.

Throughout this document, the term "conference grant" will encompass conference grants and conference cooperative agreements.

B. Background:

The NIH recognizes the value of supporting scientific meetings and conferences relevant to its mission and to public health. Scientific meetings and conferences may be funded by assistance mechanisms (R13 grants and U13 cooperative agreements) for up to five years. NIH Institutes and Centers (ICs) support awards based on their mission and stated programmatic priorities and other guidelines, as published in the [NIH Guide for Grants and Contracts](http://grants1.nih.gov/grants/guide/index.html) (http://grants1.nih.gov/grants/guide/index.html) and on the [Conference Grant website](http://grants1.nih.gov/grants/funding/r13/index.htm) (http://grants1.nih.gov/grants/funding/r13/index.htm). NIH OD Offices also provide funds for conference grants through arrangements made with an IC.

The Office of Extramural Programs (OEP) has developed a website (http://grants.nih.gov/grants/funding/r13/) for information regarding conference grants.

This website includes IC-specific contact names, and is updated frequently to provide the most recent information. Offices within the NIH Office of the Director (OD) that provide funds for conference grants also are listed in this website; however, they do not have an awarding office and must work through an IC.

C. Policy:

This policy applies only to conferences and scientific meetings supported by NIH grants (R13) and cooperative agreements (U13). It does not apply to conferences, workshops, or scientific meetings that are sponsored or initiated by NIH and funded by contracts or by direct operating funds, or workshops conducted as an adjunct to Scientific Review Group activities.

Advance written permission to submit a conference grant application is required from the primary IC Conference Grant Contact before an IC will accept it. A letter from the accepting (primary) IC Conference Grant Contact confirming advance permission to submit a conference grant application must be included as part of the PHS 398 Cover Letter component (PDF) in the application; the letter also may reflect dollar limits and other budgetary and/or program guidelines specific to the IC. Only one letter of permission is required from the accepting IC, regardless of the number of ICs and OD Offices that elect to support a conference or scientific meeting. An example of an advance permission letter is included as Appendix 1. The scientific and technical merit of conference grant and cooperative agreement applications will be evaluated by Scientific Review Groups, convened and managed by the accepting (or primary) IC.

Three annual receipt dates (December 12, April 12, and August 12) are exclusive to conference grant applications, and are provided to expedite time frames for these two award mechanisms. Conferences on AIDS/AIDS related topics should be submitted for the corresponding AIDS dates (January 7, May 7, and September 7).

Organizers of conference grants must address, in the grant application, the appropriate representation of women, racial/ethnic minorities, persons with disabilities, and other

individuals who have been traditionally underrepresented in science in all aspects of planning, organizing and executing NIH-supported meetings and conferences. If appropriate representation is not apparent, no award should be issued until program staff is assured of concerted efforts to obtain it.

R13s and U13s are excluded from Modular budget procedures, and are limited to direct costs. Some Just-in-Time procedures may apply to conference grants.

International conferences supported by grants and cooperative agreements no longer require clearance by the Fogarty International Center or the Department of State.

D. References:

1. Code of Federal Regulations – 42 C.F.R. 52h - Scientific Peer Review of Research Grant Applications and Research (http://grants.nih.gov/grants/policy/fed_reg_peer_rev_20040115.pdf)

2. NIH Grants Administration Manual; Chapter 4.1.04.204, Responsibilities of NIH Grants Administration Staff (http://odoerdb2.od.nih.gov/gmac/sources/nihgam_4.1.04.204.pdf)

3. NIH Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities - - File 4 of 5, Section on Support of Scientific Meetings (Conferences Grants) (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm)

4. NIH Manual Chapter 1186, pending release.

5. NIH Manual Chapter 1743, Keeping and Destroying Records (http://oma.od.nih.gov/manualchapters/management/1743/)

6. NIH Manual Chapter 4204-204B, Peer Review Process (http://oma.od.nih.gov/manualchapters/grants/4204-204B/)

7. NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organization (http://oma.od.nih.gov/manualchapters/grants/54104/)

8. [NIH Manual Chapter 54513](http://oma.od.nih.gov/manualchapters/grants/54513/), Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities (http://oma.od.nih.gov/manualchapters/grants/54513/)

9. [NIH Manual Chapter 54515](http://oma.od.nih.gov/manualchapters/grants/54515/), Guidelines for Dually Assigned Grant Applications (http://oma.od.nih.gov/manualchapters/grants/54515/)

10. [NIH Manual Chapter 54815](http://oma.od.nih.gov/manualchapters/grants/54815/), Implementation of Cooperative Agreements (http://oma.od.nih.gov/manualchapters/grants/54815/)

11. [NIH Manual Chapter 55010](http://oma.od.nih.gov/manualchapters/grants/55010/), Co-Funding Assistance Awards (http://oma.od.nih.gov/manualchapters/grants/55010/)

12. [NIH Notice NOT-OD-03-066](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html): Guidelines for Inclusion of Women, Minorities, and Persons with Disabilities in NIH-Supported Conference Grants (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html)

13. [NIH Notice NOT-OD-07-017](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html), Establishment of Multiple Principal Investigator Awards for the Support of Team Science Projects (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html)

14. [NIH Program Announcement PA-08-149](http://grants.nih.gov/grants/guide/pa-files/PA-08-149.html): NIH Support for Conferences and Scientific Meetings (Parent R13/U13) (http://grants.nih.gov/grants/guide/pa-files/PA-08-149.html)

15. [United States Code 42 USC § 1320b-10](http://www.dwt.com/practc/healthcr_compliance/publications/OIG_SmallGroup_Compliance/docs/CONCIVB.PDF)(a), Prohibited Acts (http://www.dwt.com/practc/healthcr_compliance/publications/OIG_SmallGroup_Compliance/docs/CONCIVB.PDF)

16. [February 3, 2006 HHS Memorandum](http://www.knownet.hhs.gov/travel/HHSInvolvementinConferencesandTravelMemo.pdf), "HHS Involvement in Conferences and Travel" (http://www.knownet.hhs.gov/travel/HHSInvolvementinConferencesandTravelMemo.pdf)

E. Definitions:

1. **Appropriate Representation** - representation based on the availability of scientists from groups that traditionally have been underrepresented in science and are known to be working in a particular field of biomedical or behavioral research.

2. **Conference (scientific meeting)** – a symposium, seminar, workshop, or other organized and formal meeting, whether conducted face-to-face or via the Internet, where individuals assemble (or meet virtually) to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such a meeting. A meeting that is conducted as part of the normal course of doing business is not considered a conference for purposes of this chapter.

3. **Domestic Conference** – a conference held in the United States (U.S.) or its territories or possessions or Canada primarily for U.S. or United States-Canadian participation even if it may include foreign speakers.

4. **International Conference** – a conference so designated by its sponsor, or one that potentially involves participants from two or more countries (other than the United States or Canada). The meeting may be held in any country, including the U.S., consistent with any Department of State (DoS) restrictions.

5. **Scientific Review Group (SRG)** – a peer review committee of primarily non-government experts (Peer Reviewers), qualified by training, experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications. No more than one-fourth of the members of an SRG may be Federal employees.

F. Roles and Responsibilities Unique to R13s and U13s:

Roles and responsibilities that apply to all Review staff, Program staff, and Grants Administration staff members are defined in the NIH Grants Administration Manual. In addition, the following roles and responsibilities are specific to extramural staff members who are involved in the administration of conference grants:

1. **Conference Grant Contact**

   Each IC and OD Office will designate a [Conference Grant Contact](). The Conference Grant Contact will be the focal point for information regarding the support of conferences and scientific meetings based on program-specific guidelines, and the appropriate program staff within the IC for further pre-submission discussions. The name of this individual will be reported to the NIH Conference Grant Coordinator The Conference Grant Coordinator, and the Conference Grant Contacts are listed on the [OER Conference Grant website]() (http://grants1.nih.gov/grants/funding/r13/index.htm).

2. **NIH Conference Grant Coordinator**

   The NIH Office of Extramural Programs, OER, OD will designate an agency coordinator who will be responsible for maintaining the website (http://grants.nih.gov/grants/funding/r13/) related to the NIH Support for Conferences and Scientific Meetings. The website provides links to the current application forms and instructions, NIH Guide Program Announcements and Notices, Contacts List, and other relevant information. In addition, the Conference Grant Coordinator will maintain a current list of IC Conference Grant Contacts and address general questions related to these mechanisms.

3. **IC Project Scientist**

   For U13 Cooperative Agreements, an IC Project Scientist will have substantial scientific-programmatic involvement and provide technical assistance, advice, and coordination above and beyond normal program stewardship for grants.

Substantial involvement as a partner would include, for example, assisting in planning the agenda, selecting speakers, organizing a symposium, determining the content of the meeting, or determining the acceptability of submitted papers. Substantial involvement would not include serving as an invited speaker or providing limited advice.

4. **IC Program Officer**

For U13 Cooperative Agreements, an IC Program Officer will be responsible for normal stewardship of the award. The Program Officer will be responsible for assessing the progress of multi-year conferences toward the accomplishment of specified milestones, and for recommending release of additional funds to the project.

In general, the role of IC Program Officer should be performed by an IC staff member other than the IC Project Scientist. Otherwise, systems must be in place to address possible conflict of interest when the IC Program Officer is also the Project Scientist for a U13 award.

G. Implementation Procedures:

1. **Advance permission**

Applicants are required to obtain advance written permission before submitting an application for support of a scientific meeting or conference, by contacting the appropriate [Conference Grant Contact](). Contacts are listed on the OER [Conference Grant website]() .

Conference grant applications may be submitted for up to five years of support by permanent sponsoring organizations for conferences held annually or biennially, and multi-year conference grants will be evaluated annually by IC staff based on scientific progress reports. Copies of proceedings or publications resulting from the conference/scientific meeting may be substituted for the final

progress report, with approval from the NIH awarding office.

A letter (email, fax, etc.) from the IC designated Conference Grant Contact must be included as part of the PHS 398 Cover Letter component (PDF) of the application. Permission to submit an application does not assure funding or funding at the level requested. Applications of interest to more than one IC may be co-funded. NIH OD Offices may participate in this activity by working through an IC.

2. **Peer review**

The Division of Receipt and Referral in the Center for Scientific Review will assign conference grant applications to the accepting (primary) IC based on the permission letter submitted with the application. Secondary assignments will be made according to established PHS referral guidelines and ICs should accept secondary assignments only when interest exists in supporting the scientific meeting or conference.

Conference grant applications will be evaluated for scientific merit by Scientific Review Groups convened by the Review Branches of the primary ICs, according to NIH policies and procedures for scientific peer review. In addition, conference grants must be recommended by the Advisory Council or Board of the primary IC prior to award. When the IC determines that sufficient need exists for substantial involvement of IC staff in the planning and conduct of a conference or scientific meeting, the designated IC official may approve the use of a U13 cooperative agreement award. Standard terms and conditions of award for U13s are included in Appendix 2.

3. **Peer review criteria**

In their critiques, reviewers will be asked to comment on the standard peer review criteria, as specified in 42 C.F.R. 52h and the Parent Funding Opportunity Announcement for R13/U13s. Reviewers also will be asked to comment on the

additional review considerations listed below. The review criteria below will be factored into the priority score:

Significance: Does this conference/scientific meeting address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these endeavors on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the format and agenda for the conference/meeting appropriate for achieving the specified goals? Is the conference/meeting timely for the subject matter? For applications designating multiple PDs/PIs, is the Leadership Plan approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the topics of the conference/meeting and the expertise of each of the PD/PIs?

Innovation: Does the conference/meeting employ novel approaches or methods to fulfill its purpose? Does the conference/scientific meeting draw together appropriate experts who may otherwise not have an opportunity to meet?

Investigators: Is(are) the PD/PI(s) well suited for organizing and fulfilling the goals of this conference/scientific meeting? Are the qualifications and past performance of the PD/PI(s) appropriate, and are they well suited for their described roles in the conference/scientific meeting? Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference/scientific meeting?

Environment: Is the conference/scientific meeting site appropriate? Does the applicant organization have the ability to contribute to the probability of success? Do the proposed meetings, exhibits, interactions, etc., take advantage of unique features of the environment or employ useful collaborative arrangements? Is institutional support evident?

Additional Review Criterion (included in consideration of priority score):

Appropriate Representation: How well do the plans for inclusion of women, racial/ethnic minorities, persons with disabilities, and other individuals who have been traditionally underrepresented in science provide for their appropriate representation in the planning, organization, and execution of the proposed conference/meeting?

Additional Review Consideration (*not* included in consideration of priority score):

Budget: The reasonableness of the proposed budget and the requested period of support will be assessed in relation to the proposed plan.

4. **Use of Government Logos**

    The terms of use for logos for the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), or any of its entities on conference materials will be governed by the applicable cooperative agreement conditions. Additional information, including information on any necessary approvals, is available in the NIH Manual Chapter 1186 (pending release). DHHS guidance also is provided in a memorandum of February 3, 2006 (http://odoerdb2.od.nih.gov/gmac/topics/scientific_hhs_memo_20060203.pdf). Ordinarily, each and every use of a Government logo by an outside organization requires review and approval by the applicable Governmental entity.

5. **Timing of Awards:**

    In general, conference grant awards should be issued before the actual start date of the conference. Awarding a conference grant after a conference has been held should only be done when an IC can determine or document that funding of post-conference activities is consistent with the approved application.

6. **Special Terms of Award**

In addition to the Cooperative Agreement terms noted in Appendix 1, all conference grants must include the following term in the Notice of Award (NoA):by the U.S. Government."

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records" (http://oma.od.nih.gov/manualchapters/management/1743/), Appendix 1, "NIH Records Control Schedule," Section 1100 – General Administration, all Items that apply and Section 4000 Grants and Awards. NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

The purpose of this manual issuance is to provide policy unique to conference grants. The most unique feature is the requirement for advance permission to submit an

application.

(1) **Office Responsible for Reviewing Management Controls Relative to this Chapter**: Office of Extramural Programs (OEP), OER/OD.

(2) **Frequency of Review**: The review will be conducted every three to five years when the application instructions and guidelines are reissued in the NIH Guide. There is minimal risk in administering conference grants.

(3) **Method of Review**: Other Review: OEP will complete an internal risk assessment in the first year after the chapter is in place. Based on this assessment, a decision will be made as to the method of review. This is a minimal risk activity based on the dollar amount (usually <$10K) of most conference grants, the categories of funds that are allowed under this mechanism, the fact that human and animal studies are not involved, and that F&A costs are not part of the budget calculation.

This is almost a self-policing policy, as the application cannot be accepted without advance NIH permission. Appendix 3 is a checklist for assessing compliance with conference grant policies.

(4) **Review Reports** are sent to: Deputy Director for Management and Deputy Director for Extramural Research (DDER). Reports should indicate that controls are in place and working well or indicate any internal management control issues that should be brought to the attention of the report recipient(s).

Appendix 1: Suggested Template for Advance Permission Letter

Dear _____

Based on discussions with appropriate Institute/Center staff, advance permission is hereby granted for submission of an R13/U13 conference grant application for support of the scientific meeting entitled _____, scheduled for _____. The

special receipt dates for conference applications are April 12, August 12 and December 12, annually. Conferences on AIDS/AIDS related topics should be submitted for the corresponding AIDS dates (January 7, May 7, and September 7).

Please attach this letter as part of the PHS 398 Cover Letter component (PDF) in your application, and forward two additional copies of the application, along with all appendix material, to my attention.

Please refer to the Conference Grant Program Announcement for supplementary instructions. If you have any questions, please let me know.

Signature -- IC Conference Grant Contact

Appendix 2: Standard Terms and Conditions of Award for U13 Cooperative Agreements

For conferences supported by cooperative agreement, the terms and conditions below (1-3) will be incorporated into the Notice of Award (NoA). The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, applicable U.S. Department of Health and Human Services (DHHS) regulations, including the grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

A U13 award is an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under a cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility reside with the awardees

for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined above.

1. Rights and Responsibilities of the Project Director/Principal Investigator(s) (PD/PIs)

Awardees have primary authorities and responsibilities to define objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusions of the conference.

The PD/PI(s) will retain custody of, and have primary rights to, information developed under the cooperative agreement, subject to government rights of access, consistent with the current DHHS, PHS, and NIH policies. Publication and copyright agreements and the requirements for financial status reports; retention of records; and terminal progress reports will be as stated in the NIH Grants Policy Statement.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

Awardees are responsible for identifying specific milestones for conferences that will be supported during the project period, when multi-year conferences are supported.

2. NIH Responsibilities

An NIH Project Scientist will have substantial scientific-programmatic involvement during conduct of this activity, through technical assistance, advice, and coordination above and beyond the normal program stewardship for grants. Substantial involvement as a partner would include, for example, assisting in planning the agenda, selecting speakers, organizing a symposium, determining the content of the meeting, or determining the acceptability of submitted papers. Substantial involvement would not include serving as an invited speaker or providing limited advice.

Additionally, an agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the NoA.

In general, the role of IC Program Officer should be performed by an IC staff member other than the IC Project Scientist. Otherwise, systems must be in place to address possible conflict of interest when the NIH Program Officer is also the Project Scientist for a U13 award.

3. Arbitration Process

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: one chosen by the awardee, a second member selected by the IC, and the third member with expertise in the relevant area who is chosen by the other two. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16, or the decision-making authority of NIH.

Appendix 3: Management Controls Checklist

Management Controls

Checklist – Key Compliance Factors

MC 54105 Conference Grants

Policy/Compliance Factor	Internal Control	Review or Sampling Technique	MC Reference	Responsible NIH Office
Each IC will designate a Conference Award Contact.	ICs must designate one person as the conference award contact.	Review of the OER website for Conference Grants	54105.C	OEP
A letter confirming advance permission must be included in the Cover Letter component (PDF) of the application.	Cover Letter components of the applications must include the letter from NIH granting advance permission to submit an application.	Random sample of R13s will be reviewed for inclusion of prior approval letter.	54105.C	OEP
Systems must be in place to address possible conflict of interest on U13s when the NIH Program Administrator/Project Scientist is the Program Officer.	ICs will have systems in place to monitor and address conflicts of interest where the NIH Program Administrator/ Project Scientist is the Program Officer.	Random sample of U13s will be made to assure no conflict exists.	54105.F	OEP

54110 - PROGRAM ANNOUNCEMENTS AND REQUESTS FOR APPLICATIONS
Issuing Office: OER 496-5366
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1.   Explanation of Material Transmitted: This chapter describes
     the procedures for the initiation, development, clearance,
     publication, and dissemination of Requests for Applications
     (RFAs) and Program Announcements (PAs) and publication of
     Notices of Availability of Requests and Requests for
     Proposals (NA/RFPs).

2.   Filing Instructions:

     Remove: NIH Manual 4110 dated 8/26/92 in entirety

     Insert: NIH Manual 4110 dated 10/01/94

3.   Distribution: NIH Mailing Keys F-401 and F-406

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o   content of this chapter, contact the issuing office listed
     above.

o   NIH Manual Mailing Keys, or for a paper copy of this chapter
     contact the Division of Support Services, ORS, on 496-1787.

o   NIH Manual System, contact the Office of Management
     Assessment on 496-2832.

o   on-line information on the NIH Manual System and on-line
     chapter text, use Enter BBS, available through WYLBUR, and
     access the MANUALS Bulletin Board or call 496-2832.

LIST OF ABBREVIATIONS

     ADEA   Associate Director for Extramural Affairs, NIH
     ADRR   Associate Director for Referral and Review, DRG
     DRG   Division of Research Grants
     EN   Early Notification
     EPMC   Extramural Program Management Committee
     GAM   Grants Administration Manual
     Guide   NIH Guide for Grants and Contracts
     IC   Institute or Center
     IAO   Institutional Affairs Office, OEP
     IRG   Initial Review Group
     MOU   Memorandum of Understanding
     NA   Notice of Availability
     NIH   National Institutes of Health
     OEP   Office of Extramural Programs, OER

OER	Office of Extramural Research, OD
PA	Program Announcement
PAR	Program Announcement with Special Referral
PHS	Public Health Service
PI	Principal Investigator
PT	Program Thesaurus
RFA	Request for Applications
RFP	Request for Proposals

A. PURPOSE: This chapter describes the procedures for the initiation, development, clearance publication, and dissemination of Requests for Applications (RFAs) and Program Announcements (PAs). Concept clearance, overlap resolution, and agreements regarding the referral and review of applications received in response to RFAs and PAs are addressed. The applicable policies set forth in the Public Health Service (PHS) Grants Administration Manual (GAM) are incorporated into the procedures described in this chapter. (5) (Numbers in parentheses, here and throughout this document, refer to the numbers of the references listed in Section E.)

B. APPLICABILITY: This policy applies to all NIH extramural programs using assistance awards (grants and cooperative agreements) to support research, research training (including fellowships), conferences, construction, and instrumentation and research and development contracts.

C. BACKGROUND: The NIH Guide for Grants and Contracts is the official vehicle for dissemination of information about the availability of assistance, research training, and research and development contracting opportunities at the NIH. Several means are used by the NIH to encourage and invite submission of applications and proposals. A brief description of each program area is published annually in the Catalog of Federal Domestic Assistance (4). The handbook, NIH Extramural Programs (14), is a compendium of scientific programs of the NIH awarding units in which potential applicants can locate additional information about specific scientific and program areas for further information. PAs and RFAs supplement NIH Extramural Programs by highlighting selected aspects of established programs and by announcing new and continuing program initiatives.

Notices of Availability of RFAs (NA/RFA) and PAs (NA/PA) must be published in the printed and electronic editions of the NIH Guide for Grants and Contracts in lieu of the PHS requirement for publication in the Federal Register. This special exception to GAM 115.5 granted by HHS to the PHS is based on the fact that the biomedical research community that would be eligible to apply for NIH research funds is reached more effectively by the NIH Guide than by the Federal Register (5).

The printed and electronic editions of the NIH Guide contain NA/PAs, NA/RFAs, Notices of the Availability of Requests for Proposals (NA/RFPs) for research and development contracts, and notices regarding NIH policy, NIH-supported conferences and workshops, and biological resources developed or

maintained with the support of NIH funding. The NAs will include a brief summary of the purpose of the RFA, RFP, or PA; the application or proposal receipt date, the anticipated number of awards and funds available for RFAs; and information about how to obtain a copy of the RFA, RFP, or PA. The electronic edition of the NIH Guide also contains the full text of the RFAs and PAs.

This revision of the NIH Manual Chapter 4110 incorporates the following changes in policy and procedures for the publication of RFAs and PAs and other items in the NIH Guide: (1) Emphasis on the electronic edition has been added, reflecting increased reliance on electronic distribution systems; (2) specific requirements regarding the focus of PAs have been added; (3) new formats for NA/RFAs and NA/PAs have been incorporated; (4) very brief notices regarding biological resources will be accepted for publication and requirements regarding such notices are set forth; (5) NA/RFPs may be submitted via a LAN-based system; and (6) the Appendices are updated to accommodate the policy and procedural changes.

D. POLICY: To be published in the NIH Guide, notices, PAs, RFAs, NA/PAs, NA/RFAs, and NA/RFPs must: (1) comply with NIH requirements for format and content as set forth in this NIH Manual Chapter, thus implementing PHS and NIH policy; and (2) must have received all applicable internal and external clearances. NIH NA/PAs and NA/RFAs must be published in the printed edition of the NIH Guide and, in addition, the full text of the PAs and RFAs must be published in the electronic edition. NA/RFPs must be published in the Commerce Business Daily, but may be published in the NIH Guide, if desired by the IC contracting office. PAs and RFAs are reviewed for compliance with PHS and NIH policy by the IAO and OEP prior to publication.

NA/PAs, PAs, NA/RFAs, and RFAs published in the NIH Guide may be distributed subsequently by other means such as mailings, publication in scientific journals, and distribution at professional meetings. The official files to be used for distribution by IC staff are found in ENTER EGUIDE on WYLBUR.

Notices and announcements from other components of the PHS and other departments and agencies may be published in the NIH Guide after review and approval by appropriate officials of the issuing agency and the OEP. The format and procedures for publication in the NIH Guide must be followed, and the notice or announcement must be consistent with NIH interests.

Notices and announcements may be published in both the NIH Guide and the Federal Register. If this is intended, the IAO must be notified when the notice is submitted for publication so that the NIH Guide and Federal Register clearance and publication procedures can be coordinated. The IAO should be notified of anticipated publication date of an NA/RFP in the Commerce Business Daily so that publication may be coordinated to the extent possible.

E.   REFERENCES:

1. Administrative Procedures Act 5 U.S.C. 552.
2. Public Health Service Act 301, Section 492.
3. Title 45, Code of Federal Regulations, Parts 74 and 92.
4. Catalog of Federal Domestic Assistance.
5. PHS Grants Administration Manual, Part 115 - Information for Potential Applicants.
6. PHS Grants Policy Statement.
7. NIH Guidelines for Inclusion of Women and Minorities in Clinical Research, FR59, 15408-15413, March 28, 1994.
8. NIH Manual Chapter 1820, "Selection of Extramural Award Instrument--Grant, Cooperative Agreement, or Contract".
9. NIH Manual Chapter 4815, "Implementation of Cooperative Agreements - Initiation, Review, Award, and Administration".
10. NIH Manual Chapter 5010, "Co-Funding Assistance Awards".
11. I&I Memorandum, OER 88-5, Triage of Applications.
12. Referral Guidelines for Funding Components of PHS, Division of Research Grants, NIH.
13. Referral Guidelines for Initial Review Groups at NIH, Division of Research Grants, NIH.
14. NIH Extramural Programs - Funding for Research and Training.

F.   DEFINITIONS:

1. The NIH Guide for Grants and Contracts is the official publication of NIH program and policy notices.

2. A Notice is an announcement of NIH policy, NIH-sponsored conferences, NIH-funded research resources, or other information about NIH of interest to the extramural research community.

3. A Notice of Availability (NA) is an abbreviated version of an RFA, PA, or RFP that provides potential applicants with information necessary to decide whether or not to obtain the RFA, PA, or RFP and from where.

4. A Program Announcement (PA) is a formal statement about a new or re-emphasized, ongoing NIH extramural activity. Except for a few programs that have only one annual receipt date, applications in response to PAs may be submitted for any appropriate receipt date and are reviewed with all other applications received at that time. Applications are referred to ICs and initial review groups (IRGs) according to published referral guidelines (12, 13). A PA for which all applications will be referred automatically to one IC for review and administration, will be designated a Program Announcement with Special Referral.

5. A Request for Applications (RFA) is a formal statement that invites grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. The RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application receipt date(s). Applications submitted in response to an RFA usually are reviewed by an IRG convened by the IC that issued the RFA.

G.   PROCEDURES:

1.   SUMMARY OF PROCEDURES FOR PROGRAM ANNOUNCEMENTS (PAs) AND
     REQUESTS FOR APPLICATIONS (RFAs)

   a.   Institute/Center (IC) obtains concept clearance for RFAs
        and RFPs.

   b.   Issuing IC staff prepares a draft of the RFA or PA
        according to required contents and format (Appendices 1 and
        2 for RFA and 3 and 4 for PA).

   c.   Issuing IC staff numbers RFA. PAs are assigned a number by
        the IAO.

   d.   For RFAs, the IC EPMC member (or designee) and the
        Associate Director for Referral and Review (ADRR), DRG, (or
        designee) agree on a receipt date for applications and
        whether the IC or DRG will conduct the review.

   e.   Clearances by grants management and IC review staff are
        obtained (8,9).

   f.   For cooperative agreements, clearances specific to
        the mechanism are obtained.

   g.   Potential overlapping interests of other ICs with the
        content of a PA or RFA are identified by the initiating IC
        and the EPMC member of each IC is contacted to seek
        resolution.

   h.   At least 28 days (but not longer than six months) prior to
        the planned publication date (always a Friday), an Early
        Notification (EN) is submitted to the electronic EN System
        (Appendix 6). ICs have 14 days to indicate overlap
        concerns. Resolution of overlap is documented by comments
        in the EN System. The ADRR, or designee, is responsible
        for approval of the resolution of overlap issues and may
        require a Memorandum of Understanding (MOU) in complex and
        contentious instances.

   i.   At least 15 days prior to the planned publication date (by
        2:00 p.m. Thursday), the RFA and NA/RFA or PA and NA/PA are
        transmitted to the Publication File for the NIH Guide on
        WYLBUR by the designated person of the IC using the
        authorized initials (Appendix 5). NA/RFPs may be sent via
        LAN or on 3.5 diskette at any time.

   j.   Final clearance for publication in the NIH Guide requires
        clearance of review and referral issues by ADRR, DRG, and
        clearance of all other policy issues by the Director,
        Office of Extramural Programs, OER, through the IAO.
        Clearance status and publication date are indicated in the
        EN file.

2.   CLEARANCE OF RFAS AND PAS

   a.   Concept Clearance.

        Each IC must document the clearance of RFA concepts, i.e.,

purpose, scope, and objectives. This clearance must include advice from the public and may be obtained through, for example, consultation with national advisory councils and advisory boards, Congressional mandate, or workshops convened specifically for advisory purposes. The purpose of the PA must include programmatic justification of the mechanisms to be included.

b. IC Clearance. The IC EPMC member has the ultimate responsibility for ensuring and assuring that all appropriate clearances have been obtained by the IC before a PA or RFA is transmitted to the IAO for publication in the NIH Guide. The clearance process must include review and comment by the IC Grants Management Officer regarding the administrative and business management aspects of the PA or RFA, including approval for the selection of the mechanism(s), and the IC chief scientific review official, if the applications are to undergo initial review by the IC. In addition, it is the responsibility of the EPMC member or designee to ensure that the NA/PAs, PAs, NA/RFAs, and RFAs conform to the content and style requirements set forth in this chapter. It is the responsibility of the IC Contract Office to ensure that necessary concept clearance for RFPs has been obtained prior to submission of the NA/RFP for publication.

c. Clearance for Cooperative Agreements. NIH Manual Chapter 1820 (8) contains additional information to consider in choosing this mechanism. The process for obtaining clearance to use the mechanism is defined in NIH Manual Chapter 4815 (9), which also addresses issues that need to be considered by the IC during program development and sets forth required language and format for RFAs. The proposal for use of the cooperative agreement mechanism must then be sent to the ADEA, NIH, accompanied by a copy of the proposed RFA.

Submission of the justification package to the ADEA 30 days prior to the planned publication date usually is sufficient to allow timely review. Like other RFAs, RFAs for cooperative agreements require the entry of an EN at least 28 days before the planned publication date. The EN for a cooperative agreement RFA may be transmitted before or at the same time that the justification memorandum for use of the mechanism is submitted to the ADEA, NIH, and the two processes can proceed simultaneously. However, the cooperative agreement RFA will not be published until approval for use of the mechanism has been obtained from the ADEA.

d. NIH Clearance. The OEP, through the IAO, is responsible for reviewing all items submitted for publication for compliance with NIH and PHS policies and ensuring that the clearance by the DRG for review and referral matters and by the ADEA for use of the cooperative agreement mechanism are obtained.

The IAO is also responsible for ensuring that all documents to be published in the NIH GUIDE meet the format and style requirements. The format, including required and suggested

language, is contained in Appendices 1-4. The GPO Manual is the reference used for grammar and punctuation. Minor copy editing will be done by the IAO. ICs will be asked to revise and resubmit if major changes are needed.

3. IDENTIFICATION AND RESOLUTION OF OVERLAPPING INTERESTS

The subject of the RFA or PA must be in accord with the scientific areas of the issuing IC as set forth in the Referral Guidelines for Funding Components of PHS (12). It is the responsibility of the issuing IC to identify, resolve, and document in the EN System, as described below in Section 3.C., any overlapping program interests that exist with another IC. The DRG may also use the comments on the EN to indicate possible instances of overlap. Resolution of issues of overlap must be approved by the ADRR, DRG, prior to acceptance of the RFA or PA for publication in the NIH Guide.

Staff of the involved ICs must make every effort to resolve overlap issues in a timely manner. If they are unable to do so, the matter will be dealt with by the ADRR, in consultation with the EPMC members of the ICs involved and the ADEA. The ADRR, DRG, may request an MOU in complex and contentious cases. Final clearance of all referral issues before publication in the NIH Guide is the responsibility of DRG. If negotiations between or among ICs regarding overlap issues are unduly prolonged, DRG has the prerogative to make a unilateral decision regarding the referral criteria to be applied. However, DRG must notify the involved ICs a full day in advance that it intends to exercise this prerogative.

a. Early Notification (EN). An EN, to inform other ICs and PHS agencies of the intention to publish an RFA or PA, must be entered at least 28 days prior to the planned publication date.

b. Memorandum of Understanding (MOU). If deemed necessary by ADRR, DRG, or designee, inter-IC and interagency negotiations regarding overlap must be documented in the form of an MOU from the EPMC member (or formal designee) of the IC issuing the RFA or PA, through the EPMC member(s) of the IC(s) with whom actual or potential overlap exists, to the ADRR, DRG. The sponsoring EPMC member is responsible for providing copies of the MOU to the program administrators of his/her IC who are involved in the RFA, the DRG liaison of his/her IC, the IAO, and the Deputy Chief for Referral, DRG.

c. Resolution of Overlap. For any given PA or RFA, the interest of other ICs will range from none to significant, and the resolution of this overlapping interest will range accordingly. Some examples of the extent of overlapping interest and possible resolutions follow:

No overlap or potential for it exists; therefore, no action is necessary.

No overlap in the emphasis of the RFA exists, but the potential exists for applications to be submitted that emphasize the interests of non-sponsoring IC(s). Comments

may be entered on the EN System that identify the potential area(s) for overlap and indicate that applications with this emphasis will be assigned according to the PHS Referral Guidelines (12). Such overlap may also result in dually assigned applications if the secondary assignee is willing to use the IRG review derived from the RFA. Language to this effect must be included in the announcement.

Significant overlap exists. In the case of PAs the resolution may be: The ICs co-sponsor and jointly publish the PA and program administrators from both ICs are listed in the INQUIRIES section.

In the case of RFAs, the resolution may be: (1) The two ICs agree and document that the applications submitted in response to a particular RFA will all be assigned to one IC as primary and the other as secondary and will be reviewed by one committee within the primary IC. Following review, certain previously (prior to review) agreed-upon applications would be reassigned to the secondary IC for funding. This procedure would not affect standard practices for assignment other than for the particular RFA or (2) The Referral Office, DRG, would make primary and secondary IC assignments as appropriate, but applications would be all reviewed by one IRG. (3) The non-sponsoring IC would agree to a one-time waiver of its overlapping interests.

ICs may want to co-fund applications of mutual interest. Co-funding agreements must be in accord with NIH Manual Chapter 5010 (10) and be documented in the EN System. In addition, the existence of an IC co-funding agreement must be stated in the RFA or PA.

4. RFA AND PA REISSUANCE

An RFA or PA will not be reissued, unless there is exceptional reason for doing so. Approval for reissuance must be requested in writing from the Director, OEP, through the Director, IAO, and will be considered on a case by case basis. In addition, the requirements for Early Notification and all other clearance procedures apply to the reissuance.

5. TRANSMISSION AND PUBLICATION OF PAs AND RFAs

   a. Early Notification (EN) File. The EN File was developed to facilitate information exchange among the ICs and the identification and resolution of referral issues. The EN is mandatory for all RFAs and PAs issued by the NIH and other PHS agencies prior to publication in the NIH Guide.

   The EN must be entered at least 28 days before the planned publication date. The EN will be removed from the active EN File after the designated announcement is published in the NIH Guide or after six months, if the announcement is not submitted for publication. The EN must be transmitted by an EPMC member or designee, using the WYLBUR initials authorized for that purpose.

The format for ENs and instructions for entering ENs are shown in Appendix 6. All items must be completed. The PURPOSE section in the EN must be identical to the corresponding section of the RFA or PA. The electronic EN File is designed to receive comments on overlap issues. Only the EPMC member or designee of the IC issuing the PA or RFA can enter information into the EN itself, but other EPMC members or their designees, using previously agreed-upon WYLBUR initials, can enter comments in the appropriate section at the end of the file. The entire file, including the appended comments, can be read by any NIH staff who have access to WYLBUR. IC staff who have concerns regarding overlap must indicate this as a comment in the EN File and must contact the issuing IC EPMC member or designee within 14 days after entry of the EN so that overlap concerns can be resolved in a timely manner.

After the PA or RFA has been entered into the Publication File, the ADRR, DRG, uses the EN file to note issues that need resolution and indicate clearance status. The notice may not be published until it has been cleared by the ADRR, or designee, for all referral and review issues, including an MOU if necessary. IAO notes in the EN file when all policy issues have been cleared for a PA or RFA and the publication date.

b. Publication File. PAs, RFAs, NA/PAs, and NA/RFAs must be emailed to the IAO by 2:00 p.m., Thursday, 15 days prior to the anticipated publication date, using the procedures described in Appendix 5. The issuing IC will be contacted if a submission does not meet the requirements for format and content and if there are grants policy concerns. If the required changes in the document are substantial, the IC will be requested to make the changes and resubmit the document.

Items will be reviewed by the DRG and IAO in the order received in the publication file. Publication will occur in the order the items are cleared, on a space available basis. If the amount of text cleared exceeds the amount of space available, priority will be given to the RFAs with the earliest application receipt dates and other items with a date limit.

Notices and NA/RFPs may be submitted to the IAO anytime via WYLBUR or LAN mail or on a 3.5 high density diskette. Notices and NA/RFPs will be reviewed by the OEP, through the IAO, for compliance with editorial and policy requirements. Publication will occur at the first possible date following OEP review and clearance.

6. PREPARATION OF DOCUMENT

The following addresses the format and contents of each component of an RFA or PA. All items must be as brief and concise as possible. An NA/PA or NA/RFA may not be more than one standard NIH Guide format page long. There is no limit for the length of notices, NA/RFPs, PAs, or RFAs, but a succinct style is recommended for clarity and efficiency of communication.

Instructions contained in application kits and other widely
distributed policy guidance must not be repeated in RFAs and PAs
unless specifically required, but any unusual features of the
award that may influence preparation of the application must be
stated. Also, information about how to obtain the application
kits and other relevant guidance must be included.

a. Numbering of RFAs and PAs. RFAs are numbered by indicating
    "RFA," the two-letter symbol for the sole or primary
    issuing IC, the last two numerals of the fiscal year in
    which the RFA is to be issued, and a three-digit number
    sequential for that IC. If more than one IC is issuing the
    RFA, the sequential number refers to the primary IC only.
    For example, the fifth RFA to be issued by the National
    Institute on Aging (NIA) in fiscal year 1995 would be RFA
    AG-95-005. If this RFA were to be issued with the NIA as
    the primary and the National Cancer Institute as the
    secondary IC, the number still would be RFA AG-95-005.
    However, the name of both ICs would be listed in the
    identification lines.

    PAs are numbered by the IAO sequentially within fiscal year
    as they are published in the NIH Guide. The PA numbering
    system includes no IC designation. If an agreement exists
    to refer the applications to an IC IRG because of the
    funding mechanism (e.g., T32), the PA number will be PAR to
    indicate that such referral will occur. PAs are numbered
    as illustrated by the following examples: The ninth PA
    published in fiscal year 1995 would be numbered PA-95-009.
    If applications in response to the sixth PA in fiscal year
    1995 were to be referred by pre-arrangement to an IC IRG,
    it would be numbered PAR-95-006.

b. Format and Content of PAs and RFAs. (Appendices 1, 2, 3,
    and 4)

    1) Identification Lines (PA, NA/PA, RFA, NA/RFA). The
    first five lines of RFAs, NA/RFAs, PAs, NA/PAs, and notices
    are the title, the release date (if applicable), the type
    of announcement and the number (if applicable), a Program
    Thesaurus (P.T.) line for subject classification, and the
    name(s) of the initiating IC(s). The P.T. code, an
    interagency program classification system, is determined by
    the DRG after the submission of the announcement for
    publication. The name(s) of the issuing IC(s) is (are)
    listed after the P.T. Codes.

    2) Receipt Date (RFA, NA/RFA). The next lines of NA/RFAs
    and RFAs are the receipt dates for letters of intent (if
    requested) and applications. A minimum of 60 days is
    required between publication of an RFA and the receipt date
    (6), but a period of at least 90 calendar days is
    preferable, particularly if complex applications are
    expected.

    3) Purpose (PA, NA/PA, RFA, NA/RFA). The PURPOSE of the
    program initiative must be stated next. This very brief
    description must be quite similar in the EN and PA,
    NA/PA, RFA, and NA/RFA. The mechanism(s) and the
    rationale for their use, e.g., recruitment of new

researchers, must be stated in this section of the PA and NA/PA. The mechanism(s), amount of the set aside, and the anticipated number of awards must be stated in this section in the NA/RFA.

4) Healthy People 2000 (PA, NA/PA, RFA, NA/RFA). The HEALTHY PEOPLE 2000 initiative must be cited if the topic of the announcement is related to those objectives. PHS-required language is presented in Appendices 1, 2, 3, and 4 and is as follows:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, (Title of RFA), is related to the priority area of   . Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

5) Eligibility Requirements (PA, RFA). The eligibility requirements must include the types of organizations that may apply and any unique requirements for the mechanism of support. Foreign applicants must be specifically included or excluded. See Appendices 1, 2, 3, and 4 for required standard language.

6) Mechanism of Support (PA, RFA). The MECHANISM OF SUPPORT available for the program must be stated (5). The RFA or PA must be consistent with the concepts, policies, and guidelines for the financial assistance support mechanism to be used. The type of mechanism must have been authorized by legislation for use by that IC and must meet the selection criteria outlined in NIH Manual Chapter 1820 (8). The anticipated average amount of the direct cost awards must be specified. If a range of sizes is desired or anticipated, the range of the amounts of direct costs must be specified. Any limit or cap on the amount of the total cost, total direct costs, or any budget category must be stated.

7) Funds Available (RFA, required; PA, optional). The amount of FUNDS AVAILABLE and the anticipated number of awards must be specified (5) in RFAs and may be specified in PAs. The anticipated number of new awards and the associated funds and the anticipated number of competing renewal awards, if any, and the associated funds must be stated.

8) Research Objectives (PA, RFA). The need for the initiative and the anticipated impact must be described. The goals or scope and the types of research and experimental approaches that are being sought must be identified. Examples of research topics may be presented, but such examples must be illustrative, not restrictive. Extensive reviews of the scientific area are not permitted.

Sub-headings such as "Background" may be useful in this section.

9) Special Requirements (PA, RFA, if applicable). Reporting requirements, coordination among investigators, and/or other special requirements of the program must be stated. RFAs for cooperative agreements must state the terms and conditions of award. Manual Chapter 4815 (9) contains required and suggested standard language for the terms and conditions of a cooperative agreement award.

10) Inclusion of Women and Minorities (PA, RFA, if applicable). It is NIH policy that women and minorities must be included in human subject study populations, unless there is good reason to exclude them (7). If applicable, these issues must be addressed in PAs and RFAs. The required language is included in Appendices 1 and 3.

11) Letter of Intent (PA, RFA). LETTERS OF INTENT may be requested, but it is not required to do so. To comply with the requirements of the Office of Management and Budget, the information that may be requested in a letter of intent is limited to a descriptive title of the proposed research, the name and address of the Principal Investigator, the identities of other key personnel and participating institution(s), and the number and title of the RFA or PA in response to which the application may be submitted. See Appendix 1 for required language.

12) Application Procedures (PA, RFA). APPLICATION PROCEDURES must be specified, including the sources of application forms and where completed applications must be submitted (5). PHS SF 398 is used for all applications except for fellowships, which require PHS SF 416. Applications may be obtained from the Office of Grants Information and must be submitted to the Division of Research Grants. See Appendices 1, 2, 3, and 4 for required language.

13) Review Considerations (PA, RFA). Applications in response to PAs go through the receipt, referral, and review cycles for investigator-initiated applications. Issuance of PAs does not override established referral guidelines (13, 14). Consequently, the IC that issues the PA will not necessarily receive either primary or secondary assignment on a particular application submitted in response to a PA. Required language is provided in Appendix 3.

Applications submitted in response to RFAs are reviewed first by the DRG for completeness and for referral in accord with the referral guidelines and, if applicable, additional referral agreements. Applications are reviewed by IC program staff for responsiveness to the RFA. Required language is provided in Appendix 1. If the application is not responsive, the issuing IC must return the application to DRG and send appropriate documentation to the Referral Office, DRG to update IMPAC. If appropriate, the Referral Office may be asked to contact

the applicant PI to determine whether or not he/she would like the application to be treated as an unsolicited grant application.

The standard review criteria are used in PAs. Changes in review criteria must be discussed with the ADRR, DRG, early in the process of developing an RFA. See Appendices 1 and 3 for language.

If applications will be triaged (11), it must be announced in the PA or RFA. The required language is included in Appendices 1 and 3.

If, in response to an RFA, the investigator submits an application essentially identical to one already submitted, but not yet reviewed, the Referral Office, DRG, will ask the applicant to withdraw either the pending application or the new one. Simultaneous submission of identical applications is not allowed, nor may essentially identical applications be reviewed by the same or different review committees.

14) Conditions of Award and Management of PA- and RFA-Initiated Assistance Awards (PA, RFA). AWARD CRITERIA, particularly any special conditions, must be stated. The administrative requirements specified in the Code of Federal Regulations (15), the PHS Grants Policy Statement (6), and PHS and NIH Manual chapters for grants pertain. In addition, special requirements apply to cooperative agreement awards, consistent with Manual Chapter 4815 (9).

It must be stated whether or not awards will be made solely on the basis of percentile or priority score and funds available. If other award criteria apply, e.g., geographical distribution of awards, preferred type of institution, priority for competing renewal applications, or preferred type of scientific methodology, they must be listed.

15) Inquiries (Notice, NA/RFP PA, NA/PA, RFA, NA/RFA). In each PA and RFA, one program and one grants management contact for each issuing IC must be listed by name, organization, address, telephone number, and email address. FAX number is optional. One contact must be listed for each Notice, NA/RFP, NA/PA, and NA/RFP.

16) Authority and Regulations (PA, RFA). The Catalog of Federal Domestic Assistance, PHS grants policy (including a smoke-free workplace), and Federal Regulations must be cited. Most NIH programs are not subject to review under Executive Order 12372 and must so state. If the program is covered under E.O. 12372, the information listed below must be included in the announcement:

(a) A brief summary of the purpose of E.O. 12372 as follows: "E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications."

(b) A statement that "Applicants (other then federally-

recognized Indian tribal governments) should contact their State Single Point of Contact (SPOCs) as early possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State." This statement urges but does not require applicants to comply with the State process.

(c) A current list of SPOCs, including their names, addresses, and telephone numbers, or the statement that "A current list is included in the application kit."

(d) The address to which SPOCs should send any State process recommendations.

(e) The specific due date for State process recommendations and a statement that: "The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date." The due date for State process recommendations is 60 days after the application deadline date for new and competing awards. A longer comment period may be provided but a shorter comment period is not permitted unless a waiver has been granted by the Deputy Assistant Secretary for Management and Acquisition. (See Part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements.)

See Appendices 1 and 3 for suggested language.

c. Format for NA/RFPs

1. The first five lines are in the same format as RFAs, namely TITLE, NIH GUIDE, RFP: nnn, P.T., and Name of IC(s) (Appendix 1).

2. The body of the NA/RFP is as published in the Commerce Business Daily.

3. The last section is INQUIRIES, which includes the information regarding how to obtain the RFP.

H. COPIES OF APPENDICES

For copies of Appendices 1, 2, 3, and 4, contact the IAO, Building 1, Room 328, X65366.

I. RECORDS RETENTION AND DISPOSAL: NONE.

APPENDIX 1: Format of Requests for Applications (RFAs)

RFA TITLE (60 characters or less; all upper case)

NIH GUIDE, (leave blank)

RFA: AB-FY-NNN

P.T.

Name(s) of IC(s)   (upper and lower case; one IC per line)

Letter of Intent Receipt Date: Month nn, 19nn
Application Receipt Date: Month nn, 19nn

PURPOSE

The intent of the solicitation is briefly summarized.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the
health promotion and disease prevention objectives of "Healthy
People 2000," a PHS-led national activity for setting priority
areas. This Request for Applications (RFA), Title of RFA, is
related to the priority area of_____. Potential applicants
may obtain a copy of "Healthy People 2000" (Full Report: Stock No.
017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock
No. 017-001-00473-1) through the Superintendent of Documents,
Government Printing Office, Washington, DC 20402-9325 (telephone
202-783-3238).

ELIGIBILITY REQUIREMENTS

Eligibility requirements for applicant institutions and individuals
must be clearly stated, including whether or not foreign
organizations are eligible to apply and/or whether or not domestic
applications may include international components. Special
eligibility requirements or restrictions, such as previous NIH
funding or years of postdoctoral experience, must be stated in this
section.

Required language: (appropriate for R01s)

"Applications may be submitted by domestic and foreign, for-profit
and non-profit organizations, public and private, such as
universities, colleges, hospitals, laboratories, units of State and
local governments, and eligible agencies of the Federal government.
Racial/ethnic minority individuals, women, and persons with
disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

The IC may draft unique language for this section or may want to
adapt some of the following to meet specific needs:

"This RFA will use the National Institutes of Health (NIH) research
project grant (R01). Responsibility for the planning, direction,
and execution of the proposed project will be solely that of the
applicant. The total project period for an application submitted
in response to this RFA may not exceed _____ years. The
anticipated award date is _____."

"Because the nature and scope of the research proposed in response
to this RFA may vary, it is anticipated that the size of an award
will vary also."

"It is anticipated that the award for the Data Coordinating Center
will be approximately $XXX direct costs per year and the award for

each Clinical Site will be $YYY direct costs per year."

"This RFA is one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures."

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for the entire program, the anticipated number of new awards, and the anticipated number of competing continuation awards, if any, must be stated.

RESEARCH OBJECTIVES

Background

This section expands the PURPOSE section concerning the nature of the research problem, provides pertinent background information that establishes the need for the research, and describes the anticipated increase in scientific knowledge to be achieved through research supported by the special program.

Other

This section must identify the research objectives and the types of research and experimental approaches that are being sought to achieve the objectives. It must indicate whether applications are to be narrowly focussed from one predominant discipline or broadly interdisciplinary. Examples of research topics may be presented if appropriate. Such examples must be illustrative, but not restrictive.

Sub-headings may be used as illustrated.

SPECIAL REQUIREMENTS

Any special reporting requirements and plans for IC involvement in cooperative agreements must be discussed. For example, any requirements for coordination among investigators (e.g., annual meetings) must be identified. In such situations, applicants must be advised to include such plans in the budget requests.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Whenever human subjects are included in the proposed research, the following language is required:

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of

Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Required language:

"Prospective applicants are asked to submit, by _____, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to:

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (301) NNN-NNNN (optional)

APPLICATION PROCEDURES

Required language

"The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the program administrator listed under INQUIRIES.

(If the IC has supplemental application guidelines, they must be mentioned here. Such guidelines must be cleared by the OEP.)

"The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review

committee in time for review. In addition, the RFA title and
number must be typed on line 2a of the face page of the application
form and the YES box must be marked.

"Submit a signed, typewritten original of the application,
including the Checklist, and three signed, photocopies, in one
package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the
application
must be sent to:

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892

"Applications must be received by _____. If an application
is received after that date, it will be returned to the applicant
without review. The Division of Research Grants (DRG) will not
accept any application in response to this RFA that is essentially
the same as one currently pending initial review, unless the
applicant withdraws the pending application. The DRG will not
accept any application that is essentially the same as one already
reviewed. This does not preclude the submission of substantial
revisions of applications already reviewed, but such applications
must include an introduction addressing the previous critique."

REVIEW CONSIDERATIONS

Required language, if applicable:

"Upon receipt, applications will be reviewed for completeness by
DRG and responsiveness by the (IC). Incomplete applications will
be returned to the applicant without further consideration. If the
application is not responsive to the RFA, DRG staff may contact the
applicant to determine whether to return the application to the
applicant or submit it for review in competition with unsolicited
applications at the next review cycle.

Applications that are complete and responsive to the RFA will be
evaluated for scientific and technical merit by an appropriate peer
review group convened by the (IC) in accordance with the review
criteria stated below.

If applicable:

As part of the initial merit review, a process (triage) may be
used
by the initial review group in which applications will be
determined to be competitive or non-competitive based on their
scientific merit relative to other applications received in
response to the RFA. Applications judged to be competitive will
be

discussed and be assigned a priority score. Applications
determined to be non-competitive will be withdrawn from further
consideration and the Principal Investigator and the official
signing for the applicant organization will be notified.

Review Criteria

o scientific, technical, or medical significance and originality
of proposed research;

o appropriateness and adequacy of the experimental approach and
methodology proposed to carry out the research;

o qualifications and research experience of the Principal
Investigator and staff, particularly, but not exclusively, in the
area of the proposed research;

o availability of the resources necessary to perform the
research;

o appropriateness of the proposed budget and duration in
relation
to the proposed research;

The initial review group will also examine the provisions for the
protection of human and animal subjects and the safety of the
research environment.

Or for research training grant applications:

o Past research training record for both the program and the
designated preceptors in terms of the rate at which former
trainees
establish independent and productive research careers

o Past research training record in terms of the success of
former
trainees in obtaining individual awards such as fellowships,
career
awards, and research grants for further development

o Objectives, design, and direction of the research training
program

o Caliber of preceptors as researchers including successful
competition for research support

o Training environment including the institutional commitment,
the
quality of the facilities, and the availability of research
support

o Recruitment and selection plans for appointees and the
availability of high quality candidates

o The record of the research training program in retaining
health-
professional postdoctoral trainees for at least two years in
research training or other research activities

o When appropriate, the concomitant training of health-
professional postdoctorates (e.g., individuals with the M.D.,
D.O.,
D.D.S.) with basic science postdoctorates (e.g., individuals with
a Ph.D., Sc.D.) will receive special consideration.

Additional scientific/technical merit criteria specific to the
objectives of the RFA must be included if they are to be used in
the review.

AWARD CRITERIA

This section must describe the factors, including the scientific
and technical merit reflected in the priority score or
percentile,
that will be used to make award decisions. RFAs can apply other
criteria such as the geographical location of the applicant
organization. The most common award criteria are: scientific
merit as determined by peer review, availability of funds, and
programmatic priorities.

INQUIRIES

Required language:

Inquiries concerning this RFA are encouraged. The opportunity to
clarify any issues or questions from potential applicants is
welcome."

Direct inquiries regarding programmatic issues to:

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (optional)
Email: (required)

Direct inquiries regarding fiscal matters to:

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (optional)
Email: (required)

AUTHORITY AND REGULATIONS

"This program is described in the Catalog of Federal Domestic
Assistance No. 93.3___, (use appropriate program number). Awards
are made under authorization of the Public Health Service Act,
Title IV, Part A (Public Law 78-410, as amended by Public Law 99-
158, 42 USC 241 and 285) and administered under PHS grants
policies
and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This

program
is not subject to the intergovernmental review requirements of
Executive Order 12372 or Health Systems Agency review.

"The Public Health Service (PHS) strongly encourages all grant
recipients to provide a smoke-free workplace and promote the non-
use of all tobacco products. This is consistent with the PHS
mission to protect and advance the physical and mental health of
the American people."

   APPENDIX 2:   Format of Notice of Availability of RFA (NA/RFA)

RFA TITLE (60 characters or less; all upper case)

NIH GUIDE, (leave blank)

RFA AVAILABLE: AB-FY-NNN

P.T.

Name(s) of IC(s) (upper and lower case; one IC per line)

Letter of Intent Receipt Date: Month nn, 19nn
Application Receipt Date: Month nn, 19nn

PURPOSE

The availability of the RFA is announced, including a brief
statement of purpose. The anticipated number of
awards and the amount of money set aside to fund applications
submitted in response to this solicitation must
be stated.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the
health promotion and disease prevention objectives
of "Healthy People 2000," a PHS-led national activity for setting
priority areas. This RFA, Title of RFA, is
related to the priority area of_____.   Potential
applicants may obtain a copy of "Healthy People 2000"
(Full Report: Stock No. 017-001-00474-0) or "Healthy People
2000" (Summary Report: Stock No. 017-001-00473-1)
through the Superintendent of Documents, Government Printing
Office, Washington, DC 20402-9325 (telephone 202-
783-3238).

INQUIRIES

The RFA, which describes the research objectives, application
procedures, review considerations and award
criteria for this solicitation, may be obtained electronically
through the NIH Grant Line (data line 301-402-
2221) and the NIH GOPHER (gopher.nih.gov) and by mail and email
from the program contact listed below.

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number

Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (optional)
EMAIL: (required)

APPENDIX 3: Format of Program Announcements (PAs)

PA TITLE (60 characters or less, all upper case)

NIH GUIDE, (leave blank)

PA NUMBER:

P.T.

Name(s) of IC(s) (Upper and lower case; one IC per line)

PURPOSE

The intent of the PA is briefly summarized, including the
rationale for using selected funding mechanism(s).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the
health promotion and disease prevention objectives
of "Healthy People 2000," a PHS-led national activity for setting
priority areas. This PA, Title of PA, is
related to the priority area of_____. Potential
applicants may obtain a copy of "Healthy People 2000"
(Full Report: Stock No. 017-001-00474-0) or "Healthy People
2000" (Summary Report: Stock No. 017-001-00473-1)
through the Superintendent of Documents, Government Printing
Office, Washington, DC 20402-9325 (telephone 202-
783-3238).

ELIGIBILITY REQUIREMENTS

Eligibility requirements for applicant institutions and
individuals must be clearly stated including whether
or not foreign organizations are eligible to apply and/or whether
or not domestic applications may include
international components. Special eligibility requirements such
as previous NIH funding or years postdoctoral
experience must state these requirements in this section.

Required language

"Applications may be submitted by foreign and domestic,
for-profit and non-profit organizations, public and
private, such as universities, colleges, hospitals, laboratories,
units of State and local governments, and
eligible agencies of the Federal government. Racial/ethnic
minority individuals, women, and persons with
disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

This section describes the mechanisms available for support of
this program, e.g., research project grants

(R01), FIRST awards (R29), program project grants (P01).

FUNDS AVAILABLE

The amount of funds available and the anticipated number of awards may be stated in this optional section.

RESEARCH OBJECTIVES

Summary

In broad terms the anticipated increase in scientific knowledge to be achieved through research encouraged by the PA is described. Examples of research topics may be presented, if appropriate. Such examples must be illustrative, but not restrictive.

Sub-headings may be used.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Whenever human subjects may be used in research proposed in applications in response to this PA, the following language is required:

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 20, 1994 (FR 59 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Required language

"Applications are to be submitted on the grant application form

PHS 398 (rev. 9/91) and will be accepted at the
standard application deadlines as indicated in the application
kit. Application kits are available at most
institutional offices of sponsored research and may be obtained
from the Office of Grants Information, Division
of Research Grants, National Institutes of Health, Westwood
Building, Room 449, Bethesda, MD 20892, telephone
301/594-7248. The title and number of the announcement must be
typed in Section 2a on the face page of the
application.

"The completed original application and five legible copies must
be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**"

REVIEW CONSIDERATIONS

Required language:

"Applications will be assigned on the basis of established Public
Health Service referral guidelines.
Applications will be reviewed for scientific and technical merit
by study sections of the Division of Research
Grants, NIH (or by the review group of the relevant Institute,
Center, or Division), in accordance with the
standard NIH peer review procedures. Following
scientific-technical review, the applications will receive a
second-level review by the appropriate national advisory
council."

If applicable:

"As part of the initial merit review, a process (triage) may be
used by the initial review group in which
applications will be determined to be competitive or
non-competitive based on their scientific merit relative
to other applications received in response to the RFA.
Applications judged to be competitive will be discussed
and be assigned a priority score. Applications determined to be
non-competitive will be withdrawn from further
consideration and the Principal Investigator and the official
signing for the applicant organization will be
notified."

Review Criteria

o scientific, technical, or medical significance and originality
of proposed research;

o appropriateness and adequacy of the experimental approach and
methodology proposed to carry out the research;

o qualifications and research experience of the Principal
Investigator and staff, particularly, but not
exclusively, in the area of the proposed research;

o availability of the resources necessary to perform the
research;

o appropriateness of the proposed budget and duration in
relation to the proposed research;

The initial review group will also examine the provisions for the
protection of human and animal subjects and
the safety of the research environment.

Or for research training grant applications:

o Past research training record for both the program and the
designated preceptors in terms of the rate at
which former trainees establish independent and productive
research careers

o Past research training record in terms of the success of
former trainees in obtaining individual awards such
as fellowships, career awards, and research grants for further
development

o Objectives, design, and direction of the research training
program

o Caliber of preceptors as researchers including successful
competition for research support

o Training environment including the institutional commitment,
the quality of the facilities, and the
availability of research support

o Recruitment and selection plans for appointees and the
availability of high quality candidates

o The record of the research training program in retaining
health-professional postdoctoral trainees for at
least two years in research training or other research activities

o When appropriate, the concomitant training of
health-professional postdoctorates (e.g., individuals with the
M.D., D.O., D.D.S.) with basic science postdoctorates (e.g.,
individuals with a Ph.D., Sc.D.) will receive
special consideration

AWARD CRITERIA

Required language:

"Applications will compete for available funds with all other
approved applications assigned to that IC. The
following will be considered in making funding decisions:
Quality of the proposed project as determined by peer
review, availability of funds, and program priority.

INQUIRIES

Required language:

"Inquiries are encouraged. The opportunity to clarify any issues

or questions from potential applicants is
welcome."

Direct inquiries regarding programmatic issues to:

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (optional)
Email: (required)

Direct inquiries regarding fiscal matters to:

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (optional)
Email: (required)

AUTHORITY AND REGULATIONS

"This program is described in the Catalog of Federal Domestic
Assistance No. 93.3___, (use appropriate program
number). Awards are made under authorization of the Public
Health Service Act, Title IV, Part A (Public Law
78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and
administered under PHS grants policies and
Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program
is not subject to the intergovernmental review
requirements of Executive Order 12372 or Health Systems Agency
review."

"The Public Health Service (PHS) strongly encourages all grant
recipients to provide a smoke-free workplace and
promote the non-use of all tobacco products. This is consistent
with the PHS mission to protect and advance
the physical and mental health of the American people."

   APPENDIX 4: Format of Notice of Availability of PA (NA/PA)

PA TITLE (60 characters or less; all upper case)

NIH GUIDE, (leave blank)

PA AVAILABLE: PA-FY-NNN

P.T.

Name(s) of IC(s) (upper and lower case; one IC per line)

PURPOSE

The availability of the PA is announced, including a brief
statement of purpose.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the
health promotion and disease prevention objectives
of "Healthy People 2000," a PHS-led national activity for setting
priority areas. This PA, Title of PA, is
related to the priority area of_____.   Potential
applicants may obtain a copy of "Healthy People 2000"
(Full Report: Stock No. 017-001-00474-0) or "Healthy People
2000" (Summary Report: Stock No. 017-001-00473-1)
through the Superintendent of Documents, Government Printing
Office, Washington, DC 20402-9325 (telephone 202-
783-3238).

INQUIRIES

The PA, which describes the research objectives, application
procedures, review considerations, and award
criteria for this program, may be obtained electronically through
the NIH Grant Line (data line 301-402-2221)
and the NIH GOPHER (Internet) and by mail and email from the
program contact listed below.

Staff Contact Name
Division (use minimum information necessary)
Institute or Center
Building, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX: (optional)
EMAIL: (required)

APPENDIX 5: Instructions for Submitting Material for Publication
in the NIH Guide for Grants and Contracts

NA/PAs, NA/RFAs, PAs and RFAs to be published in the NIH Guide
must be submitted via WYLBUR MAIL to the initials
Q2A. Entries mailed by 2:00 p.m., Thursday, to Q2A will be
considered for earliest publication on the Friday
15 days hence. An announcement may be held for a subsequent
issue because of space limitations, unresolved
referral issues, or unresolved policy clearances.

Contracting offices must make their own arrangements for IC
approvals and submission of NA/RFPs to the NIH
Guide. Submission may be to Q2A or directly to the IAO program
analyst via email.

Notices may be submitted to the IAO at any time, via email or on
a 3.5 high density diskette in WordPerfect.

Style Guide

o The maximum line length is 60 characters (set left margin to 0
   on a word processor).

o Enter text in upper and lower case, except for headings noted
   in Appendices 1, 2, 3, and 4. Some types of

terminals enter WYLBUR text in all caps unless other instructions
are given.

o Do not use indent or tab.

o All lines must be left justified.

o Do not use a hyphen to break long words; start a new line instead.

o Leave one line between headings, paragraphs, and any other
   breaks (only one line).

o Always use the "1" for numerals and never the lower case "l."

o Do not underline anything - underlining cannot be read on the screen.

o Do not use the pound sign (#).

o Do not use superscripts or subscripts.

o Do not paginate; make the document continuous. Do not
   transmit blocks of empty lines.

o Do not set any "hard pages" (control return).

o Set off all major divisions (e.g., ELIGIBILITY, INQUIRIES) by
   headings only. Do not number them.

o This is an example of how you should enter the text that you
   want set off by bullets or Arabic numbers.

o Bullets or Arabic numbers may be used for references.

o Always use the lower case "o" for bullets.

o Numbers ten and less should be spelled out and not followed by the
   numeral in parentheses.

o The numerals should be used for numbers greater than ten, e.g., 11.

o $1,000,000 should be written as $1 million.

o Reference should be to the specific IC, e.g., NEI, not "the Institute."

o The plural of an acronym, e.g., RFAs, does not use an apostrophe.

o Principal Investigator should be capitalized.

TIP: With the variety of communications software being used to
transfer files from PCs to WYLBUR, some of which
work better than others, a self-check is useful to be sure that
the entire text was transferred, that it is
upper and lower case, and that the lines of text do not wrap or
exceed the 60 character line length. After
transferring the file to WYLBUR, mail the file to your own WYLBUR
initials. Retrieve the file in WYLBUR and
check for completeness, line length, upper and lower case before
submitting to Q2A. When all looks in order,
mail to Q2A. WYLBUR will confirm "MAIL SENT TO Q2A."

NIH POLICY MANUAL

54120 – GRANT APPEALS PROCEDURE

Issuing Office: OER 301-496-5358

Release Date: 11/09/89

A. Purpose:

This issuance describes the NIH procedure for resolving certain post-award disputes between grantee institutions and the NIH.

The NIH grant appeals procedure provides NIH the opportunity to review decisions of its officials and to settle certain disputes with grantees, and fulfills the requirement for a preliminary appeals process before an appeal may be submitted to the Departmental Appeals Board for resolution.

B. Applicability:

This policy is applicable to all NIH assistance awards, i.e. grants and cooperative agreements, but not contracts or joint endeavors or interagency agreements. Hereinafter assistance awards will be referred to as "grants," and awardee institutions as "grantees."

C. References:

1. Code of Federal Regulations, Title 45, Part 16, Procedures of the Departmental Appeals Board.
2. Code of Federal Regulations, Title 42, Part 50, Subpart D, Public Health Service Grant Appeals Procedure.
3. PHS Grants Administration Manual, Part 137, Grant Appeals

Procedures.

4. [NIH Manual Chapter 1743](), "Keeping and Destroying Records".

D. Background:

The Secretary of Health and Human Services has established a Departmental Appeals Board for the purpose of reviewing and providing hearings upon post-award disputes which may arise in the administration of HHS grants. The regulation (45 CFR Part 16) that establishes the Board authorizes HHS agencies to establish informal appeals procedures which must be exhausted before a formal appeal to the Departmental Board will be allowed. The PHS procedure is published as a regulation at 42 CFR, Part 50, Subpart D. This chapter implements the PHS procedure with respect to NIH grant programs.

E. Policy:

The NIH grant appeals procedure must be used, where applicable, in the resolution of post-award disputes (see section F. below) between grantees and NIH awarding Institutes, Divisions, and Centers (awarding organizations). When these disputes are not resolved to the grantee's satisfaction under this procedure, th grantee then may, within specified limits with regard to time and scope, appeal to the Departmental Appeals Board established under 45 CFR Part 16.

F. Scope:

1. Grantees may appeal directly to NIH the following post-award adverse determinations made in writing by NIH officials:

   a. Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance, or for failure of the grantee otherwise to comply

with any law, regulation, assurance, term, or condition applicable to the grant.

b. A determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.

c. A determination that a grant is void. "Void" means a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained.

d. A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.

2.

a. Grantees may appeal directly to NIH indirect cost rate determinations made by the Financial Advisory Services Branch, Division of Contracts and Grants, affecting current or new commercial grantees.

b. Grantees may appeal directly to the affected DHHS Regional Director (or to another regional Departmental official designated by the Director) pre-award or post-award determinations made by DHHS Regional Divisions of Cost Allocation on the establishment of indirect costs rates, research patient care rates, fringe benefits, or other negotiated rates. Details concerning the procedures to be followed in filing such an appeal are contained in Code of Federal Regulations, Title 45, Part 75, Subpart A, Indirect Cost Appeals.

G. Responsibilities:

1. The Director, NIH designates the Deputy Director for Extramural Research (DDER) to oversee the administration of the NIH grant appeals procedure.
2. The DDER appoints the NIH Appeals Officer, who is responsible for administering the NIH grant appeals procedure, permanently chairing the NIH Grant Appeals Board, and managing the review of individual appeals.

H. NIH Grant Appeals Board:

NIH Grant Appeals Board All eligible post-award appeals will be reviewed by a review committee, called the NIH Grant Appeals Board (Board). The following describes the Board's structure, function, and operating procedures:

1. The Board consists of a minimum of three members. The individuals on the Board must be in positions commensurate with the responsibilities of the Board.
2. The DDER appoints the Chairperson for an indefinite or specified (at least one year) term. The DDER also designates an alternate Chairperson in those instances where the permanent Chairperson may be disqualified as a result of the nature of the appeal.
3. The members may be appointed by DDER to serve on a standing basis, by the Chairperson on a one-time basis, or by a combination of both methods.
4. None of the Board members reviewing an appeal may be from the organization whose adverse determination is being appealed or who have previously acted in the matter, or who are subject to line supervision under an official who acted in the matter, or otherwise had an actual or apparent conflict of interest regarding the case

under appeal.

5. While reviewing an appeal, the Board may grant an extension of time for presenting a case for good reasons; dismiss a case for failure to meet deadlines or other requirements; remand a case for further action by the affected organization; close or suspend a case that is not ready for review; request relevant information from the responsible parties; or waive or modify these procedures in a specific case with written notice to the involved parties.

6. The function of the Board is to make an independent evaluation of the facts as presented by both the office that made the adverse determination and the grantee. Consequently, the Board shall not consider any information outside the record established for reviewing the appeal. When one of the parties submits information to the Board independently or upon request, this information will be made part of the record and the Board shall make it available to the other party with the opportunity to comment, unless the Board determines that the submission of the additional comments is unnecessary or would serve only to delay the resolution of the appeal.

7. Generally, the Board's review will be restricted to determinations of whether the adverse determination is clearly erroneous in fact or policy, or is arbitrary or unreasonable as measured against NIH's established management practices. However, if the Board finds that the record is inadequate for a particular decision to have been made by the NIH awarding component, the Board may use any other appropriate approach to resolve the issue equitably and expeditiously.

8. The decisions of the Board are not precedent-setting and each case must be evaluated on its individual merits, regardless of the similarity with previous situations.

9. All decisions of the Board affecting the rights of the parties shall be

in writing, with copies to both sides, served by personal service, or certified mail, return receipt requested.

I. Procedures:

1. Notice of Adverse Determination
   a. Adverse determinations by NIH awarding organizations, identified in F.1. a-d. and F.2.a., must set forth the reasons for the determination in sufficient detail to enable the grantee to respond thoroughly and substantively.
   b. The notice of adverse determination must include the following statement:

   "This determination may be appealed in writing by the grantee institution in accordance with 42 CFR Part 50, Subpart D, to the NIH Appeals Officer, Room 254, Shannon Building, Bethesda, Maryland 20892. The appeal, requesting a review of the determination, must clearly identify the question in dispute; fully state the grantee's position regarding the question, including the pertinent facts and reasons in support of the position; and enclose a copy of this determination with the appeal. The appeal must be signed by both the institutional official authorized to sign assistance award applications and the principal investigator, and must be postmarked no later than 30 days after the postmarked date of this notice."

2. Submission of Appeal
   a. A grantee institution that requests an NIH review of an adverse determination must submit a written request to the NIH Appeals Officer no later than 30 days after the postmarked date of the written notification of determination.

The NIH Appeals Officer, who serves as Chairperson of the NIH Grant Appeals Board, may grant an extension of time for preparing an appeal if good cause is shown.

b. Although the request for review need not follow any prescribed form, it must contain a full statement of the grantee's position with respect to the disputed matter and the facts and reasons in support of this position. The grantee must include a copy of the notice of adverse determination with the submission.

c. The NIH Appeals Officer shall transmit a copy of the appeal to the Director, DGC/ORM/OM/PHS.

3. Acceptance of Appeal

a. Upon receipt of a request for review by the NIH Grant Appeals Board, the Chairperson will determine whether the issue is appealable in accordance with the provisions described in F.1.a-d. or F.2.a., and promptly notify the grantee whether the appeal has been accepted for review.

b. The Chairperson will promptly send a copy of the notification to the Director and the chief extramural programs officer of the awarding organization, who will promptly inform the grants management officer of the appeal. In the case of appeal of an audit determination or an indirect cost rate determination made by the NIH Financial Advisory Services Branch, the Chairperson will notify the Director, Division of Contracts and Grants, NIH.

c. When a request for review has been accepted, no further action may be taken by the awarding organization pursuant to the adverse determination until the request has been considered by the Board, except that receipt of a request for review does not affect the authority which the organization may otherwise have to suspend assistance or withhold or

defer payments under the grant during the appeals review. In addition, because of additional information received with the appeal or for other valid reasons, the responsible organization may wish to attempt to resolve the dispute through direct informal negotiations with the grantee. If settlement is achieved, the responsible organization staff must contact the Chairperson who, in turn, will arrange to have the settlement entered into the record, with the consent of the parties, as the final disposition of the appeal.

4. Review of Appeal
   a. The NIH Grant Appeal Board will, when possible, complete the review within 45 days.
   b. After acceptance of a request for review, the organization official who made the adverse determination will be requested to provide the Board with copies of all background material and documents serving as the basis for the determination. This material is to include a copy of the determination which is being appealed, the grant application and summary statements, notice of grant award(s), all correspondence between the parties pertinent to the appeal, text of the pertinent policies or regulations, audit data, and any other applicable information.
   c. c. Both grantee and NIH staff may be invited by the Board to discuss pertinent issues, or to submit additional information deemed necessary. The additional information will be included in the official record. It will be provided to the other party with the opportunity to comment, unless the Board determines that submission of additional comments is unnecessary or would serve only to delay the resolution of the appeal. If a secondary party was involved in the development of the adverse determination, the secondary

party will be notified that additional information has been made available.

d. Based on the Board's review and a majority vote, a written decision will be prepared for the signature of the Chairperson and all members of the Board. Dissenters will sign as dissenting.

5. Notice of Decision

a. The Chairperson will send the NIH Grant Appeals Board's decision to the grantee by certified mail and to the organization Director and the organization chief extramural programs officer, who will promptly inform the grants management officer, or to the Director, Division of Contracts and Grants, NIH, in the case of audit determinations and indirect cost rate determinations made by NIH. The responsible NIH organization staff will follow-up with appropriate action.

b. If the decision sustains the grantee's position, the case will be deemed ended for purposes of appeal.

c. If the decision is adverse to the grantee's position, it must include the following statement concerning the grantee's right to appeal to the Departmental Appeals Board:

"This is the final decision of the National Institutes of Health. It will become the final decision of the Department of Health and Human Services unless you appeal within 30 days after you receive this decision to the Departmental Appeals Board in accordance with the provisions of 45 CFR Part 16. If you decide to appeal, you must mail or deliver your Notice of Appeal (registered or certified mail should be used to establish the date) to the Departmental Appeals Board, Room 2004, Switzer Building 3rd & C Streets, S.W.,

Washington, D.C. 20201. Your Notice should include a copy of this decision and state the reasons for your disagreement with it. (Please send a copy of your Notice to the NIH Appeals Officer, Room 254, Shannon Building, Bethesda, Maryland 20892.) The Departmental Appeals Board will notify you of further procedures."

d. All proceedings will be appropriately documented and retained in NIH files. Internal procedures must ensure that files are kept and destroyed in accordance with NIH policy (NIH Manual 1743 Keeping and Destroying Records, Appendix 1, Part 3, Section E, Appeals and Litigations). This material will be available to the Departmental Appeals Board in case of a formal appeal.

J. HHS Appeals Procedures:

If a formal appeal of an NIH adverse determination is made to the Departmental Appeals Board, the Executive Secretary of that Board will send a copy of the appeal to the Director, Division of Grants and Contracts (DGC), Office of Resource Management (ORM), OASH.

The DGC will request the Deputy Director for Extramural Research (DDER), NIH, to develop the necessary information and send it directly to the Executive Secretary of the Departmental Board with a copy to DGC.

The Departmental Appeals Board, upon completion of its deliberations, will send its decision to the grantee and the Director, DGC, OASH. DGC will send appropriate notification to the Director, NIH. This information will be transmitted through DDER to the responsible BID Director for appropriate action. A copy will be sent to the Appeals Office for information.

K. Effective Date:

This policy is effective on date of release.

L. Additional Information:

For more information on this chapter contact the NIH Appeals Office, OER, Shannon Building, Room 254, telephone 301-496-5358.

M. Additional Copies:

For extra copies of this chapter, submit a Form NIH-414-5 "Request for Manual Chapter," to the Printing and Reproduction Branch, Division of Technical Services, Building 31, Room B4B-N-09.

NIH POLICY MANUAL

54205 - Role of the PI on Research Projects Supported by NIH

Issuing Office: OER 301-496-5967

Release Date: 11/01/91

A. Purpose:

This chapter describes the roles and responsibilities of principal investigators on research projects supported by NIH financial assistance awards, that is, grants and cooperative agreements. (The word "grant," as used throughout this chapter, also includes "cooperative agreement.")

B. Background:

The Code of Federal Regulations, Title 42, Part 52 (GRANTS FOR RESEARCH PROJECTS), defines a principal investigator as "a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project." Part 52 provides that the name and qualifications of the principal investigator must be included in grant applications and, from a postaward perspective, the regulation describes the permissible changes that a principal investigator may make in carrying out the approved project. Finally, Part 52 identifies 45 CFR Part 74 (ADMINISTRATION OF GRANTS) as a Department-wide (DHHS) regulation that applies to NIH research project grants. The Public Health Service (PHS) Grants Policy Statement represents yet another important source of policy information governing the award and administration of NIH research project grants. In sum, each of the formally- recognized policy

documents cited above (and other materials listed under "References," below) have contributed to the guidance in this chapter. In addition, the chapter reflects procedural information and expressions of policy from sources such as grant application instructions, information in the NIH Guide for Grants and Contracts, and actual case- histories involving issues associated with the role of a principal investigator.

C. Applicability:

This chapter summarizes the referenced policy and procedures which apply to awards for research project grant support. The original sources must be referred to for additional detail or procedures. Only policy implemented in the CFR and the PHS Grants Policy Statement apply specific requirements on applicants and recipients.

D. References:

1. Code of Federal Regulations, Title 42, Part 52, Grants for Research Projects.

2. Code of Federal Regulations, Title 45, Part 74, Administration of Grants.

3. Code of Federal Regulations, Title 45, Part 76, Debarment and Suspension.

4. Code of Federal Regulations, Title 37, Part 401, Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements.

5. Code of Federal Regulations, Title 45, Part 8, Inventions Resulting

from Research Grants, Fellowship Awards, and Contracts for Research.

6. Code of Federal Regulations, Title 45, Part 79, Program Fraud Civil Remedies.

7. PHS Grants Policy Statement.

8. PHS Grants Administration Manual Part 109, Overdue Reports--Discretionary Grants.

9. PHS Grants Administration Manual Part 129, Grant Suspension and Termination.

10. PHS Grants Administration Manual Part 131, Change of Grantee Institution.

11. PHS Grants Administration Manual Part 145, PHS Prior Approval Requirements.

12. PHS Grants Administration Manual Part 201, Review and Direction of the Research Effort Under Research Grants.

13. NIH Manual Chapter 4201, Release of Information on Research and Training Grants, Awards, and Cooperative Agreements.

14. NIH Manual Chapter 4204/6003-1, NIH Intramural Scientists as Principal Investigators on Grant Applications and Contract Proposals.

15. NIH Manual Chapter 4509, Personal Data Page of Form PHS-398 Grant Application.

16. NIH Manual Chapter [4510](#), Referral and Initial Review of (Grant) Applications.

17. NIH Manual Chapter [4512](#), Summary Statements.

18. NIH Manual Chapter [5201](#), Change of Grantee Institution.

19. NIH Manual Chapter [5806](#), Overdue Reports-Discretionary Grants.

20. NIH Manual Chapter [1820](#), Selection of Extramural Award Instrument - Grant, Cooperative Agreement, or Contract.

21. NIH Manual Chapter [4815](#), Implementation of Cooperative Agreements - Initiation, Review, Award and Administration.

E. Definitions:

1. Principal Investigator Federal regulations define a principal investigator (PI) as "a single individual designated by the grantee in the grant application and approved by the Secretary, HHS, who is responsible for the scientific and technical direction of the project." (See 42 CFR Part 52.) The concept of co-investigator is not formally recognized.

2. Grantee The organization to which a grant is awarded and which is responsible and accountable to NIH for the ON RESEARCH PROJECTS SUPPORTED BY NIH use of the funds provided and for performance of the grant-supported project. In unusual circumstances, an individual may be a grantee.

F. Policies/Procedures:

1. Overall Responsibilities

    Consistent with the regulatory definition of "principal investigator" (PI) (as provided above), NIH considers that individual to be the primary guiding force behind the hypothesis, development, and "hands-on" execution of the research activity and supervision of scientific and technical staff. In accepting this role, the PI also undertakes a fiscal management obligation to the grantee (as defined above) to expend grant funds for the purposes set forth in the application and the Notice of Grant Award in accordance with applicable laws and regulations. (See 45 CFR Part 79)

2. Application Requirements

    a. Identification In accordance with the appropriate instructions, applications for research project grant support must reflect the name and qualifications of the PI, as well as the level of effort to be devoted to the project.

    b. Other Support Grant application instructions (Forms PHS 398 and 2590) require a listing of the PI's "other sources of research support," both active and pending. To prevent the possibility of duplicate (overlap) funding, it is the PI's responsibility to update this information. If there are changes in the information after submission of a competing application, the PI must notify the Scientific Review Administrator (SRA) of the initial review group before the review. If changes occur after the review of a competing application, or at any

other time in the life of a project, the principal investigator must notify the appropriate Grants Management Officer (GMO) of the awarding component.

c. Personal Data The Personal Data form, which is part of the competing application package, asks the age, sex, race/ethnic origin, and social security number of the PI. Submitting the form is optional and the data obtained is used only for statistical analysis. If the form is submitted, it is separated from the application prior to review. The review of the application will not be affected by either the submission of the form or the form's content. (See NIH Manual Chapter 4509.)

d. Appointments The PI must have a formal appointment with the applicant organization, which is characterized by an official relationship between the organization and the individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the individual's official organizational relationship must entail sufficient opportunity and physical resources for the principal investigator to carry out his/her responsibilities for the overall scientific and technical direction of the project and for the organization to provide administrative and financial oversight of the project. An investigator with a full-time 12-month appointment would be considered to have a commitment to the applicant organization of 100 percent of his/her total professional effort. If, on the other hand, an investigator (concurrently) has independent commitments or appointments with other organizations, his/her commitment to the applicant organization would be some portion of 100 percent. However, when

concurrent (joint) appointments are, in fact, dependent upon each other, the joint appointment is considered to represent the individual's total professional effort. For example, a principal investigator with a university appointment may also have an appointment with an affiliated hospital and still appropriately consider his/her commitment to the university to be full time, as long as the university and the hospital are mutually responsible for the individual's total professional effort.

e. Department of Veterans Affairs (VA) Employees: Special Certification Academic institutions submitting applications on behalf of principal investigators who are also VA employees must certify that: (1) the individual is applying as part of a joint appointment that is specified by a formal Memorandum of Understanding (see next paragraph), and (2) there is no possibility of dual compensation (academic plus VA salary) for the same work, nor an actual or apparent conflict of interest regarding such work.

The Memorandum of Understanding must, at a minimum, specify: (1) the title of each appointment, (2) each functional responsibility (at both the academic institution and the VA) of the proposed principal investigator, and (3) the percentage of effort available for research. Staff may request evidence of a proper memorandum of understanding, but submission of said memorandum is not a routine requirement of the applicant. (See NIH Guide for Grants and Contracts.)

f. Non-U.S. Citizens The U.S. grantee organization shall determine, and the application should indicate, that the PI's visa will allow him/her to remain in the country a length of time sufficient to direct the project. NIH will not intercede in behalf of non-United States citizens who may be

principal investigators (or otherwise participating in a project), and whose stay in the United States may be limited by their visa status.

g. Signature To be valid and acceptable for review, an application must have been signed by the proposed PI. By signing, the principal investigator agrees to accept fiscal responsibility, as well as responsibility for the scientific conduct of the project, and to provide the required progress reports if a grant is awarded as a result of the application. "Per" signatures are not acceptable. (see Form PHS 398.)

3. Preaward Review Considerations of the Role of the PI

In instances during the peer review process where there may be questions concerning the extent of participation (percent effort) or the relationship of the PI to the project, the SRA of the initial review group (IRG) should, where possible, obtain a statement from the applicant organization, prior to the IRG meeting, regarding the primary responsibility for scientific and technical direction of the project. If the named PI's role is questionable, the SRA should guide the IRG to recommend deferral until clarification can be obtained. If the IRG determines that the named principal investigator will not be clearly responsible for the scientific and technical direction of the project, the project may not be recommended for further consideration.

If staff of the NIH awarding component, in reviewing an application or summary statement, is not satisfied that the named PI is appropriate or that the level of effort is sufficient, they must clarify the situation even if the timing of such clarification requires a delay in processing the award. No award may be made by the NIH

awarding component unless the role and level of effort of the PI is defined clearly and to the satisfaction of the awarding component.

For cooperative agreement awards, the PI has prior knowledge of and agrees to special Terms of Award which define the role of the PI and the "substantial programmatic involvement" of NIH staff in the project, and include arbitration mechanisms covering disagreements over programmatic decisions on scientific-technical matters. These terms are in addition to other grant administration policies. (See NIH Manual Chapters 1820 and 4815).

4. Release of Information

a. Privacy Act The Privacy Act of 1974 (Public Law 93-579), and associated regulations at 45 CFR Part 5b, provide certain safeguards for individuals (including principal investigators) against invasions of personal privacy. These safeguards include (1) the right of individuals to determine what records pertaining to him/her are collected, maintained, used or disseminated by NIH, and (2) the right of individuals to have access to such records and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated. (See PHS Grants Policy Statement and PHS Grants Administration Manual Chapter 7, Part 707)

b. Freedom of Information The Freedom of Information Act (Public Law 90-23), and associated regulations at 45 CFR Part 5, require the release by NIH of certain grant documents and records requested by members of the public. The applicant organization

and the PIs are to be notified by the NIH awarding component when a Freedom of Information request is received and to whom the documents will be released. The PI will be given an opportunity to identify potentially patentable or otherwise intrinsically valuable information that should not be disclosed. (See PHS Grants Policy Statement and PHS Grants Administration Manual Chapter 2, Part 202)

5. Postaward Issue Considerations of the Role of the PI

a. Reporting Accomplishments It is incumbent upon the PI to make results and accomplishments of his/her research available to the public in a timely manner. NIH prior approval is not required for publishing such results. Although responsibility for the direction or sponsorship of the grant research activity should not be ascribed to NIH, the PI shall place an acknowledgement of NIH grant support on any publication written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. An acknowledgment may be to the effect that "this publication was made possible by a grant from..." or "the project described was supported by a grant from...."

If the grantee institution and/or PI wish to have NIH join in a simultaneous news release announcing the results of a project, the action is to be coordinated with the NIH awarding component.

Two reprints of publications resulting from work on an NIH-supported grant activity must be submitted by the PI to the NIH awarding component. (See PHS Grants Policy Statement.)

b. Changes in Research Objectives It is expected and, indeed encouraged, that recipients of an NIH research grant will continually adapt their methods and technical approaches as necessary to better achieve their research goals. Minor changes in allocation of personnel or rebudgeting that will further the work are acceptable. However, proposed changes in the scope or objectives of the research must be discussed with the NIH awarding component to determine if they are appropriate with respect to the project's original goals and scope. A memo to the record will be filed to document changes in work scope. Significant changes in the goals of a project may require submission of a competitive application either for a supplemental award or for an independent grant. (See PHS Grants Policy Statement.)

c. Change in Status or Absence of Principal Investigator Postaward changes in the level of participation in the approved project by the PI are generally acceptable. However, a significant decrease in the level of effort from that level originally proposed, should be submitted in advance for approval by the NIH awarding component. Expressed in terms of a ratio, a proposed decrease in effort of 1/5 from the level originally proposed, is considered "significant." For example, if the PI is currently devoting 40% effort to the project, a reduction of 20% (1/5) would be reflected as a 32% effort (i.e., any reduction equal to or greater than 8 percentage points from 40%).

When the project will be without the active direction of its PI for a continuous period of three or more months, the NIH awarding component must be notified and plans for the continuing conduct of

the research project must be approved.

While absent from the main performance site of the project for three or more months, the PI may propose to direct the project via periodic visits and frequently scheduled communications. If such arrangements are deemed to be impractical by the GMO, the grantee institution must propose an interim PI for approval by the NIH awarding component.

If a PI withdraws from a project at any time prior to its completion, the grantee institution may submit to the NIH awarding component plans for continuation of the research under a replacement PI. If those plans are unacceptable to NIH awarding component, the grant must be terminated. (See PHS Grants Policy Statement and PHS Grants Administration Manual Part 129.)

d. Sabbatical Leave A PI's salary may be charged directly to a project for services rendered the project by that individual while he/she is on sabbatical leave, provided that the salary is proportional to the service rendered and is paid according to established institutional policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of an individual's regular salary from his/her institution. Plans for grant-supported effort of the PI during sabbatical leave, as well as plans for the continuation of the research project in his/her own laboratory, must be approved in advance by the NIH awarding component. Additional funds will not be awarded to support an

interim PI if the originally named PI is away for more than three months. (See PHS Grants Policy Statement.)

e. Change of Grantee Institution NIH Manual Chapter [5201](#) describes the policies and procedures associated with the following changes:

(1) When a PI departs from the grantee institution and the institution requests continuation of the project under the direction of another PI.

(2) When a PI departs from an institution and there is an NIH-approved, but not yet awarded (or activated) grant.

(3) When the PI departs from an institution and requests that the project be supported at another institution.

f. Requesting NIH Approvals The PHS Grants Policy Statement and Part 145 of the PHS Grants Administration Manual describe those postaward actions that require prior written approval of the awarding component. All such requests received by NIH awarding components must bear the signature of both the PI and an authorized institutional official of the grantee organization.

6. Reporting Requirements

a. Performance (Progress) Reports Well-written progress reports are central to an NIH awarding component's programmatic evaluation of a PI's research activity and an evaluation of the project's needs. They also serve several broader purposes by providing current information to NIH staff about scientific advances, aiding staff in planning future program goals, and assisting in the

preparation of reports to Congress and others about the progress in those areas of scientific research.

Annual and final progress reports are submitted with all applications for competing continuation or noncompeting continuation support, in accordance with instructions accompanying the application forms. The original and two copies of a final progress report must be submitted to the NIH awarding component within 90 days after the expiration of the project. The final report should include, at a minimum, a summary statement of progress toward the achievement of the originally stated aims, a list of the results (positive or negative) considered significant, and a list of publications resulting from the project. Two copies of reprints of publications not previously submitted should accompany the report. (See Non-competing Continuation Application.)

b. Invention Reports All inventions made in the course of (or under) an NIH research grant shall be promptly and fully reported by the PI to the grantee, who will in turn disclose the invention to the Extramural Inventions Office, OER, NIH, Building 31, Room 5B41, Bethesda, MD 20892.

In addition to prompt invention reporting (above) and regular reporting (or certification) as part of the grant application process, the principal investigator and an official authorized to sign on behalf of the grantee organization must submit to the NIH awarding component a Final Invention Statement and Certification within 90 days following the expiration or termination of grant support. All inventions that were conceived or originally reduced to practice

during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported, shall be listed on the statement. (See NIH Manual Chapter 5806 regarding Overdue Reports.)

7. NIH Intramural Research Scientists

NIH Manual Chapter 4204/6003-1 sets forth conditions and procedures under which an NIH intramural research scientist, while still employed by NIH, may develop and submit grant applications to NIH or other agencies of the Federal government, naming that research scientist as the PI for proposed research or related projects which would commence after he/she terminates Federal employment. Those requirements apply specifically to NIH intramural research scientists who have no official duties or responsibilities with respect to the review, evaluation, advice, or recommendations on grant applications submitted to NIH, and who are not otherwise involved in NIH grant administration.

G. Effective Date:

This policy is effective on date of release.

H. Additional Information:

For further information on this chapter contact the Grants Policy Office, Office of Extramural Programs, Building 31, Room 5B50. Telephone: 496-5967.

I. Additional Copies:

Copies of this manual chapter can be obtained by sending Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DTS, Building 31, Room B4BN09.

NIH POLICY MANUAL

54441 – Extension Applications and Awards (Type 4s), including MERIT

Issuing Office: OD/OER/OEP - 301-435-2729

Release Date: 01/30/12

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1. **Explanation of Material Transmitted:** This National Institutes of Health (NIH) NIH Manual Chapter (MC) describes the appropriate use of type 4 awards and the roles and responsibilities for NIH staff making awards for extensions (type 4) to existing grant awards.

2. **Filing Instructions:**

   Insert: NIH Manual Chapter 54441, dated 01/30/12.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support (DMS), OMA on 301-496-4606, or enter this URL:

  http://oma.od.nih.gov/manualchapters/

A. Purpose:

This NIH Manual Chapter (NIH MC) sets forth the requirements for non-competing extension applications/awards to existing NIH grants. Note this chapter covers those extensions that involve committing additional years to a funded project but does not cover routine extensions (with or without funds) of final budget/project periods.

B. Background:

Extension applications are requests for additional funds beyond the years previously awarded. These are often considered non-competing actions since the extension applications (type 4) do not require initial review group (IRG) review and in some cases, may not require Advisory Council or Board review. NIH uses this option for specific programs. Generally the type 4 cannot be used to expand the scope of the original application without additional peer review; however MERIT extensions can include a logical progression from that in the previously-funded competing application. Of the mechanisms for which type 4 extensions may be appropriate, only the Method to Extend Research in Time (MERIT; R37) awards must be routinely approved by National Advisory Councils or Boards, hereinafter referred to as Councils. However, other IC-specific programs may include a requirement for Council review when appropriate.

C. Policy:

1. **General:** For the purposes of this chapter, extensions are requests for additional funds beyond the years previously awarded. For some programs, extensions are used for distinct two-phase programs where specific milestones must be met before moving to the second phase. These include, but are not limited to: Fast-track SBIR (R43/R44)/STTR (R41/R42),Phased Innovation Award (R21/R33), NIH Pathway to Independence Award (K99/R00), and Exploratory/Developmental Cooperative Agreement (UH2/UH3). In other programs, this option is used to continue the initial phase of funding using the same activity code, but starting a new segment. Examples include MERIT (R37) and "two-phase" American Recovery and Reinvestment Act of 2009 (ARRA) (Pub.L. 111-5) awards that were funded with ARRA dollars in the first segment and regular appropriation funds thereafter.

Extension awards may be appropriate after the initial phase is almost complete or has been completed and the awardee has met the requirements for the extension of an existing award to the second phase as outlined within a Funding Opportunity Announcement (FOA) or program guidelines. In general, carryover is permitted between the initial phase and the extension unless it is specifically excluded by a program, or in the case of two-phase awards involving a change in funding source (see section D4 below).

2. **Method to Extend Research in Time (MERIT) Award (R37):** The MERIT award is a prestigious designation given to outstanding competing R01 grants at the time a competing application is considered for funding or sometime during the first budget period of a grant. An application cannot be elected/recommended for MERIT status during a non-competing year. MERIT awards are issued to very highly qualified R01 investigators whose competence and outstanding productivity during their previous research experience are highly likely to result in continued superior performance. Individual Institutes or Centers (ICs), along with their Council, should determine any specific additional criteria for MERIT eligibility. Criteria could include, for example, past history of superior ratings in one or more rounds of peer review, mentorship or service. After the initial competing segment, which is typically five years, MERIT awardees have the opportunity to apply for an administratively reviewed MERIT extension period of three to five years. The extension is awarded at the conclusion of the initial competing segment of the grant. The principal feature of the MERIT award is to relieve the selected applicant from writing frequent renewal applications by providing the opportunity for up to ten years of support in two segments. Thus, MERIT awards provide distinguished investigators with long-term, stable support that can facilitate and foster their continued creativity in the area of research covered by the application. Both the initial MERIT nomination and the MERIT extension nomination must be reviewed by

Council. The MERIT extension cannot represent a change in scope, but should be a logical extension of the funded competing application.

3. **Javits Award (R37):** The Senator Jacob Javits Award in the Neurosciences is a two phase seven-year research grant given by the National Institute of Neurological Disorders and Stroke (NINDS) to scientists for their superior competence and outstanding productivity. Highly meritorious competitive R01s are considered for funding as Javits Awards. Only competing applications are eligible. Javits Awards are issued to investigators with a history of exceptional talent, who have a record of substantial contributions at the cutting edge of neurological science, are leaders in the field, and who have a high likelihood of continued high productivity during the seven-year award period, and a record of service to the NIH. After an initial four-year award, Javits awardees have the opportunity to apply for an administratively reviewed extension period of three years. The extension is awarded at the conclusion of the initial competing segment of the grant. The nomination for the Javits award must be reviewed by Council. The Javits extension cannot represent a change in scope, but should be a logical extension of the funded competing application.

4. **Two-phase Awards**

    a. **Fast-track SBIR (R43/R44)/STTR (R41/R42) Awards:**
       The policies and procedures for these awards are described in
       [NIH Manual Chapter 54442](#).

    b. **Two-phase Awards other than Fast-track SBIR/STTR:**
       Applicants describe both phases of the project in the initial competing application that undergoes peer review; however, funding of the first phase does not guarantee funding of the second phase. Approval for continued funding of the second phase of the project is the responsibility of the funding IC. The application for the second phase becomes a type 4 during its first year. Examples of two-phase awards include the NIH Pathway to

Independence Award (K99/R00), Phased Innovation Award (R21/R33), and the Exploratory/Developmental Cooperative Agreement (UH2/UH3).

Applications describing two phases of research undergo peer (including Council) review as a single, combined application; thus both phases are peer reviewed. The two-phase application must be submitted as a single application. It should be clearly organized into two distinct phases and include a detailed scientific and administrative description and budget for each phase in accordance with the specific FOA.

Total project periods for the initial award and the type 4 extension period combined cannot exceed 5 years unless a deviation is approved by the Director, Office of Policy for Extramural Research Administration (OPERA). This deviation must be received prior to issuing any FOA (see OER Policy Announcement 1997-02) and the deviation approval must be included when the FOA is submitted for clearance.

The Research Strategy must include clear, measurable goals (milestones) for phase 1 that should be achieved prior to initiating phase 2. Applications are evaluated for scientific and technical merit by an appropriate scientific review group convened in accordance with the standard NIH peer review procedures. The scientific peer review group evaluates the goals and may suggest additional or alternative milestones that should be achieved prior to phase 2 funding. Milestones may be specific research achievements and/or training/career development accomplishments, as appropriate to the goals of the award. Both phases are reviewed concurrently in one peer review action.

Thus, only one impact/priority score and percentile ranking (if appropriate) are provided.

Two-phase applications receive secondary review by the Council of the NIH awarding component that is the potential funding component.

When the phase 1 is awarded, the Grants Management Specialist (GMS) notifies the Program Official (PO) and other relevant IC staff, such as the budget office, about the potential start date of the phase 2 and the anticipated total costs for each year to allow for budget tracking. In addition, the PO and GMS may jointly send an informational letter to the phase 1 recipient, establishing and defining milestones for achievement in phase 1 as well as the process for transitioning to the second phase. This information can also be included in the terms of the Notice of Award in lieu of sending a separate letter, in which case the phase 1 recipient should be directed to review the Notice of Award. When milestones are defined, these must be incorporated as a term of award.

Awardees are required to submit an extension application including a progress report prior to the conclusion of phase 1. ICs should notify the grantee of the timing of this submission via an award term or separate notification. The PO evaluates the extension application, scientific progress and compliance with requirements of the program, and may recommend that the second phase be funded, revised, or eliminated. It may be appropriate for outside reviewers to be involved in this process. If outside reviewers are involved, NIH policies regarding confidentiality and conflict of interest in initial peer review must be

followed. The PO may request additional information and conduct further discussions with the Project Director/Principal Investigator (PD/PI) as part of the review. However, the extension may not expand the scope of the original project.

After the review is complete, the PO will indicate his/her recommendation for phase 2 funding by completing the appropriate IC documentation. There is no requirement for additional Council review; however ICs may require this as part of their Council Operating Procedures. The decision to fund or not to fund the phase 2 portion is considered a preaward action and is not appealable.

Automatic carryover from the first to second phase is permitted. An expenditure data Federal Financial Report (FFR) is required within 90 days after the end of the first phase award. The Notice of Award of the first phase award will automatically include terms appropriate to the final year award.

c. **Two-phase Clinical Trials (within a 5-year Project Period)**
Some clinical trial programs involve meeting specific milestones before a second phase of the trial is approved to continue. When a program incorporates milestones to implement a phased program, both phases must still be within a total five-year project period. An IC cannot issue an extension award that extends a clinical trial beyond five years without obtaining a deviation. Two-phase clinical trials follow the policies in this Chapter.

If an IC plans to create a clinical trials program that permits trials to exceed five years, then a deviation from policy must be requested from the Director, OPERA prior to issuing the FOA (see OER Policy Announcement 1997-02).

d. **Two-phase Awards Involving a Change of Funding Source**

In some cases, as with funds from ARRA, there may be a requirement to separate a funded grant into two phases for the purposes of dividing between funding sources. For example, applications that were funded initially from ARRA funds use the type 4 record to continue funding for the remaining years of the award with funds from the regular appropriation. The commitment from the regular appropriation must be clearly indicated as part of the phase 1 ARRA-funded award. The budget/project period of the ARRA-funded segment must be terminated to coincide with the funding of the non-ARRA type 4. At no time should both funded segments overlap. In addition, there is no authority to carry over funds between segments funded from different funding sources. This use of the extension mechanism to change the source of funding applies only to ARRA-funded awards, and Office of Extramural Research (OER) approval must be sought for any other proposed use of extension awards for this purpose.

D. References:

1. http://inside.era.nih.gov/files/Activity_Code_Book.pdf
2. NIH Manual Chapter 54815, Implementation of Cooperative Agreements
3. NIH Manual Chapter 54444 - Evaluation of Grant Progress Reports By Program Officials http://oma.od.nih.gov/manualchapters/grants/54444/
4. NIH Manual Chapter 54107, Review of Applications and Award of Grants Involving Human Subjects
5. NIH Grants Administration Manual GAM Chapter 4.1.04.204 - Responsibilities of NIH Grants Administration Staff
6. NIH Manual Chapter 6380-2/54206, Responsibility for Care and Use of Animals
7. NIH Grants Policy Statement

8. The Method to Extend Research In Time (MERIT) Award (R37)
   http://grants.nih.gov/grants/guide/historical/1986_08_01_Vol_15_No_13.pdf
9. [NIH Manual Chapter 54442](#) – SBIR/STTR Fast Track Award Policy
10. [OER Policy Announcement 1997-02](#) – Single-Case Deviation from PHS/NIH Grants Policy
11. [NIH Manual Chapter 1743](#) - "Keeping and Destroying Records," Appendix 1,

E. Responsibilities:

1. **Chief Grants Management Officer (CGMO):** assures compliance with the policy requirements stated in this NIH Manual Chapter, with particular attention to the selection of the appropriate award mechanism. Along with the Program Official (PO), the CGMO assures that the appropriate award mechanism has been selected. In addition, the CGMO is responsible for requesting deviations from OPERA for any grant awards or program (FOA) that will award grants that exceed a five-year project period.

2. **Grants Management Officer/Specialist (GMO/GMS):** along with the PO, is responsible for establishing the administrative deadlines to ensure a minimal or no funding gap, notifying the appropriate IC staff regarding the potential start date of the phase 2 award and the anticipated total costs for each year, and for completing administrative and fiscal reviews. In addition, the GMO/GMS creates the type 4 record for phase 2 awards that do not require Council review and assigns the appropriate code for human subjects and vertebrate animal research (see NIH Manual Chapters [54107](#) and [6380-2/54206](#)). For R37's or R00's, the type 4 application is received by the GMO/GMS and sent to the Division of Receipt and Referral (DRR) at CSR for creation of the type 4 grant record and for Council assignment. It is the responsibility of the GMO/GMS to request the appropriate code for human subjects and

vertebrate animal research from the Office of Extramural Program (OEP) or the Office of Laboratory Animal Welfare (OLAW).

3. **Program Official (PO):** with the Chief GMO, assures that the appropriate award mechanism has been selected. The PO is also responsible for communicating with the Project Director/Principal Investigator (PD/PI) regarding the scientific aspects of this mechanism, negotiating the milestones with the PD/PI and completing an administrative review to determine whether the milestones have been achieved prior to recommending the phase 2 award. In addition, the PO is responsible for evaluating the proposed use of human subjects or vertebrate animals in type 4 applications. For type 4 records created by CSR (R37 and R00), the PO is responsible for requesting additional information from the PD/PI, if necessary, and for working with the GMO/GMS to recommend the appropriate code to OEP or OLAW. If there are concerns about either the proposed human subjects or vertebrate animal research, the PO serves as the intermediary between OEP or OLAW and the PD/PI during the resolution of concerns. Along with the GMO/GMS, the PO establishes administrative deadlines to ensure a minimal or no funding gap, and notifies the appropriate IC staff regarding the potential start date of the phase 2 award and the anticipated total costs for each year.

4. **Office of Extramural Programs (OEP), OER:** is the approving office for new mechanisms and Funding Opportunity Announcements involving extension awards. In addition, the Human Subjects Program of OEP is responsible for assessing human subjects protections. Prior to award, OEP changes human subjects codes from "20" to the appropriate code for type 4 records created by CSR (e.g., R37 and R00) (see [NIH Manual Chapter 54107](#)).

5. **Director, Office of Policy for Extramural Research Administration (OPERA), OER:** is the approving official for single-case deviations from HHS policy such as requests to issue an award with a project period

that is more than five years. See [OER Policy Announcement 1997-02](#).

6. **Office of Laboratory Animal Welfare (OLAW):** OLAW is responsible for assessing vertebrate animal protections. Prior to award, OLAW changes vertebrate animal research codes from "20" to the appropriate code for type 4 records created by CSR (e.g., R37 and R00) (see [NIH Manual Chapter 6380-2/54206](#)).

7. **Director, Division of Receipt and Referral (DRR), Center for Scientific Review (CSR):** is responsible for accepting and processing type 4 applications for the MERIT R37s and any other application that requires a Council assignment. In addition, DRR creates type 4 R00 records.

F. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual Chapter 1743, "Keeping and Destroying Records, Appendix 1," "NIH Records Control Schedule," "Section 4000, Grants and Awards."

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value, are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information

Act requests. Back-up files are subject to the same requests as the original messages.

G. Internal Controls:

The purpose of this manual issuance is to state NIH policies and the requirements governing the appropriate use of type 4 awards

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter:** Responsibility for monitoring compliance with this chapter resides with the Office of Extramural Programs (OEP), Office of Extramural Research (OER).
2. **Frequency of Review:** There will be ongoing review, taking place at least once every five years.
3. **Method of Review:** OEP will use several methods of review, including the following:
   a. Review of new requests to the NIH Guide for FOAs that will award grants that exceed a five-year project period
   b. Assessment of IC Council Operating Procedures that describe review of MERIT awards
   c. Periodic sampling of type 4 grant awards via the IMPAC II system
   d. Feedback from the Program Leadership Committee (PLC)
   e. Feedback from the Grants management Administration Committee (GMAC).

   In addition, OPERA will be routinely apprised of any difficulties in the implementation of this policy.

   Reports of findings and recommendations resulting from these types of reviews will be issued to assess compliance with the policy stated in this chapter. Common issues will be brought to the PLC and the Extramural

Program Management Committee (EPMC) for resolution and corrective action. Depending upon the nature and the extent of problems found, if any, the DDER may recommend additional review, policy guidance, and/or training of staff.

4. **Review Reports are sent to:** Deputy Director for Management (DDM) and Deputy Director for Extramural Research (DDER) indicating that controls are in place and working well or include any management control issues that should be brought to the attention of the DDM.

Appendix A - Procedures:

1. **MERIT Awards:**
   a. **Nomination**

   Program Officials or members of the IC Council may nominate a competing R01 application or funded grant during its first budget period for conversion to an R37 (MERIT) award; investigators may not apply for a MERIT award. MERIT awardees gain the opportunity to apply for an administratively reviewed MERIT extension period of three to five years. The extension is awarded at the conclusion of the initial competing segment of the grant.

   The following are required criteria for MERIT awards.
   - The candidate must be the PD/PI on a competing R01 application or grant in its first budget period.
   - Only R01s are considered for MERIT awards. Supplement (revision) applications cannot be considered a basis for MERIT awards.
   - The competing R01 application must have a superior rating.
   - The candidate PD/PI must have demonstrated superior

competence and outstanding productivity during previous research endeavors as evidenced, for example, by a continuous record of publications in the highest quality journals for that field.

- The R01 represents the PD/PI's principal area of research and should be in an area of special scientific importance or promise to the awarding IC.

ICs may have additional requirements for MERIT awards. Examples are listed in Appendix B.

A PD/PI may receive an additional R37 award from an IC on the same grant after the first MERIT award and extension have been completed. The additional R37 award would need to meet all the above noted eligibility criteria and must be a competing application. It cannot be another type 4 extension application. However, no PD/PI should hold concurrent MERIT awards from a single IC as it is unlikely that both R01s constitute independent principal areas of research. While it is possible for a PD/PI to hold concurrent MERIT awards from two different ICs, each of the nominated R01s must represent a distinct focus (principal area) of research for the PD/PI.

b. **Selection of MERIT Awardees**

The IC Council reviews staff nominations of candidates and makes recommendations to the IC director. If the IC Council does not recommend approval of the nomination, the application can be funded, or continue to be funded, as an R01.

The IC director selects MERIT awardees from among the Council-recommended nominees. Nominees are notified and

provided information about the attributes of the award and the due date for the MERIT extension application. If the nominee accepts the nomination, he or she must send an acceptance signed by an institutional Authorized Official Representative to the IC. Upon receipt of this letter, and adding it to the official file, the GMS converts the R01 record to a R37 record and issues the award accordingly. When the MERIT nomination is approved after the competing award has been issued, a revised award must be issued to reflect the conversion to the R37. MERIT awards may be exempted from competing-year administrative reductions.

c. **MERIT Extension Application**

At an appropriate time during the initial segment of the MERIT award, the IC notifies the grantee of the opportunity to submit an extension application. The communication details the required parts and format of the extension application and specifies a date for submission. The extension application must include at least a progress report, a 1-12 page research plan for the extension period and a proposed budget (modular or detailed). In addition, the application must include sections on the proposed use of human subjects or vertebrate animals. The application should be received early enough in the initial segment (approximately 16 months) so that if the IC staff and Council do not recommend approval for the MERIT extension application, adequate time remains for a regular renewal application to be submitted for continued funding through the standard peer review process. If an IC chooses to receive applications for extension at a later time in the competitive segment, it should be prepared to consider interim support for orderly termination or bridge funding.

MERIT awards to a single PD/PI cannot be converted to a Multiple PD/PI project at the time of the type 4 extension application. The conversion must be peer reviewed by an initial review group (IRG).

When the extension application is received by the awarding IC, it is forwarded by the GMO/GMS to the DRR at CSR for creation of the type 4 grant record and for Council assignment. At that time, the application is assigned a code "20" ("Human subjects involved").

d. **Review of the MERIT Extension Application**

On the basis of the extension application, the competing application that was awarded MERIT status, the summary statement, the interim progress reports, and publications resulting from work supported by the grant, the PO develops a staff recommendation. The recommendation should address the granting of an extension, its length (three to five years) and its budget levels, which will be calculated by the Grants Management Specialist. In addition, the PO must assess the proposed use of human subjects or vertebrate animals. Outside opinions may be solicited. The extension application should propose work that represents a logical progression from that in the competing application. If outside reviewers are involved, NIH policies regarding confidentiality and conflict of interest in initial peer review must be followed. The PO provides a written recommendation to Council and should indicate whether outside opinions were solicited.

Each application for extension must be reviewed by the Council. The Council is asked to recommend whether or not an extension

of support for up to five years is warranted. The review criteria include an evaluation of whether the application continues to represent the PD/PI's principal area of research and continues to be in an area of special scientific importance or promise to the awarding IC. Additional review criteria should include the timeliness and significance of the research, productivity of the applicant and progress made during the current award period, and leadership in the field. In addition, any proposed use of human subjects or vertebrate animals must be assessed in accordance with federal regulations (see NIH Manual Chapters 54107 and 6380-2/54206).

The Council recommends one of the following actions:
- approval for up to five years at a specified budget level for each budget period;
- disapproval and return of the application to the PD/PI for submission as a competing continuation; or
- deferral for additional information.

In addition, the Council should discuss any concerns related to human subjects protection or the use of vertebrate animals. After the Council meeting and in accordance with established IC procedures, the PO finalizes the summary of the Council recommendation, including any concerns about human subjects protection or the use of vertebrate animals. The summary (or "staff action form") document is stored in the official file to document the Council Action. In addition, ICs should use the appropriate system in IMPACII to document the Council Action; i.e., 1- To be considered for funding or 5- Not extended. For approved applications, the staff action form should include a budget for each recommended extension year and the scientific

and programmatic bases for the recommendation. Concerns about the use of human subjects or vertebrate animals in the proposed research should be sent to OEP or OLAW for resolution by the GMO/GMS, working together with the PO.

The IC director or his/her designated representative informs the MERIT awardee of his/her decision. If an extension is granted, the communication also specifies the length of time of the extension and the approved budget. ICs may make subsequent budget adjustments in accord with the funding plan/cost management principles in effect during the fiscal year in which the MERIT extension application is funded.

If the MERIT awardee does not receive an extension, he or she may then submit a complete R01 renewal application, using standard processes, for review as a regular competing research grant application. Awardees should receive a decision on the extension early enough to allow them, if necessary, to submit a competing renewal application in time to avoid a gap in funding.

Prior to award, OEP and OLAW assign the appropriate codes based on information in the application and information provided by the IC. If there are unacceptable protections, OEP or OLAW work with the IC and PI/PD to achieve a resolution prior to award (see NIH Manual Chapters 54107 and 6380-2/54206).

e. **MERIT award administration:** MERIT awards follow all established post-award grants administration business processes as documented in the NIH Grants Policy Statement. Therefore, MERIT awardees are eligible to apply for and receive competitive revisions and/or administrative supplements. A MERIT awardee

may also transfer his/her MERIT grant to another institution in accordance with standard NIH grant administration policies

2. **Javits Awards (National Institute of Neurological Disorders and Stroke):**

   a. **Nomination**

   Program Officials or members of the IC Council may nominate an R01 application for conversion to a Javits award; investigators may not apply for a Javits award. Javits awardees gain the opportunity to apply for an administratively reviewed extension period of three years awarded at the conclusion of the initial four year competing segment of the grant.

   The following are required criteria for Javits awards.
   - The candidate must be the PD/PI on a competing R01 application.
   - Only R01s are considered for Javits awards. Revision (previously known as competitive supplement) applications cannot be considered a basis for Javits awards.
   - The current competing continuation application must have a superior rating, typically better than 5th percentile.
   - The candidate PD/PI must have a record of substantial contributions at the "cutting edge" of the research area of the award IC, and be a leader in the field who can be expected to continue to be highly productive during the seven-year award period..
   - The PD/PI must have an established record of service to the awarding IC and/or NIH.
   - The current application represents the PD/PI's principal area of research.

b. **Selection of Javits Awardees**

The IC Council reviews staff nominations of candidates and makes recommendations to the IC director. If the IC Council does not recommend approval of the nomination, the application can be funded, or continue to be funded, as an R01.

The IC director selects Javits awardees from among the Council-recommended nominees. Nominees are notified and provided information about the attributes of the award. If the nominee accepts the nomination, he or she must send an acceptance signed by an institutional Authorized Official Representative to the IC. Upon receipt of this letter, and adding it to the official file, the GMS converts the R01 record to a R37 record and issues the award accordingly.

c. **Javits Extension Application**

At an appropriate time during the initial segment of the Javits award, the IC notifies the grantee of the opportunity to submit an extension application. The extension application is due two months prior to the end of the initial segment and must include a letter countersigned by the AOR requesting an additional three years of support, a progress report, a 1-page research plan for the extension period and a proposed budget (direct costs only). In addition, the application must include sections on the proposed use of human subjects or vertebrate animals. A budget increase of up to 10% in direct costs above the last non-competing year may be requested.

When the extension application is received by the awarding IC, it is forwarded by the GMO/GMS to the DRR at CSR for creation of the type 4 grant record and for Council assignment. At that time,

the application is assigned a code "20" ("Human subjects involved").

d. **Review of the Javits Extension Application**

The progress report summary, the research plan, and proposed budget are reviewed administratively by IC staff. In addition, any proposed use of human subjects or vertebrate animals must be assessed in accordance with federal regulations (see NIH Manual Chapters 54107 and 6380-2/54206). If approved, a Notice of Grant Award will be issued for the additional three years. Prior to award, OEP and OLAW assign the appropriate codes based on information in the application and information provided by the PO. If there are unacceptable protections, OEP or OLAW work with the PO and PI/PD to achieve a resolution prior to award.

e. **Javits award administration:** Javits awards follow all established post-award grants administration business processes as documented in the NIH Grants Policy Statement. Therefore, Javits awardees are eligible to apply for and receive competitive revisions and or administrative supplements. A Javits awardee may also transfer his/her Javits grant to another institution in accordance with standard NIH grant administration policies.

3. **Two-phase Awards other than Fast-track SBIR/STTRs:** Examples of two-phase awards, with specific procedures are included below. Without an approved deviation from Director, OPERA, an IC cannot issue an extension award that extends a grant beyond five years. Early consultation with OER is strongly encouraged any time an IC is considering a two-phase approach for a new program (other than those already in place for broad NIH IC use).

a. **R21/R33**

The R21 is funded as a type 1 R21 with commitments for any applicable

R21 future years but no commitment for the R33 future years.

The Streamlined Non-competing Award Process (SNAP) applies to both phases.

Prior to the initial award of the R21, the PO may negotiate milestones with the PD/PI. The R21 Notice of Award (NoA) must include or reference these negotiated milestones in the IC-specific terms of award. In addition, IC-specific terms regarding submission of an extension application including progress report should be included in the NoA. The PD/PI should be directed to review the NoA. When not included in the NoA, extension application submission instructions must be separately communicated to the grantee and PD/PI.

The type 4 record for the R33 is created in IMPAC II by the GMS once the extension application is received. ICs can technically create the type 4 record any time after the final year of the R21 phase is issued. Some ICs may choose to wait until the R33 application has been reviewed and approved before creating the type 4 record.

Once the type 4 record is created, the NIH office responsible for processing type 5 applications can upload the type 4 application to that record.

A sample sequence of events in IMPAC II and in the Payment Management System (PMS) for two-phase programs, except for those Two-phase Awards Involving a Change of Funding Source, is as follows:

Grant Number	Document Number
1 R21 GM012345-01 phase 1, first year	RGM012345A
5 R21 GM012345-02 phase 1, second year	RGM012345A
4 R33 GM012345-03 phase 2, first year	RGM012345B

5 R33 GM012345-04 phase 2, second year	RGM012345B

In general, the Extension application/progress report package is due **no later than** two months prior to the anticipated start date of the R33. However, the IC may require that extension applications be received earlier. The grantee is permitted to exercise their no-cost extension authority for the R21 phase if the milestones have not been achieved on schedule.

Any proposed changes in the use of human subjects or vertebrate animals in the R33 phase must be assessed in accordance with federal regulations (see NIH Manual Chapters 54107 and 6380-2/54206).

b. **Pathway to Independence Award K99/R00**

The K99/R00 program provides highly promising postdoctoral research scientists with a period of mentored support followed by a period of independent support contingent on securing an independent tenure-track or equivalent research position. The procedures described here do not apply to the K22 program used for the second phase of an intramural NIH/extramural position program, even though it is also a mentored award that offers two phases of support, because no extension award is made to initiate the second (extramural) phase. However, these procedures would apply for any IC that uses the K22 for a two-phase extramural program that is similar to the K99/R00.

Both intramural and extramural investigators are eligible to apply for the K99 award. However, from an extramural award perspective, grant awards for both the K99 and R00 phases are issued only to extramural organizations. For intramural K99s selected for funding, the funds will be provided by the intramural program during the K99 phase of the award. When the K99 application is submitted from an intramural lab in an IC that is different than the IC assigned the extramural application, the premise is that the current

intramural IC and current source of salary support do not change during the K99 portion. However, the extramural IC is responsible for monitoring progress and reviewing the application for transition to an R00. The R00 phase of such an award will be funded by the assigned (awarding) IC. Thus, the investigator will be supported by one IC's intramural program for the K99 phase of the award and by a different IC's extramural program for the R00 phase. If either an intramural or extramural K99 recipient is offered and chooses to accept a position in the NIH intramural program, the award will be terminated.

The Streamlined Non-competing Award Process (SNAP) generally applies to both phases.

The progress report and application for transition to the R00 phase of the award must be submitted to the GMS of the awarding NIH Institute or Center no later than two months prior to the proposed activation date of the R00 award by the R00 phase grantee organization. However, the IC may require that transition applications be received earlier. The requirements for the R00 application are defined in the K99/R00 FOA. In general, the application will contain a Description (Project Summary and Relevance), progress report from the K99, research plan, and budget pages along with supporting materials according to NIH requirements, including a description of the proposed use of human subjects or vertebrate animals.

If the R00 phase is to be awarded to a different institution, no Relinquishing Statement is required because the K99 is not transferred; it simply ends.

The K99 awardee may request a transition to the R00 phase before the projected end of the K99 award, but there should be a minimum of one year in the K99 phase. Carryover of funds from the K99 phase to the R00 phase is generally allowed, whether or not the awardee is changing institutions, but must be approved by the IC.

In order to create the type 4 R00 record, the GMS provides the DRR in CSR with a copy of the type 4 application. At that time, the application is assigned a code "20" ("Human subjects involved").

Extenuating circumstances or failure to find suitable employment may delay submission of the application for transition. The PO is responsible for evaluating requests for delays in accord with individual IC policies.

The grantee may exercise the no-cost extension authority for the K99 phase if it is not approved for a transition to the R00 phase or if additional time is needed before transitioning. If the K99 portion is extended, all terms and conditions, including the minimum effort requirement, continue during the extension period.

For those K99 awards that do continue into the R00 phase, all closeout documents must be submitted within 90 days after the termination date of the K99; however, the progress report submitted in any R00 application may be used as the final progress report for the K99.

At no time can the K99 and R00 segments both be active and overlapping. When a transition to the R00 occurs before the K99 phase is completed, then the K99 award must be revised to early terminate that segment to coincide with the start of the R00.

Any proposed use of human subjects or vertebrate animals in the R00 phase must be assessed in accordance with federal regulations (see NIH Manual Chapters 54107 and 6380-2/54206).

Prior to award, OEP and OLAW assign the appropriate codes based on information in the application and information provided by the IC. If there are unacceptable protections, OEP or OLAW work with the IC and PD/PI to achieve a resolution prior to award.

c. **Exploratory/Developmental Cooperative Agreement (UH2/UH3)**

The UH2/UH3 is similar to the R21/R33, described above in section 3.a. Because they are cooperative agreements, the PO may serve in the role of Project Scientist (or Project Coordinator, or Project Collaborator) or in the role of Program Official. The participation of an NIH employee who is substantially involved

under a cooperative agreement could raise concerns regarding the integrity of agency operations. Therefore, Project Scientists who **are substantially** involved in such a project are generally prohibited from participating in the administrative review of the phase 2 application, unless there is an IC plan for management of concern about bias (see NIH Manual Chapter 54815).

d. **Two-phase Clinical Trials (Within Five-Year Project Period)**

The procedures for these programs are similar to those described in Section 3.a above. IC-specific terms regarding milestones and expected timelines should be included in the NoA, and the PD/PI should be directed to review the NoA. When not included in the NoA, this information must be separately communicated to the grantee and PD/PI. When issued as cooperative agreements, the IC is responsible for assuring that all policy and procedures for cooperative agreements (see NIH Manual Chapter 54815) are followed. At no time can an extension award be issued to extend a clinical trial program for more than five years unless a deviation from OPERA has been received.

e. **Two-phase Awards Involving a Change of Funding Source – applications funded initially with ARRA funds**

Once the ARRA funded phase has ended and funding is to continue using IC appropriated funds, Grants Management staff may create the type 4 record (if not already created) and process the award for the continued funding. This assumes that a progress report has been received and reviewed by both the PO (see NIH Manual Chapter 54444) and GMS in accordance with established IC business practices.

Appendix B - Diversity of Requirements for MERIT Awards:

The following is a list of some of the requirements for MERIT nomination at one or more ICs. These are shown as examples only; requirements vary by IC.

1. The PD/PI must have had a minimum of ten years of independent research support from the NIH at the time of consideration for a MERIT Award.
2. A MERIT Award may not be offered to an investigator who has already had a MERIT Award or an equivalent award from this IC or another IC.
3. Cost is a consideration in the MERIT Award selection process. Research grants that require a large commitment of resources from the IC must be strongly justified.
4. An application must represent at least the second competing renewal of a grant.
5. An application must be a competing continuation of a grant for which the PI/PD has had continuous IC support for at least seven years, and for which no application competed in the last seven years has needed amendment.
6. The application must form the principal source of NIH support for an investigator.
7. The application must have been approved by the study section for five years of support with an impact score in the range of 1.0 and 5.0 percentile.
8. The research project should have received support for at least 10 years. Projects that have been supported by the IC for greater than seven years, but less than 10 years are eligible if they have been ongoing for at least 10 years with other support.
9. The grant must have been approved for at least five years.
10. The investigator must have a strong record of service and mentorship to the scientific community.

11. Preference is given to investigators whose applications have not required an amendment.

NIH POLICY MANUAL

54442 – SBIR/STTR Fast Track Award Policy

Issuing Office: OPERA/OER/OD 435-0949

Release Date: 08/01/2003

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1. **Explanation of Material Transmitted:** This chapter provides updated policies and procedures for administering National Institutes of Health grant awards submitted under the SBIR/STTR Fast-Track application procedures.

2. **Filing Instructions:**

    Remove: NIH Manual Chapter 4442 dated 03/15/2001.
    Insert: NIH Manual Chapter 4442 dated 08/01/2003.

PLEASE NOTE: For information on:

- To sign up for email notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This chapter outlines the responsibilities and operating procedures for awarding Small Business Innovative Research/Small Business Technology Transfer Research Fast Track grants.

B. Responsibilities:

The SBIR/STTR Programs are structured in three phases, the first two of which are supported using SBIR/STTR funds. Traditionally, SBIR and STTR applicants submit two

distinct applications for each of the two phases. Phase I establishes the technical merit and feasibility of proposed research. Phase II continues the research efforts initiated in Phase I with the ultimate goal of achieving commercialization of the results. No Federal SBIR or STTR funds may be used to support Phase III, the commercialization phase. Small firms are encouraged to pursue this phase through private sector commercialization or by obtaining non-SBIR/STTR government follow-on contracts for additional technology development. Previously, the Phase II application could not be submitted until after the Phase I application had been funded. The Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast-Track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together.

Fast-Track SBIR/STTR applications are eligible for consideration upon meeting the following criteria:

- o Fast-Track SBIR/STTR applications for both Phase I and Phase II must be submitted together for concurrent initial peer review and evaluation. The PHS 398 application forms are available at http://grants1.nih.gov/grants/funding/phs398/phs398.html.

- o In order to identify the application as such, the words "Fast-Track" must be shown on line 2 of the face page of the Phase I and Phase II applications.

- o The Phase I application must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II. Failure to provide clear, measurable goals may be sufficient reason for the scientific peer review group to exclude the Phase II application from Fast-Track review. The scientific peer review group will evaluate the goals and may suggest other milestones that should be achieved prior to Phase II funding. The Phase I and Phase II applications will receive a concurrent review. Fast-Track applications will receive secondary review by the advisory council or board

of the NIH awarding component that is the potential funding component. Staff will review progress after Phase I prior to any decision to award Phase II funds.

The small business concern must submit as a part of the Phase II research plan, a concise Commercialization Plan [formerly Product Development Plan] (limited to fifteen pages). It should address each of the following areas:

Value of the SBIR/STTR Project, Expected Outcomes, and Impact. Describe, in layperson's terms, the proposed project and its key technology objectives. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

Company. Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

Market, Customer, and Competition. Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the

market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation. Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product. Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. (It is very important that you understand and know the competition.)

Intellectual Property (IP) Protection. Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

Finance Plan. Describe the necessary financing you will require, and when it will be required, as well as your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

- Letter of commitment of funding.

- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.

- Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.

- Specific steps you are going to take to secure Phase III funding.

Production and Marketing Plan. Describe how the production of your product/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/service. For example, explain plans for licensing, internet sales, etc.

Revenue Stream. Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Place relevant letters following letters from consultants and collaborators.

Phase III funding may be from any of a number of different sources including, but not limited to: SBIR/STTR firm itself; private investors or "angels"; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms.

C. Policy:

Fast-Track Phase II applications may be funded following submission of the Phase I progress report and other documents necessary for continuation. Phase II applications will be selected for funding based on the awarding component's

assessment of the Phase I progress report, and determination that the Phase I goals were achieved; an update and verification of the Commercialization Plan [formerly Product Development Plan] and any commitment(s) for funds and/or resources from an investor or partner organization, as described below; the project's potential for meeting the mission of the awarding component and for commercial success; and the availability of funds.

D. References:

1. Small Business Innovation Research Program Reauthorization Act of 2000, Public Law 106-554 http://www.acq.osd.mil/sadbu/sbir/pl106-554.pdf

2. Small Business Technology Transfer Program Reauthorization Act of 2001, Public Law 107-50 http://www.acq.osd.mil/sadbu/sbir/pl107-50.pdf.

3. Omnibus Solicitation of the NIH, CDC and FDA for SBIR/STTR Grant Applications at: http://grants.nih.gov/grants/funding/sbir.htm

4. Small Business Innovation Research (SBIR) Program Policy Directive at http://www.sbaonline.sba.gov/SBIR/sbirpolicydirective.html

E. Definition:

Fast-Track. A review option available to those small business concerns (applicant organizations) whose applications simultaneously satisfy review criteria for both Phase I and Phase II, which enhances the probability of the project's commercial success. Applications that do not meet these criteria may be redirected for review through the standard peer review procedures. In some cases, the Scientific Review Group may review and score only the Phase I portion of a Fast Track application, if the application does not include a Commercialization Plan that includes the seven items listed in Section B.4 above, or the application does not contain clear, measurable Phase I goals that are appropriate for demonstrating feasibility, or the Phase II project is significantly less meritorious than the Phase I project. Fast Track offers two major

advantages:

> h. Concurrent submission and peer review of both Phase I and Phase II projects.
>
> i. Minimal or no funding gap between Phase I and Phase II.

F. Responsibilities:

In addition to the standard Program and Grants Management responsibilities, the following reflect specific responsibilities applicable to this mechanism:

The Program Director is responsible for:

- negotiating the Phase I milestones with the PI;
- determining whether the milestones have been achieved prior to the Phase II award; and
- communicating with the PI regarding this complex mechanism.

The Grants Management Specialist is responsible for coordinating the activities necessary to ensure a smooth transition to the Phase II award. This includes:

> § establishing the administrative deadlines to ensure a minimal funding gap;
> § notifying the appropriate IC staff regarding the potential start date of Phase II and anticipated total costs for each year; and communicating with the grantee regarding this complex mechanism.

G. Procedures:

Under the Fast-Track initiative, two distinct applications (Phase I & Phase II) are simultaneously submitted and reviewed.

1. **Phase I:**
   a. The Phase I is entered into IMPAC II as a Type 1 R44 (SBIR)/R42 (STTR) at the time of receipt by the Center for Scientific Review

(CSR).

b. The Phase I will be funded as a Type 1 R44/R42, with no commitment for Phase II in future years.

c. For Phase I administrative review, the appropriate IC Phase I checklist should be used.

d. For Fast-Track Phase I awards, automatic carryover authority from Phase I to Phase II and the Streamlined Non-competing Award Process (SNAP) apply.

e. An FSR and invention report for the final Phase I budget period will be required 90 days after Phase I ends, so the common FINAL YEAR footnote should be included on all awards to ensure notification of this requirement.

f. In addition to the standard SBIR/STTR footnotes, the Phase I Notice of Grant Award (NGA) should include the following terms and conditions of award:

"The Fast-Track Phase II application may be funded following submission of an original PHS 2590 Non-competing Grant Progress Report (plus two copies). Follow the simplified instructions under the Streamlined Noncompeting Award Process (SNAP) found at: http://grants1.nih.gov/grants/funding/2590/phs2590.pdf. for all portions except the research plan, which should include the following:

○ A Phase I Final Progress Report: Follow the application instructions in the NIH SBIR/STTR Phase II Solicitation: Section 8. Research Plan, Item c. Preliminary Studies/Phase I Final Report at http://grants1.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.pdf or http://grants.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRS

[TTR.doc](TTR.doc)

- o A section labeled Milestones (l) identifying either the milestones described in the original Phase I application as approved by the peer reviewers or the milestones modified by the peer reviewers and negotiated with the grantee; and (2) describing the progress achieved relative to the milestones.

- o A one-page abstract describing the research plan for Phase II . (See Section 6. D, "Plans" of the progress report summary). If the aims have not been modified from the original Phase II application, state this. If they have been modified, give the reviewed aims and the reason for the modifications.

- o An updated Commercialization Plan [formerly Product Development Plan] as necessary, if changes have been made from the original submission.

> Funding for the Phase II application will be contingent upon (1) assessment of the Phase I progress report and determination that the Phase I goals and milestones were achieved; (2) An update (as necessary) of the Commercialization Plan; (3) determination of the project's potential for meeting the mission of the awarding component and for commercial success; (4) review and approval of other documents necessary for continuation; and (5) availability of funds.

> The Grant Progress Report is due two months prior to the anticipated start of Phase II and should be sent to the following address:

(fill in blank)

The appropriate grants management and program staff of the awarding component will review the Phase I Grant Progress Report. If the continuation request is not approved, written notification will be sent to the applicant."

[**NOTE:** It is possible for the IC to delay a funding decision for the Phase II application due to the need for a pecified amount of time to fulfill/accomplish the established milestones. It is also possible for the IC to expedite funding for the Phase II if the milestones are completed before the originally anticipated start date.]

g. When the Phase I NGA is issued, grants management staff should notify the appropriate IC staff regarding the potential start date of the Phase II and anticipated total costs for each year.

h. The grants management specialist will create the Phase II Type 4 record in IMPAC after the Phase I award is released. Budget information may be included at this time for the Phase II.

Beginning with FY2003 Phase 1 competing grants, sample sequence of events in IMPAC and for the PMS for multiple years PhaseI/Phase II Fast-Track are:

Grant Number		Document Number
1 R44 AZ12345-01	Phase I first year	RAZ123456A
5 R44 AZ12345-02	Phase I second year	RAZ123456A
4 R44 AZ12345-03	Phase II first year	RAZ123456B
5 R44 AZ12345-04	Phase II second year	RAZ123456B

i. At the option of the IC, the Program Director should send a letter to the grantee (countersigned by the GMO) establishing and defining the process for receipt of the Phase II award. This letter should include evaluation criteria for acceptable progress, clear definition of the milestones, review issues expressed in the Summary Statement, and any other relevant expectations.

The informational letter included as Appendix 2 should be sent to the grantee organization after the Phase I award has been issued. This will provide for receipt of the above information and help ensure a smooth transition to Phase II.

j. The grants management specialist must notify the grantee of the F&A (IDC) rate negotiation requirement. For grantees that do not currently have a negotiated F&A (IDC) rate agreement with the Federal government, the IDC rate for Phase I is the proposed rate not to exceed 40% of total direct costs (no base exclusions). The Division of Financial Advisory Services (DFAS), NIH will not negotiate an IDC rate agreement for Phase I awards.

If the requested IDC rate for Phase II exceeds 25% of the total direct costs (no base exclusions), the grants management specialist must notify the grantee of the IDC rate negotiation requirement. The grantee should contact DFAS at (301) 496-2444 at the time the Phase I is awarded.

2. **Phase II:**
   a. The Phase II will be awarded as a Type 4 R44/R42. The Phase II award should normally be included under SNAP and given carryover authority.
   b. The Grant Progress Report is due to the awarding I/C two months

prior to the end of the Phase I award.

c. It is recommended that a letter be sent at least four months in advance of the Phase II start to inform the grantee organization of the process for insuring a smooth transition to Phase II. A generic version of this letter is included as Appendix 2 at the end of this document.

d. When the Grant Progress Report (PHS 2590) is received, the Grants Management Specialist will forward the information to the Program Director (PD) for review of progress and achievement of the stated milestones. It may be appropriate for an outside reviewer to be involved in this process. If the PD determines that progress has not been adequate, additional information may be requested. If the PD ultimately determines that adequate progress has not been made, the grantee must be advised of the decision in a letter written by the PD, countersigned by the GMO, along with advice of the option of submitting a competing Phase II application for the non-Fast-Track peer review.

e. After the review is complete, the PD will indicate his/her recommendation for Phase II funding by completing the appropriate IC documentation. Since both Phase I and Phase II applications received simultaneous review by Council, there should be no need for additional Council discussion before deciding to fund the Phase II.

f. A streamlined review of the Phase II should be documented by using the appropriate IC checklist. Verify that the IDC rate is the current negotiated rate. If the proposed rate does not exceed 25% of total costs (no base exclusions), the grantee is not required to have a negotiated rate.

Once these issues have been addressed satisfactorily, the award can be

processed.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](), "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Section 4000 covers NIH Grants and Awards and Section 1100-G covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Internal Controls:

The purpose of this manual issuance is to state NIH policies and the

requirements governing the acceptance and administration of SBIR/STTR Fast-Track Awards.

3. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

4. **Frequency of Review:** The frequency of review will be based on the outcome of a risk assessment that will determine how often a internal control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

5. **Method of Review:** OPERA will utilize the NIH Internal Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Internal Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

6. **Review Reports are sent to:** The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

Appendix 1 – FAQs

Q: Can both Phases be funded from the same fiscal year?

A: Yes. Since each Phase is considered a distinct competitive segment (even though reviewed together) multi-year funding is not an issue.

Q: If program staff determines that progress has not been adequate and the Fast-Track Phase II is not recommended for funding, is that decision appealable?

A: No. The decision to fund or not to fund the Fast-Track Phase II is considered a preaward action. As such, it is not appealable. The grantee has the option of submitting a non-Fast-Track Phase II application for peer review. There are established time frames for submitting a Phase II application.

Appendix 2 – Informational Letter To Phase I Awardees of SBIR/STTR Fast-Track Applications

To be sent out after the Phase I award has been issued.

Our Reference:

Dear :

As a recipient of a FastTrack SBIR/STTR grant, we would like to insure that the transition from Phase I to Phase II is completed as smoothly and expeditiously as possible. The Fast-Track mechanism provides an opportunity for your research to proceed from Phase I to Phase II without the normal hiatus that occurs when only the Phase I application is funded and Phase II depends on a formal application and review. However, in order for the Phase II (Type 4) application to be funded, progress under Phase I must be evaluated and deemed successful, based on the expectations stated in the initial application.

The purpose of this letter is to inform you of the process that has been instituted

to ensure that all Fast-Track Phase II applications receive an appropriate scientific evaluation.

Two months before the end of the Phase I budget period, or as soon as you have sufficient data to demonstrate that the stated milestones have been accomplished, you must complete a PHS 2590 application. This is the standard non-competing grant progress report continuation application, which is available at the following URL: http://grants.nih.gov/grants/funding/2590/2590.htm. In order for the Program Director to evaluate whether or not your Phase I milestones, your PHS 2590 Progress Report summary should include:

- A Phase I Final Report: Follow the application instructions in the NIH SBIR/STTR Phase II Instructions. See Section 8. Research Plan, Item c. Preliminary Studies/Phase I Final Report at http://grants1.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.pdf or http://grants.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.doc
- A section labeled Milestones: (l) Identify either the milestones described in the original Phase I application as approved by the peer reviewers or the milestones modified by the peer reviewers and negotiated with the grantee; and (2) Describe the progress achieved relative to the milestones.
- A one-page Abstract: Describe the research plan for Phase II . (See Section 6. D, "Plans" of the Progress Report summary). If the aims have not been modified from the original Phase II application, state this. If they have been modified, give the reviewed aims and the reason for the modifications.
- An updated Commercialization Plan [*formerly Product Development Plan*], as necessary, if changes have been made from the original submission.
- Any specific concerns conveyed in the summary statement from the initial review of the Phase I application; and
- Any additional documentation that the Program Director requests in order

to evaluate progress.

The application should be sent to the following address:

(fill in blank)

If you have not accomplished the milestones set out in Phase I, you may wish to delay your request to start Phase II. In such a case, you should notify the Grants Management Specialist named on the Notice of Grant Award of your intent to extend the Phase I without additional funds after you have discussed this situation with the Program Director.

Once we receive the Phase II application (PHS 2590), the Program Director will evaluate the application with respect to success in meeting the Phase I milestones. Outside opinions may be obtained as part of this process. If progress is deemed adequate, the Phase II award will be made after Grants Management has reviewed the fiscal and administrative aspects of the application. If the evaluation is unfavorable, there are two options:

(1) You may extend the Phase I project for up to 12 months additional time in order to meet the milestones. You must notify the Grants Management Specialist named on your Notice of Grant Award of the extension; however, you should not request additional funds to enable you to meet the Phase I milestones.

(2) It may be necessary to remove the application from the Fast Track process and submit a competing Phase II application through the regular SBIR/STTR process.

If you have any questions regarding this process, please contact the Program Director for scientific and technical guidance and the Grants Management Specialist (Officer) for administrative and fiscal advice. Also, it would be very beneficial if you would contact the Program Director for advice prior to preparing

the Phase II application.

Sincerely,

Program Director   Grants Management
Specialist

(Officer)

bcc:

Grants Management Program File

Last Updated: 02/21/2003

NIH POLICY MANUAL

54444 - Evaluation of Grant Progress Reports by Program Officials

Issuing Office: OEP/OER/OD 435-2769

Release Date: 10/01/01

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1. **Explanation of Material Transmitted:** This chapter contains the policy and procedures for monitoring scientific project performance on National Institutes of Health grant awards.

2. **Filing Instructions:**

Remove: None

Insert: NIH Manual Chapter 4444 dated 10/01/01

PLEASE NOTE: To sign up for email notification of future changes, please go to the [NIH Manual Chapters LISTSERV](#) Web page.

A. Purpose:

This chapter states NIH policies and procedures for monitoring extramural research progress by Program Officials/Project Officers. This evaluation complements the fiscal and administrative evaluation by Grants Management Specialists and provides a format for the evaluation of progress on non-competing NIH grants and cooperative agreements. The standard established in this policy does not preclude awarding units from developing additional or customized reporting information for specific programs or mechanisms provided all elements of the standard format are

included in the process.

B. Applicability:

This policy is applicable to all NIH non-competing progress reports. Exception: invention reporting is not required for educational awards (i.e., training grants, fellowships).

C. Background:

Grant project performance reports are required no less than annually by regulation (45 CFR 74.51, link provided below) and are necessary for Program Official/Project Officer evaluation of scientific progress. Program Officials/Project Officers review these reports to evaluate, monitor and assess scientific progress to ensure that funds are appropriately expended and that the commitment of additional funds is supported by the reasonable expectation of continued progress on the project. .

D. Policy:

Grant project performance monitoring is required on an annual basis. Evaluation of progress must be made and forwarded to grants management in sufficient time to allow a continuation award to be issued prior to the committed budget period start date. Scientific progress of the grant must be determined to be satisfactory by a Program Official/Project Officer before additional funds can be awarded for continuation of the project. Itemized below are areas that must be addressed by Program Officials/Project Officers in reviewing annual progress reports. Awarding units may establish additional requirements. Appendix 1 also provides this information and source documentation.

- Is progress satisfactory?

- Is there a change in the scope, goals, or objectives of the project?

- Is there is a change in key personnel?

- Is there evidence of scientific overlap?

- Determine if there are human subject issues or concerns.

- Determine if there are animal welfare issues or concerns.

- Determine if an invention is being reported in the progress report.

- Other issues that must be resolved before issuing an award.

E. Responsibilities:

Grants Management Officers are responsible for assuring that all grant awards: conform to statutory authority, regulations, policy directives, and administrative guidelines; are within available funds; constitute valid obligations for recording in the official accounting records; include appropriate terms and conditions of award; and, are issued prior to the committed budget period start date.

Program Officials/ Project Officers are responsible for evaluating the scientific/technical progress on all non-competing grant progress reports on an annual basis, and keeping the Grants Management Officer/Grants Management Specialist informed of concerns/changes that may impact on future funding, require close project monitoring, or special terms of award. If progress is satisfactory and reporting conditions have been met, the completed monitoring report should be signed and forwarded to the Grants Management Officer/Grants Management Specialist in sufficient time to allow a continuation award to be issued prior to the committed budget period start date.

F. References:

1. 45 CFR 74.51(d) Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments, and Indian Tribal Governments - Monitoring and Reporting Program Performance http://www4.law.cornell.edu/cfr/45p74.htm#45p74s51

2. 45 CFR 92.40(b)(2) Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments-- Monitoring and reporting program performance.http://www4.law.cornell.edu/cfr/45p92.htm#45p92s40

3. NIH Grants Administration Manual Part 4.1.04.604 Responsibilities of NIH Grants Administration Staff. http://odoerdb2.od.nih.gov/gmac/sources/nihgam_4_104_604.html

4. DHHS Grants Policy Directive Part 1.04 General HHS Responsibilities http://www.hhs.gov/grantsnet/adminis/gpd/gpd104.htm

5. DHHS Grants Policy Directive Part 3.06 Post Award Reports and Recordshttp://www.hhs.gov/grantsnet/adminis/gpd/gpd306.htm

6. PHS Application Kits http://grants.nih.gov/Grants/OER.htm

7. NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2001/part_iia_7.htm

G. Procedures:

The Grant Project Performance Monitoring Report (see Appendix 1) must be completed by the Program Official/Project Officer prior to additional funds being awarded for continuation of the project. The report should be forwarded to the Grants Management Specialist and made part of the official grant file. The name of the Program Official/Project Officer

evaluating the progress report and the date of the review must be included as part of the record.

These reports may be prepared and processed electronically. The ICO module of the IMPAC II system will be modified to reflect this policy.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Section 4000 covers NIH grants and awards and Section 1100-G covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be

retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

1. Office Responsible for Reviewing Management Controls Relative to this Chapter: Responsibility for monitoring compliance with this chapter resides with the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER). Compliance issues will be referred to the Director, Office of Extramural Programs (DOEP).

2. Frequency of Review: On-going review, no less than every five years.

3. Method of Review: OPERA will use the NIH Grants Management Compliance Model (GMCM) to maintain appropriate oversight of the use of grant progress reports. The GMCM contains a file review component to ensure that I/C grant files are properly maintained and processed with regard to monitoring progress performance. The GMCM will monitor these reports. Until this monitoring can be accomplished electronically using the ICO module of IMPAC II system, the official grant file will be documented with a copy of the report signed and dated by the Program Official/Project Officer. An award will not be released until the report has been completed and issues satisfactorily addressed.

Reports of findings and recommendations resulting from GMCM reviews or other similar types of reviews will be issued to assess compliance with the policy stated in this chapter. Common issues will be brought to the Project Officers/Program Officials Forum (POPOF) for resolution and corrective action. In addition, the DOEP will be routinely apprized of any difficulties in the implementation of this policy. Depending upon the nature and the extent of problems found, if any, the Grants Management Compliance Board or the DOEP may recommend additional review, policy

guidance and/or training of staff.

Review Reports are sent to: DDER and DOEP.

[APPENDIX 1 -]{.blue} Grant Project Performance Monitoring Report

NIH POLICY MANUAL

54502 – Notification to Unsuccessful Applicants and Inactivation
of Favorably Recommended but Unfunded Applications

Issuing Office: OER 301-496-2241

Release Date: 04/10/87

A. Purpose:

This chapter states NIH policy for notifying unsuccessful grant and cooperative agreement (CA) applicants and for administratively inactivating favorably recommended but unfunded applications. It implements for NIH those portions of PHS Grants Administration Manual, Part 118, dealing with notification to unsuccessful applicants, and supersedes NIH Manual 4502 dated January 1, 1981. This policy applies to all grant and CA applications recommended for disapproval by the appropriate advisory group, and those recommended for approval but for which funding is not available.

B. Background:

NIH policy limits the time that grant applications may be kept in a competitive status when recommended for approval but remaining unfunded. Institute or Division (BID) action is required to inactivate applications whose priority score is poorer than an annually determined level. I&I Memoranda OERT 85-6 and 86-8 authorized BIDs to reactivate and pay original applications after initial review group (IRG) review of amended applications, without approval of the Associate Director for Extramural Affairs (ADEA), NIH.

C. Definitions:

1. **Disapproved applications** – grant and CA applications for which the appropriate advisory group recommended disapproval.
2. **Deferred applications** – applications for which the review has been formally postponed to a subsequent cycle.
3. **Applications recommended for approval, but unfunded** – applications recommended for approval by the appropriate advisory group, but for which funds are not currently available.
4. **Appropriate advisory group** – scientific/technical IRG for research and training applications under $50,000 direct costs for each year, and for fellowship applications; National Advisory Council/Board required for applications over $50,000 direct costs for each year.

D. References:

1. PHS Grants Administration Manual Part 118, Ranking, Approval, and Funding of Grant Applications and Notification to Unsuccessful Applicants
2. [NIH Manual Issuance 4515](), Guidelines for Dually Assigned Grant Applications

E. Policy:

1. Each applicant shall be notified in writing within 30 days following appropriate advisory group meetings, of recommendations to disapprove or to defer an application for future review (see C.4.). BIDs will send to each applicant principal investigator or program director the summary statement(s) from advisory group reviews of their applications.
2. Applications recommended for approval, that are not awarded in the first fiscal year in which they compete for funds and are not administratively inactivated during that period, may be carried over to a second fiscal year ONLY if they are being actively considered for

funding, the second fiscal year budget offers some promise that funding may be possible, and the carryover action receives necessary concurrence. (See F.3.)

In July each year, after consultation with the Extramural Program Management Committee, the ADEA will notify the BIDs of the priority score cut-off level established for that fiscal year. As a minimum, no application with a priority score poorer than the published level shall be carried forward to the succeeding fiscal year. Exceptions may be approved for individual and specific applications, or classes of applications, identified by staff and justified as being of particular program interest.

For those applications carried over, final decisions as to whether to make awards will be made as early as possible in the second fiscal year, but only in rare cases later than March 31 of that year. (This specific time-limited provision does not apply to training or construction grants.)

3. Upon receiving an amendment to an existing application, DRG will immediately inactivate the original application via the Resume of Transactions (ROT).
4. The BID program staff may reactivate and fund the original application at any time up to the date of the initial review group meeting at which the amended application is to be reviewed.
5. To reactivate or fund any application after the IRG meeting at which an amended version of that application is reviewed, or to reactivate any application after March 31 of the second year, prior written approval must be obtained from the BID Director or designee(s).
6. When an application has been dually assigned, policy and procedures in NIH Manual 4515, Guidelines for Dually Assigned Grant Applications, take effect. If neither the primary nor secondary assignee

can make the award within the specified time, the primary assignee will notify the applicant of the administrative inactivation.

F. Implementation:

When an application has been recommended for approval but remains unfunded because sufficient funds are not currently available, the applicant will be notified that the application is being held for that reason. The notifying letter will be issued in the shortest period of time, and in all cases less than 60 days following the appropriate advisory group meeting. Care shall be taken to avoid giving applicants a false sense that a commitment is being made, thereby raising expectations unjustifiably. These letters will indicate the period of time during which each application will be held for further consideration for funding, by noting the date upon which it will be inactivated. The inactivation date will be no later than September 30 for applications with priority scores poorer than the fiscal year's determined priority score cut-off, or, as an approved exception, March 31 of the second fiscal year in which the application competes for funding. Awarding units will use one of the following procedures for notifications regarding inactivation of approved-unfunded applications:

1. For applications to be administratively inactivated immediately after IRG or Council/Board review:
    a. a letter will be sent to the applicant institution giving notice of the inactivation;
    b. a copy of the letter will be sent to the Executive Secretary of the IRG responsible for review of the application; and
    c. concurrent with the above, Form NIH 901-1, Grant/Application Change Notice, will be prepared and sent to the Systems and Data Management Section, SAB, DRG. This notifies the DRG IMPAC system that the application is no longer pending. The Change Notice will also be the basis for including the action on

the Resume of Transactions (ROT).

    d. If preferred, a copy of Form NIH 901-1 may be sent to the Executive Secretary in lieu of the letter specified in (b) above.

2. For applications to be held for consideration up to September 30:

    a. a notifying letter, indicating the specific date on which the application will be inactivated, will be sent to the applicant institution immediately following appropriate advisory group review, with a copy to the Executive Secretary of the IRG;

    b. if the date of inactivation stated in the notifying letter is prior to September 30, the awarding unit will prepare Form NIH 901-1 and send it to the SAB, DRG before the inactivation date (see F.1.(c) above.); and

    c. in September, the SAB, DRG, will provide each BID with a computer-prepared list of all applications subject to inactivation on September 30, i.e., all approved-unfunded applications with a priority score poorer than the published level for that fiscal year.

    d. Exceptions may be made for individual applications, or classes of applications, identified and justified by BID staff as being of particular program interest and meeting the conditions cited under E.2. Those exceptions should be indicated on the computer list, sent with the appropriate justification to the ADEA for concurrence, and returned to SAB before September 30. Those not so reported to SAB will be automatically inactivated in the IMPAC system on October 1.

3. For applications to be held for consideration until March 31 of the second fiscal year:

    a. a notifying letter indicating the March 31 inactivation date, or in the case of those applications originally scheduled for inactivation on September 30, an extension of the inactivation date to March 31, will be sent by the BID to the applicant institution, with a copy to the Executive Secretary of the IRG;

and

b. in March, the SAB, DRG, will provide each BID with a computer-prepared list of all applications subject to inactivation on March 31.

c. If BIDs wish to delay the inactivation of an individual application beyond March 31, they must so indicate on the computer list, send the list to the ADEA for review and concurrence, and return the list to SAB before March 31. Those not so reported to SAB will be automatically inactivated in the IMPAC system on April 1.

4. If, for some unusual circumstance, it is necessary that the awarding unit reactivate an application which has been previously inactivated (See E.5., above) approval must first be obtained from the BID Director or designee. Form NIH 901-1 will be prepared by the awarding unit, after receiving the approval to reactivate an approved-unfunded application, and sent to the Systems and Data Management Section, SAB, DRG.

G. Effective Date:

This policy is effective on date of release.

H. Additional Information:

For further information on this manual chapter, contact the Extramural Programs Management Office, OERT, Shannon Building, Room 314, telephone 496-2241.

I. Additional Copies:

For extra copies of this chapter, complete Form NIH 414-5 and send it to the Printing and Reproduction Branch, DTS, Building 31, Room B3BE07.

NIH POLICY MANUAL

54513 - Management and Procedures
of NIH National Advisory Councils and Boards
in Their Review of Extramural Activities

Issuing Office: OD/OER/OEP 301-435-2729

Release Date: 2/07/12

1. **Explanation of Material Transmitted:** This chapter contains revised and updated policy and implements those portions of the National Institutes of Health Reform Act of 2006 (http://www.nih.gov/about/reauthorization/HR6164EnrolledVersion.pdf) that apply to management and procedures of National Advisory Councils or Boards in their review of extramural activities, and rescinds OER Policy Announcements 2007-01 – "Implementation of the 2006 NIH Reform Act: Review Procedures for Grants at or Below $50,000," 2002-01 – "Advisory Council Review of NIH Awards to Individual Postdoctoral Fellows," 1999-01 – "Council Operating Procedure for Expedited En Bloc Concurrence." This revision updates policy primarily to include concept clearance for new initiatives.

2. **Filing Instructions:**

    Remove: NIH Manual Chapter 54513, dated 2/28/11.
    Insert: NIH Manual Chapter 54513, dated 2/07/12.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support, OMA on 301-496-2832, or enter this URL: http://oma.od.nih.gov/manualchapters.

- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This chapter sets forth National Institutes of Health (NIH) policies and procedures for the management and review procedures of NIH National Advisory Councils or Boards, hereinafter referred to as Councils, in their review of NIH extramural programs as well as grant and cooperative agreement applications, including concept clearance for new initiatives. This chapter does not apply to advisory committees managed by the NIH Office of the Director (OD), except with respect to their second-level review of grant and cooperative agreement applications and to concept clearance.

B. Applicability:

This policy applies to all NIH Institutes and Centers (IC) having Councils that advise, consult, and recommend on matters related to the activities of the operating components and the policies concerning such activities.

C. Background and Legislative Authority:

1. **Advisory Councils: The Public Health Service Act (PHS Act) and the National Institutes of Health Reform Act (NIH Reform Act)**

   The PHS Act, as amended, requires that the Secretary of the Department of Health and Human Services (DHHS) (or, for the National Cancer Advisory Board (NCAB), the President) "shall appoint an advisory council for each national research institute which shall ... advise, assist, consult with and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities ..." (PHS Act, Section 406 [284a] (a)(1)). [Note: unless otherwise specified, hereafter, reference to "Section" pertains to the PHS Act and the bracketed number refers to the corresponding sections of the United States Code.]

   "The Council of each national research institute ... may review applications for grants and cooperative agreements for research or training and for which Advisory Council approval is required under Section 405 [284] (b)(2), and recommend for approval applications for projects which show promise of making valuable contributions to human

knowledge ..." (Section 406 [284a] (a)(3)(A)(ii)). Funding of a grant or cooperative agreement may occur only after it has been favorably recommended by a technical and scientific peer review group (see Section 405 [284] (b)(2)(B)(i)). In addition, awards, with the exception of National Research Service Award (NRSA) fellowships, may not be made without concurrence by the Council for the national research institute involved (see Section 405 [284] (b)(2)(B)(ii) of P. L. 109-482, the NIH Reform Act of 2006, which revised 492A [289a-1] (a)(2) of the PHS Act concerning review of grant applications prior to funding).

While the PHS Act (Section 405 [284] (b)(2)(B)) did not require NIH Institutes to have Advisory Council/Board review and approval of research grants and cooperative agreements requesting $50,000 or less in direct costs, the revisions to Section 492A(a)(2) of the PHS Act made by the NIH Reform Act require Advisory Council approval for any grant or cooperative agreement that is subject to technical and scientific peer review under Section 492. Thus, under section 492 [289a] of the PHS Act, Council review and approval is required for all research grants and cooperative agreements subject to peer review, regardless of funding level. Training grants and fellowships and other non-research grant applications are not "proposals to conduct or support research," thus they are not subject to the Advisory Council/Board review and approval requirement (as described above) imposed by the NIH Reform Act of 2006. However, Kirschstein-NRSA institutional research training grants must be reviewed and approved by the appropriate Advisory Council/Board, according to Section 487 [288] (b)(2) of the PHS Act, which states: "The making of grants under subsection (a)(l)(B) for Ruth L. Kirschstein National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted."

Councils of the national research institutes are also involved in the review of intramural research programs (Section 492 [289a] (b)) and make recommendations on the acceptance of gifts (Section 406 [284a] (a)(2)); however, such activities are beyond the scope of this manual chapter.

One Council member from each national research institute serves on the NIH Council

of Councils, and there must be some overlap between the two appointments (Section [282 (l)]). The individual must be a member of the Council at the time of appointment to the Council of Councils.

The Fogarty International Center (FIC), the National Institute of Nursing Research (NINR), the National Institute on Minority Health and Health Disparities (NIMHD), the National Library of Medicine (NLM), and the National Center for Complementary and Alternative Medicine (NCCAM) are not covered by the above citations, although their Advisory Councils or Boards serve essentially the same functions. The FIC is covered under the general PHS authority: "the Secretary may delegate to such council or committee such advisory functions relating to grants–in–aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate" (Section 222 [217a] (c)). The NINR, NIMHD, NLM, and NCCAM Advisory Councils are authorized separately under Sections 464X [285q-2], 464Z-3 [285t], 466 [286a], and 485D [287c-21] respectively.

2. **The Federal Advisory Committee Act:**

   The Federal Advisory Committee Act (FACA) (http://www.gsa.gov/portal/content/100916) and the Federal Advisory Committee Management Final Rule (http://www.gsa.gov/portal/content/104034) apply to Councils and require the following:

   a. All Councils must operate according to a Charter that is officially filed with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction over the IC being advised and with the Library of Congress, among others (41 CFR 102-3.70). The NIH Office of Federal Advisory Committee Policy (OFACP) should be consulted for questions concerning charters.
   b. All meetings must be announced in the Federal Register at least 15 calendar days before they are held and the announcement must contain certain required information (41 CFR 102-3.150).
   c. Meetings may only be closed if they fall under one of the exemptions in 5 U.S.C.

552b(c). See Appendix 1 for more details.

d. A Designated Federal Official (DFO), referred to as the Executive Secretary at NIH, must be designated for every Council or committee and must be a permanent full or part-time Federal employee. A DFO or Executive Secretary must be present to convene a federal advisory committee meeting. To ensure compliance, it is highly recommended that the Executive Secretary receive formal training on the requirements of FACA. OFACP should be consulted for questions about DFOs.

e. The Executive Secretary must ensure that the minutes are prepared within 90 days after the end of the meeting, and that two reports are completed annually: their committee's portion of the Annual Comprehensive Review of Federal Advisory Committees and the Closed Meeting Report. See Appendix 1 for more details.

D. Policy:

1. **Extramural Program Review:**

Consistent with the charter of each Council, the Director of each IC may establish a system for the Council to: 1) periodically review extramural programs and 2) make recommendations about research activities. The periodicity and depth of these programmatic reviews may be established by the IC Director with advice from the Council. The purposes of this review by Council are to:

a. provide advice on the use of grant, cooperative agreement, and Research & Development contract funds in the IC's portfolios and conduct of research and related activities;

b. obtain information and provide advice on program management and administration;

c. ensure IC responsiveness to public needs;

d. encourage initiatives for the support of high quality science and conduct concept review of potential research initiatives; and

e. assist the IC in establishing objectives and priorities, in identifying resource allocation factors, and in enhancing program management and effectiveness.

2. **Application Review:**

   Councils provide the second level peer review of applications for grants and cooperative agreements. The initial peer review process is detailed in Manual Chapter 4204-204B.

3. **Intramural Program Review:**

   As noted earlier, the intramural review function of Council is beyond the scope of this manual chapter (see NIH Manual Chapter 3005).

4. **Representation on the Council of Councils:**

   One member or former member of each IC Council serves on the NIH Council of Councils. The IC Director nominates three current Council members, two scientists and one lay member, to serve on the NIH Council of Councils. One of three is selected by the NIH Director, and the final slate must be approved by the Secretary, DHHS.

5. **Concept Clearance:**

   A concept describes the basic purpose, scope, and objectives of a potential solicitation of grants and/or contracts. The concept may be developed into a variety of Funding Opportunity Announcements (FOAs) or Requests for Proposals (RFPs). Concept clearance is the process by which ICs receive public advice on the merits of the potential initiative. Approved concepts are published to inform researchers about NIH interests and potential funding opportunities. However, there is no requirement for ICs to develop an approved concept into an RFP or FOA with set-aside funds.

   Concept clearance for Research & Development contracts is described in Manual Chapter 6315-1.

   For FOAs, such as Requests for Applications and Program Announcements with set-aside funds, in which an IC intends to set aside funds to stimulate research in a well-defined scientific area in order to accomplish specific program objectives, the IC must document the clearance of the supporting concept (see NIH Manual Chapter 54110). This process must include advice from the public which may be obtained through, for

example, review by the Council. Concept clearance may also be accomplished by referring to a Congressional mandate or by workshops convened specifically to solicit public input.

E. Primary References:

1. Public Health Service Act as amended, 42 USC 241, 42 USC 284a
2. National Institutes of Health Reform Act P.L. 109-482
3. Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. 552b
4. Federal Advisory Committee Management; Final Rule, 41 CFR Parts 101-6 and 102-3
5. NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management
6. NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for NIH Special Government Employee Advisory Committee Members
7. NIH Manual Chapter 3005, Review and Evaluation of Intramural Programs
8. NIH Manual Chapter 6315-1, Initiation, Review, Evaluation, and Award of Research & Development (R&D) Contracts
9. NIH Manual Chapter 54110, Program Announcements and Requests for Applications
10. OER Policy Announcement 2011-01: Revised Policy for Appeals of NIH Initial Peer Review (http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2011_01.htm)
11. NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organizations
12. NIH Manual Chapter 4204-204B, Peer Review Process.
13. NIH Manual Chapter 54107, Review of Applications and Award of Grants Involving Human Subjects
14. NIH Manual Chapter 54515, Guidelines for Dually Assigned Grant Applications
15. NIH Manual Chapter 6380-2/54206, Responsibility for Care and Use of Animals.
16. NIH Manual Chapter 54810 – National Research Service Awards
17. OER Policy Announcement 2001-02 (REVISED): Use of Electronic Communications by NIH Federal Advisory Committees (http://nih-extramural-intranet.od.nih.gov/nih/policies/oer_announce_2001_02.htm)
18. OER Policy Announcement 2000-06: FY 2000 End of Year Procedures For Awarding Applications Involving Human Subjects (http://nih-extramural-

intranet.od.nih.gov/nih/policies/oer_announce_2000_06.htm)

19. NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, http://oma.od.nih.gov/manualchapters/management/1743/

F. Implementation and Procedures:

1. **Operating Procedures:**

   Operating procedures to be used by Councils are to be developed by the IC with the advice of Councils and in conformity with the PHS Act, the NIH Reform Act, peer review regulations and NIH policy. Such procedures are to be reviewed annually at a meeting of the Council. When these procedures are initially established or substantially changed, the IC must submit them to the Deputy Director for Extramural Research (DDER), Office of Extramural Research (OER) or designee who will review for compliance with the PHS Act, the NIH Reform Act, NIH policy and peer review regulations. Requirements and key features are summarized with suggested procedures in Appendix 1. The Council can delegate to the IC Director the authority to act upon unusual or extenuating circumstance to make exceptions to the Operating Procedures, after consultation with Council. Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures. Any actions of this exceptional nature must be appropriately documented as necessary for the official record, and should be reported to Council at its next scheduled meeting.

2. **Administrative Procedures:**
   a. Chair: With some statutory exceptions, the Chair of an Advisory Council is selected by the Secretary of DHHS from among the appointed members, except that the Secretary may select the IC Director to serve as Chair. One such statutory exception is NCAB, where the President selects the chair. The term of office of the chair is two years.
   b. Executive Secretary: The IC Director must designate a member of the staff of the IC to serve as the Executive Secretary of the Council.
   c. Meetings: The Chair and the Executive Secretary call meetings, which must take place at least three times each fiscal year. The NCAB and the National Heart, Lung, and Blood Advisory Council (NHLBAC) must meet at least four times per year. The meeting location is subject to approval by the IC Director.

d. Conflict of Interest/Waivers: NIH Manual Chapters 1805 and 1810-1 provide guidance for handling conflict of interest matters for Special Government Employee Advisory Committee Members.

e. Confidentiality: All materials relating to the review of grant and cooperative agreement applications, including initial review summary statements and staff recommendations, must be treated as confidential by Council members. Members must not discuss review proceedings with anyone outside of the Council or appropriate NIH staff and must refer to the appropriate staff any inquiries from applicants or others about pending applications. Council members, as special government employees, must abide by all laws and regulations regarding the electronic and physical security of the applications and associated materials.

f. Quorum/Voting Members: Unless otherwise established by statute or by the Council charter, a quorum is a majority of the currently appointed members of the Council. Unless otherwise established by statute or by Council charter, ex officio members, but not liaisons, shall be included in establishing a quorum. For Councils established under Section 406 [284a], ex officio members are non-voting. Thus, only those ex officio members of the Councils of the NLM, FIC, and the NINR are voting members.

g. Electronic Communication: Council members may use IC e-mail and Web-based systems such as chat rooms to gather information or conduct research, to analyze relevant issues and facts, or to draft proposed position papers for deliberation by the full Council. Chat room exchanges may not include discussions of Council business that would normally be addressed during a meeting. Thus, Council members may not use an IC chat room to deliberate in preparation for a vote or to vote on any matter, participate in chat room exchanges for the purpose of deliberating on the substantive matters upon which the Council provides advice and recommendations, or take any action that is for deliberation by the full Council at a meeting that meets the public notice and public participation requirements of FACA. It is important for IC staff and Council members using an IC web-based system or chat room to remember that relevant issues and facts gathered in the chat room must be fully discussed by the full Council in open session before advice is given to a Federal official, and that the

public must be kept informed of all issues being deliberated by the Council. Council meetings, open or closed sessions, may be held using electronic or Web-based systems, but they must be convened according to the requirements of FACA.

3. **Review of Applications:**

At a minimum, with the exception of those applications not requiring Council review as noted in Section C above, each IC must present for Council review all applications that may be considered for funding and any applications involving appeals that require Council action. The IC Director, with consultation by Council, may determine whether other applications are to be presented routinely to Council. While Council may review applications that have been streamlined by the Scientific Review Group ("not discussed"), applications that have been designated as "Not Recommended for Further Consideration" by the Scientific Review Group may not be brought to Council for review. The summary statements from applications can be presented to Council members in the Electronic Council Book, a part of the NIH electronic data system, or in an alternative NIH electronic data system. Council consideration may take either of two forms: Action on Individual Applications or En Bloc Action.

   a. Consideration of Applications Individually

      (1) Each IC, with its Council, shall determine circumstances that warrant identifying particular kinds of applications for individual discussion. Criteria could include, for example, size, support mechanism, or subject matter.

      (2) Applications involving appeal letters may be individually considered. Council responsibilities for reviewing appeals are detailed in OER Policy Announcement 2011-01.

      (3) Applications to be considered for funding by the IC must be brought to the attention of Council if they involve any of the following:

         (a) applications with procedures or conditions that may violate policies related to animal welfare (code 44 or 48) (see NIH Manual

);

(b) all applications with procedures or conditions that may violate policies related to the welfare of human subjects (code 44 or 48)(see NIH Manual Chapter 54107);

(c) all studies with concerns about the representation of gender and/or minorities and/or children (any codes ending with "U");

(d) applications from foreign institutions (see NIH Manual Chapter 54104);

(e) all applications with hazardous materials or procedures that may not propose adequate protection to research personnel and/or the environment; and

(f) all applications that may not provide for appropriate biosafety, biocontainment, and security of Select Agent(s).

Councils will also specifically review:

(a) nominations that have been identified for MERIT awards; and

(b) applications for extension of MERIT Awards.

(4) In addition to the applications identified above, the IC Director or any Council member may ask that any individual application or group of applications be discussed.

b. En Bloc Action: Applications not considered individually may be acted upon as a group. When a Council concurs with the recommendations made in initial review on a group of applications, the Council may, without any conflict of interest implications, vote en bloc concurrence with the initial review recommendations.

4. **Disagreement Between Council and Initial Review Recommendations:**

Procedures for resolving and documenting instances where applications recommended by initial review are not recommended by Council, are presented in Appendix 1.

Disagreements by Council may be based on programmatic balance, scientific and technical merit, or other considerations.

When a Council recommendation is based on scientific and technical merit, such an application may be deferred for re-review by the same or different Scientific Review Group. If after re-review the Council still disagrees with the recommendation of initial reviewers based on scientific and technical merit, the Council should note this in the record.

Applications may not be considered for funding unless recommended by both the Scientific Review Group and the Council. A Council decision not to recommend an application with a favorable initial review for reasons other than scientific and technical merit may be based on a variety of considerations, including several of those listed under F.3.a.(3) (above). Such applications need not be deferred for re-review by a Scientific Review Group, but the issues may be resolved by NIH staff as befits the situation. If issues are resolved to Council's satisfaction, such applications could be considered for funding. If an IC with a secondary assignment wishes to fund a deferred application, and the primary IC approves, the application can be transferred to the secondary assignee for funding.

5. **Notation System for Council Actions:**

A Council may not change the numerical ratings (e.g., impact/priority score, percentile, criterion scores) resulting from the initial review, nor may it change the codes associated with animal welfare, the welfare of human subjects or the representation of gender and/or minorities and/or children. However, the Council may recommend that the IC change the order of consideration of certain applications for funding. The following codes shall be used to indicate Council action in relation to the numerical rating:

a. CON (Concurrence) – Concurrence with initial review recommendation;
b. HPP (High Program Priority) – Raised in order of consideration for funding;
c. LPP (Low Program Priority) – Lowered in order of consideration for funding;
d. OTH (Other) – Council favorable recommendation of an application that did not receive a favorable initial review, or an unusual action that cannot be identified

as CON, HPP, or LPP, such as changes in recommended budget and/or duration of support. Use of this code is optional at the IC's discretion.

In addition, a Council may specifically recommend that an application receiving a favorable recommendation in initial review not be considered for support. In such a case, the following designation would be used:

e. NRC (Not Recommended by Council) – Not recommended by Council and, thus, may not be considered for funding.

6. **Concept clearance:**

The concept clearance process for FOAs is described in Manual Chapter 54110. All appropriate clearances must be obtained by the IC before an FOA with set-aside funds is transmitted for publication in the NIH Guide.

For contract solicitations (Requests for Proposals), it is the responsibility of the IC Contract Office to ensure that necessary concept clearance has been obtained in accordance with Manual Chapter 6315-1.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual Chapter 1743,"Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Section 1100-G (all items that apply).

NIH e-mail messages. NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional Oversight Committees, if requested, and are subject to Freedom of Information

Act requests. Back-up files are subject to the same requests as the original messages.

H. Internal Controls:

The purpose of this manual issuance is to provide guidance to the ICs for the management and review procedures of NIH National Advisory Councils or Boards.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:**

   Responsibility for monitoring compliance with this chapter resides with the Office of Extramural Programs (OEP)/OER.

2. **Frequency of Review:**

   On-going review, no less than every five years

3. **Method of Review:**

   OEP will verify that each IC has established Council Operating Procedures and review them for consistency with this chapter.

4. **Review Reports are sent to:**

   Reports are sent to the DDER. Reports should also be sent to the Deputy Director for Management. Reports should indicate that controls are in place and working well or indicate any internal management control issues that should be brought to the attention of the report recipient(s).

Appendices:

Appendix 1. Procedures:

1. **Announcement and Closure of Council Meetings**

   In accordance with the Federal Advisory Committee Act, all Council meetings must be announced in the Federal Register at least 15 calendar days before the date of the

meeting. Council meetings shall be open, but may be closed in accordance with provisions of the Government in the Sunshine Act (P.L. 94-409, [Section 552b(c)]) during the review of grant or cooperative agreement applications. Closed meetings are permitted when the discussion of applications is likely to disclose "trade secrets and commercial or financial information obtained from a person and privileged or confidential" or "information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy." Closing of meetings or portions of meetings for other reasons must be approved by formal determination by the NIH Branch of the HHS Office of the General Counsel (OGC).

2. **Selecting Criteria for Individual Consideration of Applications**

   Applications most often brought up for specific discussion include those in which:

   a. a policy issue has been identified;
   b. the summary of the discussion suggests that members of the review panel had divergent opinions;
   c. some aspect of the Scientific Review Group recommendation is questioned or cannot be resolved by IC staff;
   d. the recommended budget is unusually large or does not appear to be appropriate to complete the proposed work;
   e. the research objectives proposed are of particular interest or concern to the IC;
   f. the Scientific Review Group recommended that the scope and/or duration of the project be decreased.
   g. An appeal of initial peer review warrants discussion by the Council members.

3. **Administrative Decisions and Actions that Do Not Require Council Recommendations**

   The following staff actions do not require Council recommendations but may be presented to the Council for information purposes:

   a. change of principal investigator or program director on a project that will continue to receive support at the same grantee institution;
   b. change of institution by a principal investigator who will receive previously recommended support for the project continuing at the new institution;

c. supplemental support to existing research and training awards;

d. extension of project period dates without additional funds;

e. restoration of time and support that the Scientific Review Group recommended eliminating;

f. administrative actions mutually agreed upon between the IC and Council in the formal operating procedures that have been adopted;

g. applications deferred for re-review prior to the Council meeting.

4. **Council Activity Documentation**

There must be an official meeting file for each Council meeting, which contains, at a minimum, the membership list, agenda, reports, conflict of interest documentation (unless stored separately), minutes, and all handouts available during the open session of the Council meeting. All records related to Council meetings, including the official meeting file, must be maintained in accordance with NIH Policy Manual, Chapter 1743.

Minutes of Council meetings must be prepared, reviewed, and certified by the chair within 90 calendar days of the meeting. FACA Section 10(3)(c) and 41 CFR 102-3.165 specify the contents of the minutes.

Two reports about each Council are completed annually: the individual IC's portion of the Annual Comprehensive Review of Federal Advisory Committees and the Closed Meeting Report. The Annual Comprehensive Review identifies the activities and accomplishments of each advisory committee and its contents are specified by FACA. Certified meeting minutes or meeting summaries fulfill the requirements for the Closed Meeting Report.

Since Council meetings are only partially closed to the public, the reports and minutes from the open portions should not include any information that might compromise the closed sessions. Guidelines for the minutes and the annual reports are provided by the Office of Federal Advisory Committee Policy (OFACP).

5. **Council Procedures Review**

Each awarding component (IC) shall develop, with the advice of Council, operating procedures for the Council review of applications. These procedures would include, for

example, IC-specific rules concerning which applications are reviewed or given special attention by Council, or how Council subcommittees, if any, are constituted. These procedures must be reviewed once each year with Council members with the understanding that they also must be approved by the DDER, OER. The DDER will review procedures for compliance with the PHS Act, peer review regulations and NIH policy when they are first established. The IC must provide the DDER with any substantial revision of these procedures in a timely way to allow review.

6. **Expedited En Bloc Concurrence**

Each IC, with its Council, may implement a procedure to streamline the en bloc concurrence with Scientific Review Group recommendations to expedite funding actions by the IC. These procedures must be approved and included as part of the Council Operating Procedures, and will identify those applications eligible for expedited en bloc consideration and the minimum information to be provided to Council members.

A Council member or members may be selected by the Executive Secretary or Chair to provide expedited en bloc concurrence on behalf of the Council. As such, however, these individuals do not, in a legal sense, constitute a "subcommittee" of Council. The award process may be initiated as soon as expedited en bloc concurrence is obtained. At each meeting, Council will be informed of the results of expedited en bloc actions. Council standard operating procedures or by-laws should reflect this practice. Conditions for expedited en bloc concurrence might include projects within a certain range (e.g., only applications with scores in the competitive range) and could vary from Council round to Council round; or en bloc concurrence might exclude grants based on the dollar level of the award (e.g., $500,000 or the IC's dollar level that requires individual discussion) as well as specific types of grants (such as multi-site clinical trials, applications from foreign institutions, or projects with human subjects/animal welfare concerns/comments). Multiple individuals on the Council may perform this function, with each having responsibility for a specific, and possibly independent, category of applications. Specifying minimum information to be provided to the Council member(s) will be part of IC procedures agreed upon by Council, but will typically include name, institution, project title, requested dollars (or recommended dollars) if available, and percentile rank and/or impact score. All Council members may have

access to the information provided to the designated Council member(s), including the date by which the IC expects a response. Any Council member(s) may bring an application to full Council consideration without the need for justification.

7. **Documentation and Procedures Relating to Council Non-concurrence**

A written statement documenting the rationale for Council non-concurrence with any initial review recommendation shall be provided by IC staff to the appropriate Scientific Review Officer (SRO) within ten (10) working days after the Council meeting.

For all Council deferrals, the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) will serve as the focal point for subsequent actions. In addition to the written rationale (see above), IC staff will complete appropriate forms (as specified below) and forward them to DRR within 10 days following the Council meeting. When the deferral is for re-review of an application originally reviewed by CSR, the tracking chart (See Appendix 2) is required. IC staff may contact the Principal Investigator/Project Director (PI/PD) regarding a Council recommendation for re-review only after the appropriate documentation has been provided to CSR and agreement has been reached between the IC and CSR about the re-review. When deferral for re-review involves initial review conducted in an IC, or when applications are deferred for subsequent Council consideration without re-review, the Council Deferral Tracking Chart and a Change Request Form (Form NIH 901-1) must be submitted along with the written rationale. The Change Request Form should show the change in Council date and/or Scientific Review Group assignment. The CSR DRR will take appropriate action and notify appropriate staff.

Disagreements concerning re-review of a deferred application are resolved by the DDER, OER, NIH. The DDER will forward the final decision to the CSR DRR and to the IC.

When the Council action differs from the Scientific Review Group recommendation, the letter notifying the PI/PD/applicant institution of the Council's recommended action will also explain its variant action.

The official meeting files must contain documented explanations of any actions

identified as OTH. For those applications reviewed by a Scientific Review Group, a copy of the documentation shall be forwarded to the SRO's office.

Appendix 2 – Tracking chart:

COUNCIL DEFERRAL TRACKING CHART

Principal Investigator	Application Number	Original SRG	Council recommendation Type Deferral* SRG*	Br Ju

*
0-No deferrals by Council
1-Re-review by Same Study Section
2-Re-review by Different Study Section
3-Site Visit
4-Additional Expertise
5-Postponed by Council for Next Council
6-Administrative Deferral After Council

For non-CSR applications, a
Council for the next council
(901s) must accompany this
and/or date.

**
If a specific Study Section is recommended
by Council for re-review by a CSR study
section, it can be named, but the final
assignment of the application will be
at the discretion of the Division of Receipt & Referral.

***
Provide a brief justification and/or
attach a full justification (e.g., council
minutes), as appropriate.

Council Deferral Tracking C
& Referral 10 working day

NIH POLICY MANUAL

54515 - Guidelines for Dually Assigned grant Applications

Issuing Office: OER 402-0854

Release Date: 10/26/92

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1. **Explanation of Material Transmitted:** This chapter states the procedures for processing grant and cooperative agreement applications which may be assigned to two NIH Institutes or Centers.

2. **Filing Instructions:**

   Remove: NIH Manual 4515 dated 7/1/82.

   Insert: NIH Manual 4515 dated 10/26/92 (Keep this transmittal sheet as long as any pages of this chapter are in effect.).

3. **Distribution:** NIH Manual Mailing Keys F-401 and F-406

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- On-line information, enter this URL:
  http://oma.od.nih.gov/manualchapters/

- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This chapter states the procedures for processing grant and cooperative agreement applications which may be assigned to two NIH Institutes, or Centers (ICs). It supersedes Manual Chapter 4503 dated July 1, 1982.

B. Applicability:

This procedure is applicable to all NIH grants programs and, when appropriate, to cooperative agreement applications (hereafter both referred to as grant applications).

C. Background:

When the scientific areas and the research or training proposed in a grant application are relevant to the program responsibilities of two ICs, the Referral Section, Referral and Review Branch (RRB), Division of Research Grants (DRG), assigns the application to both ICs. The IC that, in the judgment of the Referral Office, has the more relevant program responsibility is designated as the primary assignee. The other IC that has an interest in the application is designated as the secondary assignee. On occasion, an application may receive a dual assignment for informational or other reasons. For example, an application referred to one IC may be an extension of a research program currently funded by another IC; the focus of a competing renewal application may be such that it now falls within the purview of an IC other than the one originally providing support.

D. References:

1. **NIH Manual Chapter 4502**, Notification to Unsuccessful Applicants and Inactivation of Favorably Recommended but Unfunded Applications

2. **NIH Manual Chapter 4513**, Review of NIH Programs and Grant and Cooperative Agreement Applications by National Advisory Councils and Boards.

E. Implementation:

1. Changes of assignment prior to council review.

When a primary assignment of an application is to be changed, the IC requesting the change must submit Change Request Form 901 to the Chief, Referral Section, RRB, DRG, signed by referral liaisons and program officials of both ICs, requesting the change in assignment. Secondary assignments can be added or deleted at the request of the secondary IC, using a Change Request Form 901, subject to approval by the Referral Section, RRB, DRG. These changes will be published in the DRG's Resume of Transactions (ROT), which is a continuing list of administrative changes on grants and pending applications, prepared and distributed by the Information Systems Branch, DRG.

2. Changes of assignment following council review.

The primary and secondary assignee ICs shall advise one another as soon as possible of specific recommendations and comments of their National Advisory Councils or National Advisory Boards, hereafter referred to as Councils, that would affect IC funding decisions on dually assigned applications. Notification of a proposed action should occur within two weeks after Council meetings. It is not necessary to inform ICs of en bloc concurrence with IRG recommendations

Applications Recommended for Further Consideration by Initial Review Groups:

a. Recommendations for Further Consideration by Both Councils

Following the Council meeting and approval of a pay plan, the primary assignee will notify the secondary assignee in writing of the funding status of dually assigned applications. If the primary assignee does not intend to make an award, the secondary assignee must be given the opportunity to do so. If the secondary assignee wishes to fund the application, the primary assignee must be notified. A Change Request Form from the designated IC Referral Liaison of the secondary assignee IC should be submitted to the Referral Branch, DRG, requesting that the application number be changed, and stating the IC's commitment to fund the application during the current round. This Change Request Form must also be signed by the releasing (primary) Referral Liaison.

For Type 1 applications the primary assignee may hold the application in pending status only through the earliest start date following the next Council round, or September 1, whichever occurs first. If the primary assignee does not plan to fund the application by that time, the secondary assignee shall be notified of the opportunity to fund. Such notification must precede initiation of steps to inactivate the application.

If the primary IC wishes to delay the transfer of a Type 2 application to the secondary, pending a final funding decision, the primary IC must provide interim support to avoid a gap in funding.

b. Recommendation for Deferral by Council of Primary Assignee

Immediately following a deferral recommendation by the Council of the primary assignee, that IC shall notify the secondary assignee of its action and reasons for the deferral recommendation. If the primary and secondary assignees agree that the secondary assignee will fund the application, a jointly signed Change Request Form 901 should be sent to

the Referral Section, DRG. The secondary assignee shall then communicate its funding plans to the applicant. If, however, both the primary and secondary assignees decide to await further review by the Council of the primary assignee, the primary assignee shall notify the applicant that final action is deferred.

NIH POLICY MANUAL

54519 - Scientific, Budgetary, & Commitment Overlap

Issuing Office: OER/OPERA/GPO 435-0949

Release Date: 02/15/00

1. **Explanation of Material Transmitted:** This chapter contains the policy and procedures for identification and resolution of scientific, budgetary, and commitment overlap on National Institutes of Health grant and cooperative agreement applications and awards.

2. **Filing Instructions:**

   Remove: None
   Insert: NIH Manual Chapter 4519 dated 02/15/00

PLEASE NOTE: To sign up for email notification of future changes, please go to the [NIH Manual Chapters LISTSERV](#) Web page.

A. Purpose:

This chapter outlines the responsibilities and operating procedures for review, program, and grants management staff in dealing with actual or potential scientific, budgetary, and/or commitment overlap on NIH grant applications and awards. This chapter is applicable to all NIH grant and cooperative agreement (hereinafter referred to as grant) applications and awards.

B. Background:

Identification and resolution of overlap by NIH staff is a significant responsibility. Proper resolution of specific overlap cases inspires confidence among peer reviewers and grant applicants that the grant system is fair and equitable and that funds are appropriately awarded to the research community and judiciously administered by NIH.

Overlap of support (scientific, budgetary, and/or commitment of an individual's effort that exceeds 100 percent) is not permitted. Applicants for NIH grants are required to complete the Application for a Public Health Service (PHS) Grant (PHS 398) or the Application for Continuation of a PHS Grant (PHS 2590). These application kits provide some information on this subject and includes an "Other Support" page, which requires applicants to identify all financial resources (Federal or non-Federal) that are available to the principal investigator (PI) or program director (PD) and other key personnel, in direct support of their research endeavors.

The members of a scientific review group (SRG), the scientific review administrator (SRA), the program administrator, and/or the grants management specialist may identify overlap in the review of the Other Support page. Further, the identification of overlap may result from the personal knowledge of any of the participants named above regarding activities not reported on the Other Support page.

Questions of overlap should be resolved only in post-Council/pre-award negotiation through the combined efforts of program and grants management staff. In addition, questions of overlap should be resolved with appropriate interactions with applicant organizational officials, including the PI. A SRG critique and budget recommendation should not be based on overlap or the perception of overlap. Overlap, or potential overlap, is to be addressed only by an Administrative Note in the Summary

Statement.

C. References:

1. Code of Federal Regulations, Title 42, Part 52, Grants for Research Projects

2. <u>NIH Grants Policy Statement</u>, NIH Publication No. 99-8 October 1998 available at http://odoerdb2.od.nih.gov/oer/policies/policies.htm#documents

3. PHS Grants Administration Manual, Part 104, "Required Documentation under PHS Grant Programs"

4. PHS Grants Administration Manual, Part 105, "Monitoring the Performance of Discretionary Grants"

5. Application for a Public Health Service Grant (PHS 398) and Application for Continuation of a Public Health Service Grant (PHS 2590)

6. NIH Manual 1743, "Keeping and Destroying Records"

7. NIH Manual 4205, "Role of the Principal Investigator on Research Projects Supported by NIH"

8. NIH Manual 4512, "Summary Statements"

9. NIH Manual 4514, "Role of Staff at Peer Review Advisory Committee Meetings and Exchange of Information Among Review, Program, and Grants Management Staff"

10. NIH Manual 4518, " Peer Review Appeals "

11. NIH Manual 4811, "Notification and Treatment of Released Funds Resulting from Issuance of a Research or Academic Career Award"

12. NIH Manual 5808, "Establishment and Documentation of Files and Other Records, Including Monitoring Actions, for NIH Grant Programs"

13. Handbook for Scientific Review Administrators, prepared by the Center for Scientific Review, NIH.

D. Definitions

1. **Appointment** - An assignment at the applicant organization that formalizes an official relationship between the applicant organization and an individual. Such a relationship might not necessarily represent an "employment" relationship (e.g., it may not necessarily involve salary or other remuneration). In all cases, however, the PI's official organizational relationship must provide sufficient opportunity and resources for the PI to carry out his/her responsibilities for the overall scientific and technical direction of the project. (See NIH Manual Chapter 4205.)

2. **Key Personnel** - Individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salary is requested or received from the project.

3. **Other Support** - All financial resources available in direct support of an individual's research endeavors. These funds may be Federal or non-Federal (including commercial or institutional monies). Federal funds may include, but are not limited to research grants, cooperative agreements, or contracts. Training awards, prizes, income from royalties[1] or gifts are not considered financial resources for the purpose of this issuance.

4. **Overlap** - There are three distinct types of overlap.

   a. **Scientific overlap** occurs when substantially the same research is proposed in more than one application; or is submitted to two or more different funding sources for review and funding

consideration; or a specific research objective and the experimental design for accomplishing that objective are the same or closely related in two or more pending applications or awards, regardless of the funding source.

b. **Budgetary overlap** occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already funded or provided by another source.

c. **Commitment overlap** occurs when any project-supported personnel (including support staff and key personnel) has time commitments (percent effort) exceeding 100 percent, regardless of how the effort/salary is being supported or funded.

5. **Principal Investigator (PI)/Program Director (PD)** – An individual designated by the recipient to direct the project or program being supported by the grant. This individual is responsible and accountable to the recipient organization officials for the proper conduct of the project or program.

6. **Total Effort** - For the purposes of this issuance, total professional effort is considered to be 100 percent of an individual's obligation whether one or more organizations are involved. This applies to all personnel on a project, that is, key personnel as well as support staff.

An individual with only a single full-time appointment at one institution would be considered to have a commitment to the applicant organization of 100 percent of his/her total professional effort. * [2] A person with a half-time appointment with one organization and no other concurrent appointments would be considered to have 100 percent of his/her total professional effort devoted to that organization, even though it is just a 50 percent commitment.

If an individual has concurrent **independent** commitments or appointments with more than one organization, his/her commitment to the **applicant** organization would be less than 100 percent, with all commitments totaling 100 percent. An example may include a PI/PD that has an affiliation and appointment with a university and a small company. Another example may include commitments to a university, a hospital, and a non-profit or for-profit organization. In some cases, there may be an affiliation between the university and hospital, or there may be no affiliation. In each case, the terms of employment must be defined.

An appointment may be devoted exclusively to or divided among teaching; organized research (i.e., research activities at an organization that are separately budgeted and accounted for); clinical responsibilities; indirect activities, such as research administration or departmental administration; and other organizational duties. The concept of total effort includes those ancillary activities such as training and attendance at professional seminars that enhance the ability of the individual to fulfill his/her obligations to the organization. Where there is concern about potential overlap of commitment by an individual, information may be requested as to the distribution of the total effort commitment between research and non-research activities. It does not include activities that are unrelated to the fulfillment of the employee's obligation to the organization(s) (e.g., private consulting, private practice).

a. Maximum Effort - An individual's maximum commitment of effort to a combination of grants and all other commitments (at the applicant organization or a combination of organizations) is 100 percent. The ability to devote 100 percent effort to research is limited by the extent of other required institutional responsibilities such as teaching, administrative duties, and clinical activities. For instance, it would be unusual for an investigator working at an academic or clinical organization to be able to

devote 100 percent effort to research, given the concomitant obligations of such a position.

b. **Minimum Effort** - The principal investigator is the guiding force behind the hypothesis, development, and execution of the funded research activity, and is responsible for the supervision of scientific and support staff. A minimum level of effort may be recommended by the SRG, determined by the I/C, or stated in specific program guidelines. If a minimum level of effort is required, it should be specifically stated as a term of award.

E. Policy:

Overlap of support (scientific or budgetary) or over commitment of an individual's effort is unallowable. Management of overlap is a critical responsibility of NIH staff as it relates to their role as stewards of public funds. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project and that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort.

F. Procedures:

The following procedures are organized chronologically, beginning with initial review of the application and continuing through the post-award stage.

1. **Application Review**:

It is **not** the responsibility of the SRG to resolve overlap issues via adjustments to the budget, duration of support, or in the priority score itself. Thus, it is the responsibility of SRAs to properly advise SRG members of their role and responsibility in identifying actual or potential

overlap. SRAs must advise SRGs that resolution of overlap is an administrative responsibility for program and grants management staff and that any concerns regarding overlap must be confined to Administrative Notes in the Summary Statement.

a. Prior to the SRG meeting, the SRA should review the "Other Support" information in the grant application. If the information does not adhere to the competing grant application guidelines, or if it suggests or identifies potential overlap, the SRA should contact the PI in advance of the review meeting to request clarification.

b. In the case of large multi-project applications and/or other complex reviews, program staff, grants management staff, and review staff may confer prior to the SRG meeting. Therefore, in addition to other administrative and budgetary matters, overlap issues should be identified and, whenever possible, resolved prior to the SRG meeting. If overlap with another application(s) is identified, staff may query the extramural information system, Information for Management, Planning, Analysis, and Coordination (IMPAC), to obtain the funding status of other active or pending NIH and certain PHS applications. When further clarification is necessary, additional information should be obtained by the SRA from the PI or staff of the other Institute/Center (I/C) or funding agency prior to the review meeting.

c. If an issue of overlap was not raised specifically by the SRG members but is identified by the SRA, she/he may still include an Administrative Note regarding the overlap in order to bring it to the attention of program and grants management staff.

d. In the modular grant format, Other Support information is provided only on a Just-In-Time basis. The paragraphs, as referenced above, would not

apply.

2. **Pre-award Stage (prior to competitive award)**:

It is the responsibility of program and grants management staff to routinely review, for issues of overlap, those grant applications that fall within the funding range. As part of this process, scientific aims and the budget are reviewed and total committed effort for each investigator is tallied. If potential overlap is identified in scientific aims, specific budgetary items, or total committed effort, it will be necessary to review overlap further as described below. Depending upon the outcome of the additional review for overlap, adjustments to the research plan, budget, or commitment of personnel may be necessary. In some unusual instances, the award may be delayed or not issued.

a. Scientific Overlap (see definition in Section D4a.above: If the research plan in the pending application is completely duplicative of either other pending applications or an active award, the PI must negotiate with NIH staff concerning which grant will be funded. If there is partial duplication, it will be necessary to modify the pending application, other applications, or the active award prior to NIH's funding the pending application. If the withdrawal/termination is not effected prior to issuing the pending award, a special term on the award would be appropriate. Depending upon the amount of scientific overlap, staff might choose not to fund the pending application.

If scientific overlap is associated with budgetary overlap, budgetary negotiations by grants management staff may be in order (see below). The PI must be given the opportunity to discuss the issues with staff and participate in the discussion regarding how to resolve the scientific overlap, although the final decision rests with NIH staff. Staff will ensure that eliminating a specific research objective does not compromise the

scientific merit of the pending proposal. If so, staff should consider not funding the application or request that it be re-reviewed. It may be necessary for the PI/PD to submit revised aims documenting the new approved scope of the project.

b. **Budgetary overlap** (see definition in Section D4b. above): The deletion of budgetary overlap may be accomplished by grants management staff, in collaboration with program staff (and other funding components or agencies as necessary) through discussions with the PI/PD and/or with the authorized business official of the applicant organization. Typically the pending grant will be modified when budgetary overlap occurs with a funded award.

c. **Commitment Overlap** (see definition in Section D4c. above): Commitment overlap may be resolved by decreasing committed effort on one or more projects/activities in order to reduce the total to the maximum of 100 percent. A decision to decrease effort of the PI significantly on a funded research project (a 25 percent or more reduction of funded effort) may constitute a change of scope and thus would require prior approval from the awarding component or agency. In some cases, reduced effort on a project(s) could compromise the proposed or funded research. (For example, a decrease from 40 percent to 30 percent effort is a change of 25 percent, even though it is only a reduction of 10 percentage points.)

When negotiating reductions in committed effort, it is important to consider institutional commitments, if any, and the possibility that other minimum levels of effort may apply to specific NIH or I/C programs or mechanisms.

Grants management staff will discuss the issue with the PI/PD and negotiate where the reduction will occur. This negotiation will be conducted following consultation with program staff from the I/C and other affected awarding components. Adjustments to effort must consider the

level of effort necessary for the conduct of the research and the level of effort devoted to non-research commitments, e.g., teaching, clinical, administrative. This is always true for PI/PD and true only for individuals identified on the award notice. If approved/funded effort of other key personnel is critical for the project, there should be a special term of award, as follows: "Significant change in effort requires the approval of the awarding component." Furthermore, when effort is reduced to adjust for commitment of overlap, the award notice should be footnoted to document the approved level of effort for the PI/PD and any key personnel. Awards may be revised and funds reduced or restricted depending upon resolution of overlap issues.

d. **Requesting Other Support Information**: As part of the usual review of an application, I/C staff may request updated Other Support information (active and/or pending) at the time of award. Updated information may be requested if there appears to be a substantial amount of pending support, or a significant amount of time has lapsed since the application was submitted, or if potential overlap has been identified during review. The purpose of requesting an update to Other Support is to identify and eliminate overlap and to ensure that sufficient and appropriate levels of effort are available to commit to the pending project. The I/C staff should contact the applicant's Office of Sponsored Research, or a similar business office, to obtain updated information on active and pending support. This information should be provided in a similar format as shown in the competing application kit.

e. **Resolution of Overlap**

(1) When overlap is identified and there is a question regarding the currency or accuracy of other support information, including non-research organizational commitments, grants management staff may request updated information concerning other support from the business official of

the applicant organization. It may be necessary for the applicant organization to provide information or a detailed description regarding other responsibilities or commitments and projects, or provide copies of other applications or awards.

(2) Coordination of overlap between NIH I/Cs and/or other agencies or funding components is an important aspect of resolving overlap. When resolving any question of overlap, program and grants management staff should coordinate their efforts and work as a team in collecting information and arriving at a decision. Based on additional information received from the PI/PD, program and grants management staff will determine the appropriate action and decide whether budgetary adjustments are needed. In order to make these determinations, staff must consult, as necessary, with other components within NIH, other Government agencies, or private organizations to resolve questions of overlap.

(3)When adjusting for overlap, the customary practice is to modify the pending application, rather than adjust the funded grant(s). However, it may be necessary to reduce or modify a funded grant. For example, the PI/PD may wish to modify one or more other active grants in order to comply with effort requirements associated with the to-be-awarded grant. In such instances the other affected NIH awarding component(s) must be notified and provide any necessary approvals in writing. Significant changes in budget or effort require the approval of the awarding component(s) or agency(ies). Awards may be revised and funds reduced or restricted depending upon resolution of the overlap issues. As always, the official grant file must be documented.

(4) Any budgetary or other changes due to resolution of overlap will be reflected on the Notice of Grant Award and/or in the Terms and Conditions of Award.

(5) In some cases (e.g., where significant adjustments are involved), the business or organizational official should be requested to submit a letter, countersigned by the PI/PD, for the official grant file acknowledging the terms of the overlap resolution. If more than one NIH I/C or funding agency is involved, the grantee should be directed to submit this letter to all involved parties. It may also be necessary to submit a revised budget.

(6) According to NIH policy (see NIH Manual Chapter 4811), funds budgeted in an NIH-supported research grant for an individual's salary, applicable fringe benefits, and associated Facilities & Administrative (F&A) costs, but freed as a result of funding a research or academic career development award for that individual, may not be used for any other purpose. An exception exists when the career award recipient no longer participates in the career award grant-supported activity and another individual replaces him/her and requires comparable remuneration. This action requires prior written approval of the awarding component.

3. **Post-award Stage (changes during noncompetitive segment)**:

The PI is required to report any substantial changes in other support or other overlap issues in the non-competing application. If overlap is identified at the time of the submission and review of the noncompeting continuation application, whether due to changes in the Other Support or from another source, the same procedures as detailed above will be followed.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Item 4000 covers NIH grants and awards and item 1100-G

covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.   E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

H. Accountability and Management Controls:

The purpose of this manual issuance is to state the basic requirements for addressing scientific, budgetary, and commitment overlap associated with assistance awards from the NIH. Responsibility for accountability and management controls for this chapter reside with the Division of Grants Policy (DGP), Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER). The frequency of review

will occur on an as needed basis or on an ad hoc basis. The Method of Review will be Other Review.

DGP, working with the NIH Grants Management Advisory Committee (GMAC), is developing a NIH internal grants management compliance model (GMCM). Part of the GMCM will contain a file review component to ensure that I/C grant files are properly maintained and processed with regard to scientific, budgetary, and commitment overlap issues. Reports of findings and recommendations resulting from GMCM reviews or other similar types of reviews will be issued to I/Cs for appropriate action. Common issues will be brought to the GMAC for resolution and corrective action. Depending upon the nature and the extent of problems found if any, the Director OPERA may recommend additional policy guidance or training for grants management staff.

Review Reports are sent to: DDER and DDM

Footnotes:

[1] Potential income to be derived from specific project would be included in that project's section on program income.

[2] There are two exceptions to this, explained fully in NIH Manual Chapter 4205 Section F.2.e.: if an investigator has a Department of Veterans Affair (VA) appointment jointly with a full-time university appointment, the two obligations combined constitute total professional effort. If an individual has appointments with more than one organization, and the appointments are dependent upon each other (i.e., the two organizations are mutually responsible for the individual's total professional effort), the joint appointment is considered to represent the individual's total professional effort.

NIH POLICY MANUAL

54705 – Scientific Review and Evaluation Award Award and Management

Issuing Office: OER/OPERA 301-435-0949

Release Date: 06/01/03

1. **Explanation of Material Transmitted:** This manual chapter updates the policy and procedures used by Institutes and Centers that engage in scientific peer review of grant and cooperative agreement applications, contract proposals and/or applications for the Loan Repayment Program under the peer review system.

2. **Filing Instructions:**

   Remove: NIH Manual 4705 dated 11/25/83 in its entirety.
   Insert: NIH Manual 54705 dated 06/01/03.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office above

- NIH Manual System, contact the Division of Management Support (DMS), OMA, OM, on 301-496-4606.

- on-line information on the NIH Manual System and on-line chapter text, use: INTERNET http://oma.od.nih.gov/manualchapters/

- Notification of changes to NIH Manual Chapters and Delegations of Authority through email, go to http://list.nih.gov/archives/nih-manual-chapters.html

A. Purpose:

The purpose of this chapter is to set forth the policy and procedures governing the use of Scientific Review and Evaluation Awards (SREAs).

B. Applicability:

This policy is applicable to all National Institutes of Health (NIH) Institutes and Centers (ICs) that engage in scientific peer review of grant and cooperative agreement applications, contract proposals and/or applications for the Loan Repayment program under the peer review system.

The policies and procedures outlined in this Chapter serve as broad guidelines for SREA operations, and each IC is authorized to adapt these policies as warranted by their local requirements. For instance, the increased use of technology, the use of SREA service centers, and other factors may make certain specific procedures irrelevant. For these reasons, IC modifications to the tenets of this Chapter are allowable on the condition that they do not violate or compromise appropriations law, NIH internal control policy, or other requirements.

C. References:

1. Code of Federal Regulations, Title 42, Part 52h – "Scientific Peer Review of Research Grant Applications and Research and Development Contract Project"
2. NIH Manual Chapter 1500-12 "Travel for Consultants, Experts, and Private Citizens" available at:
   http://oma.od.nih.gov/manualchapters/management/1500/
3. NIH Manual Chapter 1500 "Travel Policies and Procedures" available at:
   http://oma.od.nih.gov/manualchapters/management/1500/
4. NIH Manual Chapter 5807 – "Submission and Receipt of Financial Status Reports" available at: http://oma.od.nih.gov/manualchapters/grants/5807/

D. Definitions:

1. **Committee meeting** – any gathering of advisory committee members (whether in person or through electronic means) held with the approval of an agency for the purpose of deliberating on the substantive matters upon which the advisory committee provides advice or recommendations.

2. **Consultant** – An individual who is a non-Federal employee who has been appointed to an initial/integrated review group, invited to participate on a special emphasis panel, or serves as a temporary member.

3. **Federal Government Employee** – An individual whose term of federal employment is to serve 131 working days or more during any period of 365 consecutive days.

4. **Initial Review/Integrated Group (IRG)** – A group composed of primarily non-Federal scientific experts that conduct the initial scientific and technical merit review of grant and cooperative agreement applications, contract proposals and/or applications for the Loan Repayment program.

5. **Public/Consumer Advocate** – An individual chosen to serve on an Initial/Integrated Review Group or Special Emphasis Panel (SEP) as a public member. This person is allowed to serve based on their experience and knowledge of a disease, health status, or public health problem. For IRG committees, this reviewer is invited initially to attend meetings as a temporary member. Public members may subsequently be invited to become regular members of the review group for a term of one year. Each one year term would be a term of "availability" to participate in review meetings, with actual service at each meeting based on the need for their experience/expertise. For SEP meetings this individual will serve as a regular SEP member and will be coded in CM IMPAC II as "public".

6. **Scientific Review Administrator (SRA)** – An NIH Health Scientist Administrator who is responsible for arranging, conducting, and managing the initial review process for applications and proposals.

7. **SREA** – A Scientific Review and Evaluation Award (Cooperative Agreement –

U09) in support of the activities of peer review groups.

8. **SREA Officer (hereafter referred to as Officer)** – A senior staff member of the awarding IC who is designated to administer SREAs. This individual is usually the Chief Grants Management Officer, an Administrative Officer, Committee Management Officer or Director of Extramural Program Activities or his/her designated official. The individual's affiliation must be organizationally separate from immediate peer review responsibilities.

9. **SREA PI (hereafter referred to as PI)** – The individual member of the IRG named as the Principal Investigator, to whom the SREA is issued, and who is responsible for its administration, on behalf of the IRG or SEP.

10. **Scientific Review Groups (SRGs)** – The generic, functional name for any group engaged in scientific and technical peer review. SRGs may be individually chartered or part of a larger chartered group. They are commonly called study sections in the Center for Scientific Review (CSR) and review committees in the ICs. Special Emphasis Panels are also considered SRGs.

11. **Special Government Employees (SGEs)** – Members serving on National Advisory Councils, Boards of Scientific Counselors, and Program Advisory Committees are appointed by personnel action and are Special Government Employees. SGEs are appointed or employed to perform temporary duties on an intermittent basis and less than 130 days in a calendar year, with or without compensation. When paid for their services, SGEs are paid from NIH operating funds. Members of SRGs are not Special Government Employees.

12. **Special Emphasis Panel (SEP)** – A chartered committee whose membership is fluid, with individuals designated to serve for individual meetings rather than for fixed terms of service.

13. **Temporary Member** – When NIH staff determines there is need for additional expertise on Scientific Review Groups, they may invite appropriate experts to serve as special reviewers. NIH Extramural Policy Announcement 1996-03

(http://odoerdb2.od.nih.gov/oer/policies/oer_announce_1996_03.htm) provides for any "fully participating reviewer" to vote and assign a score, whether a

regular member of a chartered group or not. For this purpose, a "fully participating reviewer" is one who is formally assigned as a reviewer or discussant; or who is present, has reviewed and evaluated the application, and has participated in the deliberation on its scientific and technical merit at the review meeting. These special reviewers are designated as "temporary members" for the meeting in which they participate and have the rights and obligations of regular members during that meeting; however, they do not contribute to a quorum.

E. Policy:

Scientific Review and Evaluation Awards (SREA) support the activities of Initial/Integrated Review Groups and Special Emphasis Panels through an assistance mechanism. Because NIH staff are substantially involved in monitoring the expenditure of funds, SREAs are awarded as cooperative agreements (Activity Code U09). A SREA must adhere to the following guidelines:

1. There is usually one SREA for each chartered IRG. In those cases where a chartered committee has two or more sections, e.g., Program Project Review Committees A and B, or so-called flexible study sections, a single SREA should be used. Any exception to this general rule requires justification on the basis of scientific program organization, increased efficiency, and cost effectiveness. Any exception must be approved by the Deputy Director for Extramural Research (DDER), NIH.

   For those ICs that do not have an Initial/Integrated Review Group and use the SEP mechanism, the NIH senior official managing the SEP will designate an individual to serve as PI and implement appropriate internal controls.

   Consultants are reimbursed for expenditures by check. Checks are issued by:

   a. the IC or the Center for Scientific Review (CSR) Service Center, NIH. They write, sign and issue checks with the PI's name, on his/her behalf;

or

    b. the PI of the SREA grant can write, sign and issue checks.

2. Reimbursement of travel, per diem, and payment of consultant fees and other expenses for non-government members of initial/integrated review groups, special emphasis panels, and temporary members are allowed for:

    a. attendance at IRG meetings;

    b. attendance of both on-site and reverse-site visits where evaluations are made of applications or proposals;

    c. telephone, mail and electronic reviews, e.g., telephone conference calls and web based reviews;

    d. mail reviews at the discretion of each IC

3. Payment of other costs directly related to activities within the responsibilities of the IRG:

These activities include attendance at IRG-initiated workshops, seminars, or similar meetings that survey the "state of the art" in a particular scientific field, and/or identify where scientific support should be expanded, curtailed, or redirected. If the costs of such a meeting are to be from SREA funds, prior approval must be obtained from the SREA Officer (or other senior official designated by the IC Director) in order for the IRG members to participate. The purpose of these meetings should be closely associated with the IRG's responsibilities and should benefit the Government.

4. SREA funds may **not** be used for:

    a. reimbursement of Federal Government employees;

    b. support (directly or indirectly) of IC intramural, collaborative, or extramural activities that are the immediate operational responsibilities of an awarding unit;

    c. program planning activities (see Section K.2); and

    d. costs obligated or incurred prior to the beginning date of the SREA.

5. The PI may not transfer the responsibilities for administering the award funds

to any other individual or organization without prior written approval of the
Officer in the awarding IC.

6. Each IC identifies its own SREA functions and assigns responsibility for those
functions to ensure adequate responsibility and independence from immediate
review responsibilities and to ensure adequate internal controls.

F. Responsibilities:

1. **Scientific Review Administrator (SRA)**: The SRA for each IRG or SEP shall:
    a. designate, in conjunction with a senior official or other assigned official,
       the Principal Investigator (PI);
    b. notify the Officer of any change in member or PI status;
    c. ensure that non-Federal members and consultants in physical
       attendance at meetings are provided a copy of Form NIH 1715-2 "Claim
       for Reimbursement of Travel Cost, Per Diem, and Consultant Fee" to
       claim reimbursement of approved costs, and are instructed to return the
       completed form to the SREA office or collect appropriate information
       needed for reimbursement for consultants participating only by mail or
       telephone; and
    d. provide an attendance record or roster of IRG SEP meetings, project
       site visits, or other IRG-related events to the SREA office or appropriate
       office.

2. **Officer**: Each IC selects a senior staff member who is responsible for the
SREA mechanism. The Officer may designate the staff that performs the
operational aspects of the award; however, the functions of the Officer are to:
    a. determine if the designated PI is a bonafide member of the scientific
       review group that the SREA is supporting;
    b. determine that the award of a SREA for new or continuing activities is
       appropriate and that the proposed level of funding is adequate but not
       excessive;
    c. establish a SREA checking account on behalf of the PI (see Section

I.3);

    d. review and approve any proposed use of the award funds;

    e. approve travel advances (see Section J.3);

    f. reconcile the award account monthly;

    g. ensure submission of the annual and final Financial Status Reports (FSR) on behalf of the PI ([NIH Manual Chapter 55807](#));

    h. close out awards as appropriate;

    i. ensure timely issuance of a Notice of Grant Award should the PI change; and

    j. maintain records in accordance with [NIH Manual Chapter 1743](#) – "Keeping and Destroying Records".

3. **Principal Investigator**: When check writing is handled externally, the PI shall:

    a. issue checks for travel advances and payments;

    b. reconcile the SREA bank account with the Officer on a monthly basis;

    c. remit to the Federal Government interest payment received as they are credited to the account (see Section I.3); any interest on SREA checking accounts in the NIH Federal Credit Union is automatically remitted to OFM;

    d. maintain necessary records and other supporting documents on a monthly basis (as required by the Officer); and

    e. return all remaining SREA documents to the Officer upon termination of the award.

G. Implementation:

1. **Appointment of SREA's Principal Investigator (PI)**: The SRA selects the PI, and the Officer confirms the PI's eligibility (see Section F.2a and E.1). Once the selection is made, the grants management office or other appropriate office is notified in writing of the PI's name, institution, social security number, address, telephone number, length of appointment, beginning date, AND approximate amount of the initial award.

2. **Application**: The following documents must be sent to the PI:

    a. a letter of appointment (Appendix 1);

    b. a blank grant application face page, Form PHS-398 (Appendix 2) to be signed by the PI and returned to the Officer who forwards a copy to grants management for processing. The PHS-398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html;

    c. NIH Federal Credit Union Member Application & Agreement (Appendix 3) to be signed by the PI and returned to the Officer who will open the account;

    d. an Image Digitizing Form (Appendix 4), to be signed by the PI and returned to the Officer for inclusion in the checkwriting system; and

    e. Appendix 5 - Policies & Requirements document.

H. Award Process:

1. **Award Mechanism:** The appropriate mechanism for the SREA is a cooperative agreement (activity code U09). (See Appendix 6 for sample notice.)

2. **Terms and Conditions:** If an award is made to a PI who personally signs the checks, in addition to the standard terms of acceptance, the Notice of Grant Award must include the following statement:

   "The awardee must comply with the NIH's Statement of Policies and Requirements Governing the Acceptance and Administration of Scientific Review and Evaluation Awards, as attached."

3. **Staff Contacts:** The award indicates the Officer's (or designee) name and address as the contact point for the PI.

4. **Project Period:** The project period of the SREA usually coincides with the term of appointment of the PI and may be for a period of up to four years.

5. **Obligation of Funds:** The estimate of funds required for an initial 12-month budget period is obligated at the time of the initial award to the central

accounting system. If the original obligation nears depletion, additional support is obligated as either a revised award within the same fiscal year, or as a supplement (Type 3) to the budget period if beyond the original fiscal year. Funds are obligated for successive budget periods (12-month increment) as non-competing continuation awards (Type 5).

6. **New Principal Investigators:** Awards to new PIs on continuing SREAs are accomplished as change ob f grantee institution actions (Type 7). The SREA Type 7 will continue to carry the same grant number as the original award and will serve as a consistent identifier for the IRG. The budget year will change to the next consecutive year, rather than revert to an -01 designation.

The Type 7 may be issued at the time of transfer based on an actual unobligated balance. If there are outstanding vouchers that will be charged to the current budget period, the Type 7 may be issued based on either an estimated balance, or that portion of the funds obligated by the Notice of Grant Award but not advanced to the checking account. The PI is instructed to remit a check for any undisbursed balance in the checking account, which will be reported as an unobligated balance on the FSR and made available under the new SREA award. The check is made payable to "**DHHS/National Institutes of Health**" and sent to the Government Accounting Branch, Office of Financial Management, 31 Center Drive, Room B1B05, MSC-2050, Bethesda, MD 20892-2050. A revised Type 7 award may be required based on the Financial Status Report.

I. Provision of Funds:

1. **Funds Control:** The Officer makes periodic advances of funds to the NIH Federal Credit Union (NIHFCU) on behalf of the PI to cover estimated expenses for a one month period. The Officer, in consultation with review staff, estimates cash requirements to cover anticipated needs for the next month. Estimates are made under good practices for

cash flow management, are realistic, and not excessive. The amount in the SREA bank account should always be kept at a level that enables the PI to make prompt disbursements without having excessive cash on hand.

2. **Cash Requests:** For each required advance of funds (see Appendix 7, Cash Request Memo), the Officer prepares a memorandum to the Government Accounting Branch at the address designated in Section H.6.

3. **Deposit:** Payment may be made to an account established by the PI in a financial institution near the PI's place of employment.

   or

   Funds awarded and advanced to the PI are deposited in an interest bearing account in the NIHFCU by direct deposit from OFM. The IC may expect the deposit to occur within two working days of the receipt of the cash request from OFM.

4. **Provision of Checks:** By agreement with the NIH, the NIHFCU provides a regular supply of checks, charged to the grant, bearing the name of the committee and the address. These checks have carbon copies that remain in the checkbook.
   a. The Government Accounting Branch, OFM taxpayer identification number (52-0599027) is assigned to each account for the purpose of Internal Revenue Service tax reporting.
   b. The NIHFCU provides a copy of the monthly account statement to the awarding unit. Each account is provided an "overdraft" feature. The interest on SREA checking accounts maintained at the NIHFCU is automatically remitted to OFM; however, PIs in the field who do not use the NIHFCU must make arrangements through their bank to have the interest forwarded to NIH.

5. **Check Signature Records:** The PI provides the Officer with the

name(s) of the individual(s) who is authorized to write checks, his or her title or position, and a copy of bank signature authorization cards or other signature facsimile. These records are made a part of the SREA files and are checked monthly.

J. Payment of Expenses:

6. **Vouchers:** Claim for Reimbursement of Travel Cost, Per Diem, and Consultant Fee voucher (Form NIH 1715-2 - see Appendix 8) is used to claim and authorize the consultant's payments from the SREA.

   Prior to a committee meeting or site visit review personnel partially completes and distributes Form NIH 1715-2 with information about allowable costs and instructions for completion of the form to each participating consultant. The completed form is returned with appropriate receipts to the Officer immediately following the meeting or site visit.

   For those consultants participating only by telephone or mail, review personnel collect the appropriate information from the consultant to complete the Form 1715-2. The form may then be forwarded to the Officer after the consultant's participation has been completed. Vouchers exceeding six hundred dollars ($600) for any one meeting may not be handled using this streamlined procedure. The reviewer would follow procedures in the immediate paragraph above.

7. **Attendance Report:** Immediately following each committee meeting or site visit, the SRA sends the following information to the Officer:
   - name of committee;
   - location of the meeting, dates of meeting, start and adjournment times;
   - names of participating consultants;

- o number of days each attended and the compensation to which each is entitled; and
- o other pertinent information such as meeting room rental, authorized car, and travel advances.

8. **Travel Advances:** Advance payments are requested of the SRA and may be approved by the Officer.

   . Advance of funds is generally not available for consultants; if necessary, the SRA should request approval from the Officer.

   a. A public/consumer advocate who participates as a temporary member of a committee and lacks the financial resources to cover the cost of travel until such time as they can be reimbursed, is authorized for receipt of a travel advance. The procedural steps for advancing funds are as follows:

      1) The public/consumer advocate (or other member with special needs) notifies the SRA of his/her need for an advance of funds.

      2) The IC SREA office reviews the request for the travel advance; calculates the amount of the advance; calls the consumer advocate (or other member) if there are any unresolved problems with the request; prepares a Form NIH 1715-2 voucher with dollar amount of the advance inserted; and, obtains signature/approval of the IC SREA Officer.

      3) The IC SREA office forwards the approved Form NIH 1715-2 voucher to the PI or IC check writer, who issues a check for the authorized amount and sends the check along with Form NIH 1715-2 to the consumer advocate (or other member).

4) When the SRA prepares the Attendance List after the meeting, the SRA will note "Advance Authorized" beside the name of the consumer advocate who requested the travel advance. The attendance list certified by the SRA is forwarded to the IC SREA Office.

5) After the meeting, the consumer advocate (or other member) submits the regular Form NIH 1715-2 claim for reimbursement voucher directly to the IC SREA office for audit and processing for payment. The audit involves matching the final claim against the initial travel advance voucher and Attendance List; entering the amount of the fee authorized by the Attendance List; making any necessary adjustments to the claim; approving the claim; and forwarding the claim to the PI or IC check writer for payment.

6) The IC SREA office is responsible for obtaining necessary refunds from the consumer advocate. In the event that the intended travel is not performed, the advance is promptly refunded and redeposited in the SREA account. A record of travel advances are kept in the IC file and shown on the claim for reimbursement to avoid any possibility of dual compensation.

9. **Administrative Expenses:** These expenses include hotel meeting rooms, shredding classified documents, teleconference costs, and overnight delivery service. Overnight delivery service costs must benefit the Federal Government.

10. **Processing and Auditing Vouchers:** Upon receipt of the completed reimbursement Form NIH 1715-2 the Officer, or his/her designee, audits the claim for completeness, accuracy, and allowability of the

costs being claimed. All required documents, such as carrier tickets and hotel receipts, must accompany the reimbursement voucher. The claims must be consistent with the SRA's attendance record (as noted in the post-meeting attendance roster) taking into account any travel advances applied by the SRA.

The following instructions apply when the PI is directly responsible for handling disbursements/reimbursements in the SREA account.

11. **Processing and Auditing Vouchers When Handled by the PI:** The IC SREA or review staff completes the voucher(s) and signs the appropriate approval block(s). The approved vouchers are then sent to the PI for payment.
12. **Disbursements by the PI:** All disbursements made from the SREA are on standard checks issued by the PI and are supported by pre-audited and approved vouchers with the exception of routine administrative expenses (see Section J.8 below). Only the PI or authorized alternate(s) may issue checks for disbursement from the SREA.
13. **Reimbursement of PI Expenses:** The PI routinely pays for supplies, secretarial, postage and other administrative items by check as the costs are incurred. The PI sends all invoices and receipts to the SREA Officer monthly for verification and audit of these expenses.

K. Award Administration:

14. Expenses chargeable to the SREA

    Proposed expenses other than those listed below must have the prior approval of the Officer or the Chief Grants Management Officer.

    . **Consultant Fees**

1) Consultant fees may be paid to consultants as defined in Section D.1. Payment must be made directly to the consultant and not to his/her institution.

2) Consultant fees earned by members of IRGs, temporary members who serve on such review groups, and individuals participating on SEPs are payable for each day (or parts of days) that services are rendered at a meeting, on a project site visit, or for time expended for approved review group business.

3) Consultant fee reimbursement for Teleconference Meetings:

   a) Consultant fees may be paid when an individual participates either by teleconference in a review meeting, or when the entire review is conducted by telephone conference call;

   b) Consultant fees may be paid for a formally scheduled teleconference discussion by reviewers after submission of reviewer critiques;

   c) Consultant fees may be paid for teleconference sessions to discuss the triage of applications;

   d) Consultant fees may be paid for participation in formally scheduled pre-meeting teleconference orientation sessions with reviewers. Only those reviewers who participate on the designated dates for the pre-orientation meeting consisting of Review, Program and Grants Management or Contract Management staff will receive the consultant fee.

> *Note*: An established fee is paid per day, not per meeting, government-wide. See
> *http://delegations.nih.gov/DOADetails.aspx?id=1543*
> .
>
> e) Consultant fees may be paid for mail reviews at the discretion of each IC.

a. **Per diem:** The regular method of computing per diem reimbursement rates is based on: (1) the GSA schedule of per diem rates that members, temporary members, and SEP participants pay for lodging costs, plus (2) a fixed amount to cover costs for meals and miscellaneous expenses. The computed lodgings-plus reimbursement rate must be in accordance with the per diem rate authorized by Federal Travel Regulations. In designated high rate areas, reimbursement will be governed by the prevailing maximum rate allowable at the time or justify actual payment with an actual expense allowance memo. (**Per diem expenses or travel for government employees are paid from direct operating funds.**)

b. **Travel costs:** For regular members of the IRG, temporary members directly related to the review group business, and individuals participating on a SEP, travel costs are reimbursable from the SREA. Air or train travel must be government-rate fare, tourist, or economy.

   If business/first class travel is required to accommodate a medical condition or disability, the Officer must receive a medical certificate **following the practices for federal staff**. This certificate must be sent to the Travel Service Center for authorized issuance of business/first class tickets. Appropriate travel instructions are provided to each traveler by the SRA. A

permanently disabled individual may be authorized use of premium class accommodations for up to three (3) year intervals after this time frame has lapsed, proper medical certification must be updated for record keeping purposes.

c. **Automobile rental:** Automobile rental is allowable as a direct charge for individual or group travel only if such an arrangement is approved by the Officer, is less expensive than alternate means of travel, or is otherwise more advantageous to the Federal Government.

d. **Conference room rental:** Reimbursement for conference room rental is allowable for IRG or site visit activity when Federal Government space is not available. Charges for the rental of meeting room or other conference services, including rental of equipment required for the meeting, are usually added to the room rental bill sent to the IC SRA chairing the meeting. The SRA verifies charges billed for the meeting room or conference services and submits the bill to the Officer for review, approval, and payment.

e. **Supplies:** Purchase of supplies (e.g., postage, envelopes, copier paper, accounting ledgers, checkbooks, and duplication) needed by the PI or the chairperson of an IRG are reimbursable.

f. **Telephone, telegraph, fax, and on-line computer charges:** Charges incurred by members directly related to regular or electronic review group business, project site visits, or non-meeting review group activities are reimbursable from the SREA. Charges for these activities should be reflected on Form NIH 1715-2 (See Appendix 8).

All charges not directly related to review business (personal calls, unauthorized internet charges, etc) are reimbursed in

accordance with Federal guidelines.

   g. **Other expenses:** Certain other expenses relevant to review
      group activities, including publication costs, may be charged to
      the SREA with prior approval of the Officer or the Chief Grants
      Management Officer. When negotiated in advance, SREA funds
      may be used to reimburse costs for pertinent secretarial and
      clerical services relevant to SREA activities in the PI's office.

   h. **B-1 visitor's visa:** Individuals traveling under a B-1 visitor's visa
      may be reimbursed for incidental or per diem expenses that
      constitute reasonable business expenses. Visa application and
      issuance fees are a permissible travel expense for individuals on
      official temporary duty Government travel, and thus a
      permissible use of appropriated funds. See http://www.gao.gov/.

15. Expenses **not** Chargeable to the SREA:

   . Dues (i.e. scientific societies and clubs);

   a. Consultant fees, per diem, or travel reimbursement to Federal
      Government employees;

   b. Honoraria payments or rewards where the primary intent is to
      confer a distinction on the recipient;

   c. Equipment purchases, patient care costs, and other expenses
      not directly related to review activities;

   d. Social activities – this restriction includes bar charges,
      entertainment, gifts for members, and similar expenditures;

   e. Personal travel;

   f. Dependent care; and

   g. Unauthorized internet expenses.

L. Reconciliation and Expenditure Reporting:

16. Monthly Reconciliation of Accounts - The Officer and the PI are

responsible for reconciling the account records on a monthly basis. The reconciliation should bring into agreement records concerning cash requests, expenditures, and the monthly bank statements. For accounts established in the NIHFCU, the bank statements are sent directly to the awarding unit. The PI will have carbon copies of the checks in the checkbook. For accounts at other financial institutions, the PI will have to provide the bank statement and cancelled checks as they routinely provide travel vouchers and other paid invoices. (see section I.3)

17. Financial Status Reports (SF-269) are available at:

http://forms.psc.gov/forms/sf/SF-269.pdf

. Annual Reports – The Officer provides a Financial Status Report (FSR) form to the PI with instructions for completion and return to the Officer. Following audit and approval by the Officer, the FSR is submitted to OFM at the address indicated in Section H-6. The report is submitted within 90 days after the end of each budget period. This annual report is mandatory.

a. Final Report – When the SREA is terminated for any reason, or if there is a change in PI, a final Financial Status Report must be submitted within 90 days following such action.

— When handled internally at NIH:

The Officer requests a check from the NIHFCU to close out the existing account. The closeout check (made payable to DHHS/National Institutes of Health), FSR, audit reports, and a request to transfer the account balance to the new PI are forwarded to the Government Accounting Branch at the address provided in Section H.6.

— When handled by the PI who has a bank account at his/her home location:

The PI must remit a check (signed by a bank official and made payable to DHHS/National Institutes of Health) for any undisbursed funds in the account. This check, along with the final report, must be mailed to the Officer, who forwards the closeout package to OFM at the address in provided in Section H.6.

If the submission of the Final Status Report is due to a change in the PI only, the existing checking account at the NIH Federal Credit Union should be officially closed. Correspondence officially requesting closure of the account and a credit union draft for any remaining funds should be sent to the NIHFCU at the following address:

Vice President for Finance and Technology
NIH Federal Credit Union
600 Jefferson Plaza, Suite 400
Rockville, MD 20852-6475

M. Internal Revenue Service Reporting:

IRS Form 1099, "Statement for Recipients of Non-employee Compensation," is provided to consultants who receive an aggregate of NIH consultant income of $600 or more in any calendar year. NIH consultant income includes travel and per diem, as well as consultant fees. While the IRS regulations do not permit NIH to exclude travel and per diem reimbursement from the amount reported on the Form 1099, only the consultant fee (honorarium) is taxable. Consultants are encouraged to keep Form NIH 1715-2 or the check stub in order to substantiate those portions of reported income that are not taxable. For further information, please refer to Title 26 of the Federal Regulations.

N. Effective Date:

This policy is effective on the date of release.

O. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Item 1100-G-20 covers SREA files, and Item 4000 covers NIH Grants and Awards. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail: NIH e-mail messages (including attachments) created on NIH computer systems or transmitted over NIH networks evidencing of the activities of an agency or have informational value, are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property and if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same request as the original messages.

P. Internal Controls:

The purpose of this manual issuance is to state NIH policies and the requirements governing the acceptance and administration of Scientific Review and Evaluation Awards.

18. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

19. **Frequency of Review:** The frequency of review will be based on the outcome of a risk assessment that will determine how often an internal control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

20. **Method of Review:** OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board (MCCMB) will oversee the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

21. **Review Reports are sent to:** The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as

appropriate, the DDER, the Director, OPERA, and the Deputy Director for Management.

Appendices

Appendix 1 – [Appointment Letter to PI – IC](#)

Appendix 2 – [Blank Face Page of Form PHS 398](#)

Appendix 3 – [NIHFCU Member Application and Agreement](#)

Appendix 4 – Image Digitizing Form – For a hard copy, contact the Center for Scientific Research at (301) 435–1131

Appendix 5 – [NIH Statement of Policies and Requirements Governing the Acceptance and Administration of SREAs](#)

Appendix 6 – [Sample Notice of Grant Award](#)

Appendix 7 – [Sample Memorandum Requesting Cash Request](#)

Appendix 8 – [Sample Form NIH 1715–2](#)

NIH POLICY MANUAL

54805 - Research Grants Awarded to Non-Affiliated Individuals

Issuing Office: OER 301-496-5967

Release Date: 2/1/85

A. Purpose:

This issuance sets forth the policy which applies to research grants awarded to non-affiliated individuals as grantees rather than to an institution or organization.

B. Applicability:

This policy is applicable to NIH research project grants.

C. References:

1. NIH Manual Chapter 4209, Cost Sharing in Research Grants

2. NIH Manual Chapter 5202, Prior Approval of Use of NIH Grant Funds Including Rebudgeting

3. [NIH Manual Chapter 5602](#), Management of and Accountability for Equipment Acquired Under NIH Grants

D. Policy:

In exceptional cases, a research project grant may be made to a non-affiliated individual in the United States rather than to an institution or organization. In such cases, special administrative features pertain (see E.

Implementation below).

E. Implementation:

1. *Allowances and Expenditures*

   No indirect cost allowance will be provided to individuals as grantees; nor may they use grant funds for alterations or renovations, or for the purchase of fixed equipment. Otherwise, the expenditures policies applicable to research grants made to grantee institutions and organizations are applicable to grants made to individuals.

2. *Human and Animal Subject Research*

   In accordance with Department of Health and Human Services Regulations, 45 CFR 46, and the Public Health Service Animal Welfare Policy, 1-43, no individual may receive NIH grant funds for non-exempt human subjects research or animal research unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under a written Assurance of Compliance or the individual makes other arrangements with the Department. For information concerning human subjects and/or animal assurances and related arrangements, contact the Office for Protection From Research Risks, Building 31, Room 4B09. Telephone: 496-7005.

3. *Cost Sharing*

   The non-payment of indirect costs on grants to individuals satisfies cost sharing requirements.

4. *Equipment*

   Title to equipment acquired by an individual as a grantee shall vest upon acquisition in the Federal Government with final disposition to be determined by the awarding unit upon termination of the project.

5. *Payment of Grants Funds*

   Individuals as grantees may obtain an advance of funds on a monthly basis in the amount of estimated disbursements to be made during a

month, or on a reimbursable basis, by writing a letter identifying their grant number and cash requirements to:

Accounting and Indirect Cost Section

Federal Assistance Accounting Branch

Division of Financial Management

National Institutes of Health

Building 31, Room B1B04

9000 Rockville Pike

Bethesda, Maryland 20205

6. *Prior Approval*

   Authority Individuals as grantees must obtain prior approval from the Grants Management Officer of the NIH awarding unit for all proposed programmatic changes and rebudgeting actions for which prior approval is required.

7. *Reporting*

   The individual as a grantee has the same reporting requirements as a grantee institution or organization.

F. Responsibility:

Although the individual is held entirely responsible for the grant, personal indemnity bonds are not required. The awarding unit Grants Management Officer and designated program official are jointly responsible for regular contact with the grantee individual to ensure that the terms of the grant are being met.

G. Effective Date:

This policy is effective on date of release.

H. Additional Information:

For further information on this chapter contact the Grants Policy Office, Office of Extramural Research and Training, Building 31, Room 1B58. Telephone: 301-496-5967.

I. Additional Copies:

For copies of this manual chapter send a Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07.

NIH POLICY MANUAL

54810 - National Research Service Awards

Issuing Office: OPERA/OER 435-0949

Release Date: 6/16/97

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1. Explanation of Material Transmitted:

This chapter is being revised to reflect policy and procedure changes affecting National Research Service Awards. It addresses both the institutional grant and the individual award, as well as the payback requirements for recipients of support.

2. Filing Instructions:

- **Remove:** NIH Manual 4810 dated 08/16/84 in entirety

- **Insert:** NIH Manual 4810 dated 6/16/97

3. Distribution: NIH Manual Mailing Keys F-401 and F406 (transmittal sheet only): Chapter text is available on-line. See the last bullet on this page for on-line information.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- On-line information, enter this URL:
  http://oma.od.nih.gov/manualchapters/

- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

I. General

A. Purpose

The purpose of this chapter is to set forth the policy and procedures governing the general provisions, award, and management of National Research Service Awards. It addresses both the institutional grant and the individual award, and the payback requirements for recipients of support.

B. Applicability

This policy is applicable to all NIH Institutes and Centers that award institutional training grants or individual fellowships under the National Research Service Award (NRSA) authorization of Section 487 of the Public Health Service Act.

C. References

1. Code of Federal Regulation, Title 42, Part 66 National Research Service Awards.

2. Public Health Service Act, Section 487 as amended (42 USC 288).

3. PHS Grants Policy Statement, April 1, 1994.

4. PHS Grants Administration Manual Part 203, Compensation of Students and Trainees under Research Grants.

5. PHS Grants Administration Manual Part 300, Predoctoral and Postdoctoral Trainee Support.

D. Background

Section 487 of the Public Health Service Act (42 USC 288), provides authority for the National Institutes of Health (NIH) to award National

Research Service Awards (NRSA) to support predoctoral and postdoctoral training. This section states that the Secretary shall provide National Research Service Awards for predoctoral and postdoctoral training of individuals to undertake biomedical and behavioral research at domestic and foreign, public and private institutions (profit and non-profit). Section 487 (a) (1) (B) authorizes institutional NRSA grants limiting NRSA support to training and research at public and nonprofit private entities. The National Research Service Award legislation requires recipients to pay back to the Federal Government their initial 12 months of NRSA postdoctoral support by engaging in health-related biomedical or behavioral research, research training, health-related teaching, or any combination of these activities (See [Section IV](#)). Title 42 of the Code of Federal Regulations, Part 66, is applicable to these awards.

E. Nondiscrimination

The NIH research training and career development programs are conducted in compliance with applicable laws that provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance. Applicant organizations are required to have appropriate Assurance of Compliance forms filed with the Office of Civil Rights, Office of the Secretary, DHHS before a grant may be made to that institution. The NIH awarding component should be contacted if there are any questions concerning compliance.

II. Individual National Research Service Awards (Fellowships)

A. General

The Congress of the United States enacted the National Research Service Act Program in 1974 to help ensure that highly trained scientists would be available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Under this congressional authority, the National Institutes of Health (NIH) awards NRSA individual postdoctoral fellowships (F32) to the most promising applicants to support full-time research training related to the mission of the NIH awarding components. Some specialized individual predoctoral fellowships (F31s and F30s) and Senior Fellowships (F33s) are also provided under the NRSA. For individual predoctoral fellowships, NIH awarding components have different requirements. Thus specific program announcements should be consulted for guidance.

National Research Service Awards (NRSA) are made to individual fellowship applicants selected for award as a result of national competition for research training in specified health-related areas. All NIH awarding components except the Fogarty International Center (FIC) and the National Library of Medicine (NLM) make individual awards under NRSA. FIC & NLM have unique funding authorities for fellowships that are not under the NRSA.

1. Eligibility

a. Research Areas

National Research Service Awards may be made for research training in areas which fall within the mission of the NIH awarding components. Applications which do not fit these areas will be returned. An increased emphasis has been placed on the research training of physicians. The Secretary, DHHS, is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of two

consecutive years of biomedical and behavioral research training.

b. Research Training Program

The NRSA fellowship must be used to support a program of research training. It may not support studies leading to the M.D., D.O., D.D.S., D.V.M., or other clinical, health professional degrees; nor to support residencies, the primary purpose of which is the attainment of a medical or nursing specialty. Research trainees in clinical areas are expected to devote full time to the proposed research training and to confine clinical duties to those which are part of the research training.

2. Degree Requirements

a. Predoctoral

Individuals must have received, as of the activation date of their NRSA award, a baccalaureate degree and must be enrolled in and training at the post baccalaureate level in a program leading to the award of a Doctor of Philosophy of Science (Ph.D. or Sc.D.) or a combined clinical degree and Ph.D. degree such as M.D./Ph.D.

b. Postdoctoral

Before an NRSA award can be activated, individuals must have received a Ph.D., M.D., D.O., D.D.S., D.V.M., O.D., D.P.M., Sc.D., D.Eng., D.N.S., or equivalent doctoral degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree granting institution that all degree requirements have been met is also acceptable.

c. Senior Fellows

As of the beginning date of their award, senior fellows must have received a doctoral degree (as in A.2.b. above) and must have had at least seven

subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific background by acquiring new research capabilities. In addition, these awards will enable individuals beyond the new investigator stage to take time from regular professional responsibilities for the purpose of increasing their capabilities to engage in health-related research. Senior fellowships are made for full-time research training. Health professionals may utilize some of their time in clinical duties which are part of their research training.

3. Citizenship

The individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award. A non-citizen national is a person, who, although not a citizen of the United States, owes permanent allegiance to the U.S. They are generally persons born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must be in possession of a currently valid Alien Registration Receipt Card (I-551), or must be in possession of other legal verification of such status. For example, if an individual is in possession of the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Since there is a six-month limitation on this validation, it is the responsibility of the sponsoring institution to follow-up and assure that the individual received the I-551 prior to the six month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the fellowship program announcement may submit an application for an individual NRSA fellowship. The submission of documentation concerning permanent

residency is not required as part of the initial application. Any applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

Applicants who have been lawfully admitted for permanent residence; i.e., are in possession of an Alien Registration Receipt Card or other legal verification of such status, should check the Permanent Resident box in the citizenship section on the face page of the fellowship application. Applicants who have applied for and have not yet been granted admission as a permanent resident should also check the same box, but should write in the word "pending."

Individuals on temporary or student visas are not eligible for support from the NRSA.

4. Sponsorship

a. General

Before submitting a fellowship application, the applicant must identify a sponsoring institution and an individual who will serve as a sponsor and will supervise the training and research experience. The sponsoring institution may be private (profit or nonprofit) or public, including the NIH Intramural Programs and other Federal laboratories. The applicant's sponsor should be an active investigator in the area of the proposed research who will directly supervise the candidate's research. The sponsor must document in the application the training plan for the applicant as well as the availability of staff, research support, and facilities for high-quality research training. Applicants proposing training at their doctorate institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences that would broaden their scientific background.

b. Foreign Sponsorship

Under exceptional circumstances an individual may request support for training abroad. In such cases, the applicant is required to provide detailed justification for the foreign training and why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Only in cases where there are clear scientific advantages will the foreign training be considered for funding.

5. NIH Employees

Both Civil Service employees and PHS Commissioned Officers at NIH are permitted to compete for predoctoral and postdoctoral fellowships. The proposed training should be primarily for career development rather than for the immediate research needs of NIH. The employee's supervisor must disassociate him/herself from the review and award process. Successful NIH applicants for the predoctoral or postdoctoral fellowship awards must either resign from NIH or take leave without pay prior to activating the award. (There is no obligation or commitment by the NIH or the fellow for future employment at NIH upon termination of the fellowship.)

6. Individuals on Active Military Duty

The NIH has no restriction against career military personnel applying for research fellowship awards while on active military duty. At the time of application, a letter from the applicant's branch of the military service should be submitted endorsing his/her application and indicating willingness to continue normal active duty pay and allowance during the period of the requested fellowship. If an award is made, the institutional allowance and necessary tuition and fees permitted on a postdoctoral program will be paid. However, stipends, health insurance, and travel

allowances will not be reimbursed. Payment of concurrent benefits by NIH to active duty career military awardees is not allowed.

B. Application and Receipt Dates

1. Application

Each applicant must submit an application using the Form PHS 416-1. At least three letters of reference on his or her behalf must also be submitted. The major emphasis of the application should be the research training experience and broadening of scientific competence. The application must include the sponsor's Facilities and Commitment Statement. By signing the face page of the application, the applicant indicates that he or she has read the payback information and will meet any payback provisions required under the law as a condition for accepting the National Research Service Award. Applicants and sponsoring institutions must comply with policies and procedures governing the protection of human subjects, the humane care and use of live vertebrate animals, and the inclusion of women and minorities in study populations.

On the application face page, applicants should indicate (in the Request for Applications section) the initials of the NIH Institute most appropriate to the research area of the application. If the application is submitted in response to a Program Announcement (PA) or Request for Application (RFA) from a particular Institute, the applicant should identify the number of the PA or RFA on the face page. This information will be used as a guide in the application assignment process.

2. Concurrent Applications

An individual may not have two or more competing NRSA applications pending review concurrently in the National Research Service Award program.

3. Application Availability

Application kits containing forms, instructions, and related information may be obtained from:

The Division of Extramural Outreach and Information Resources, OER, NIH
6701 Rockledge Drive, MSC 7910
Bethesda, MD 20892-7910

Phone: (301)-435-0714

E-mail: asknih@odrockm1.od.nih.gov

4. Receipt Dates

Individual fellowship applications undergo a review process that takes between five and eight months. The annual receipt dates and review cycle are found in Appendix 2.

C. Review

Each initial and competing renewal application will be evaluated for scientific merit by an NIH Scientific Review Group (SRG). Review criteria for this evaluation will include the applicant's past academic and research record, the research training proposal, the sponsor's general qualifications, the training environment, publications, references, and the applicant's research goals. Individual fellowship applications receive a secondary level of review by Institute staff.

It is important to remember that the purpose of the fellowship program is for research training. Major considerations in the review are the applicant's potential for a productive scientific career, the applicant's need for the proposed training, and the degree to which the research training proposal,

the sponsor, and the environment will satisfy these needs.

D. Notification of Action

Shortly after the initial review meeting, each candidate receives a mailer that includes the SRG recommendation/priority score and the name of a program official in the assigned NIH awarding component. A copy of the summary statement is automatically forwarded to the applicant as soon as possible. The applicant will be notified by letter concerning the final review recommendation. Any questions about initial review recommendations and funding possibilities should be directed to the appropriate institute program official, not the scientific review administrator of the SRG. A Notice of Research Fellowship Award will be issued to applicants selected for funding.

E. Period of Support

All fellows are required to pursue their research training on a full-time basis, normally defined as 40 hours per week or as specified by the sponsoring institution in accordance with its own policies.

No individual fellow may receive more than five years of aggregate NRSA support at the predoctoral level and three years of aggregate NRSA support at the postdoctoral level, including any combination of NRSA support from institutional and individual awards. Any exception to this requires a waiver from the Director of the NIH awarding component or designee based on review of justification from the individual and sponsoring institution. The grounds for approving extensions of support are as follows:

1. Physicians/Clinicians

Individuals requiring additional time to complete training, either as a

participant in a combined M.D.-Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon certification of the recipient's good academic standing and justified need for the exception to policy.

2. Interruptions (Break-In-Service)

Requests for additional time will also be considered if an event unavoidably has altered the planned course of the research training; the interruption has significantly detracted from the nature or quality of the planned research training; and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation, which prevents a trainee or fellow from pursuing research training in an effective manner for a significant period of time. Requests for extension of support will also be considered if a short additional period would provide the fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

3. Other Exceptions

Requests that do not arise from circumstances considered in E.1 or E.2 above will be considered if they are accompanied by an exceptionally strong justification. Requests must be made in writing to the NIH awarding component by the fellow. The fellow's sponsor and an authorized institutional business official, must endorse the request certifying the need for additional support. The request must include a sound justification and specify the amount of additional support for which approval is sought. Requests must be approved by the Director of the awarding component or designee.

F. Initiation of Support

1. Process

The awarding component will notify the individual of the intention to make an award and confirm the actual plans for the start of the fellowship support. The Notice of Research Fellowship Award will be issued so that the individual may begin the fellowship immediately on or after the issue date, or permit a period of up to six months for the individual to finalize arrangements, such as the completion of degree requirements, final coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The fellow must start the period of training under the award by the latest activation date as shown on the Notice of Research Fellowship Award; i.e., six months from the award issue date. Extensions of the activation period may be granted in unusual circumstances. Written requests for extensions should be submitted by the fellow, and countersigned by the sponsor and authorized institutional business official.

The day the fellow begins training, the Activation Notice and the Payback Agreement (only for postdoctoral fellows in their first 12 months of NRSA postdoctoral support) must be completed and submitted to the awarding component (see Section H.1.a.(1) and (2)). A stipend may not be paid until these forms are submitted and the fellow begins training. If necessary for payroll purposes, the Activation Notice and Payback Agreement may be submitted up to 30 days in advance of the start date. However, any change in this planned activation start date must be reported immediately to the business office of the institution and the awarding component. If an award is conditioned upon the completion of degree requirements, certification of completion by the degree granting institution must be submitted with the Activation Notice.

The initial award is usually for 12 months. Subsequent periods of approved

fellowship training are consecutive with the first year of support and are usually in 12-month increments. If a fellow decides not to activate the award, or to terminate early, he or she should notify the institutional business office, the sponsor, and the awarding component immediately in writing.

2. Payment

a. Domestic

(1) Domestic, non-Federal sponsoring institutions receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The domestic institution directly pays the fellow and disburses all other awarded costs.

(2) Federal Laboratories Fellows training at Federal laboratories are paid stipends directly by the awarding component through the Office of Financial Management (OFM), which also reimburses the fellow for appropriate expenditures from the institutional allowance.

b. Foreign

Fellows training at foreign sites receive stipends directly from OFM; however, the institutional allowance is awarded to and disbursed by the sponsoring institution.

G. Financial Provisions

Costs are normally provided based on a 12-month budget period. Awards for less than 12 months will be prorated accordingly.

1. Stipends

A stipend is provided as a subsistence allowance for fellows to help defray

living expenses during the research training experience. It is not provided as a condition of employment with either the Federal Government or the sponsoring institution. Changes in stipend levels are published in the NIH Guide for Grants and Contracts. Stipends must be paid in accordance with stipend levels set by this policy. No departure from the standard stipend schedule, as provided from the fellowship, may be negotiated by the sponsoring institution with the fellow.

a. Levels (Current annual stipend amounts are detailed in Appendix 1)

(1) Predoctoral

One stipend level is used for all predoctoral candidates, regardless of the level of experience.

(2) Postdoctoral

The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience at the time the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the fellow must be paid at that level for the entire grant year. The stipend for each additional year of NRSA support is the next level in the stipend structure and does not change mid-year.

(3) Senior Fellows The amount of the NRSA stipend to be paid shall be commensurate with the base salary or remuneration which the individual receiving the award would have been paid by the institution with which he or she has permanent affiliation on the date of the fellowship award, but in no case shall the stipend award exceed the current NRSA stipend limit set by NIH. Fringe benefits are not provided with this award. The level of

NRSA support will take into account concurrent salary support provided by the institution, and the policy of the sponsoring institution.

b. Stipend Supplementation

Fellows are supported for 12-month full-time training appointments for which they receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation does not require any additional obligation from the fellow. An institution can determine what amount of stipend supplementation, if any, will be provided according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may Public Health Service (PHS) funds be used for supplementation.

An individual may make use of Federal educational loan funds or V.A. benefits when permitted by those programs as described in Section G.1.e. below.

c. Compensation

It is recognized that fellows may seek part-time employment coincidental to their training program in order to further offset their expenses. In circumstances of actual employment, the funds provided as compensation (salary or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation. Funds characterized as compensation may be paid to fellows when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in the PHS Grants Policy Statement. Under these

conditions fellows may be compensated for actual employment on Federal grants, including PHS research grants. However, it is expected that compensation from research grants will occur on a limited part-time basis for employment apart from the normal training activities which generally require a minimum of 40 hours per week (see Section E).

Compensation may not be paid from a research grant which supports the same research that is part of the fellow's planned training experience as approved in the fellowship application. Fellowship sponsors must approve all instances of employment on research grants in order to verify that the circumstances will not detract from or prolong the approved training program.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved NRSA training program. Additionally, compensation must be in accordance with institutional policies applied consistently to both federally and non-federally supported activities and supported by acceptable accounting records determined by the employer-employee relationship agreement.

d. Concurrent Benefits

National Research Service Award may not be held concurrently with another Federally-sponsored fellowship or similar Federal award which provides a stipend or otherwise duplicates provisions of the NRSA.

e. Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the Veterans Administration (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

f. Taxability of Stipends

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. The Tax Reform Act of 1986, Public Law 99-514, impacts on the tax liability of all individuals supported under the NRSA program. New statutory requirements were effective as of January 1, 1987. Degree candidates may now exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are now required to report as gross income all stipends and any monies paid on their behalf for course tuition and fees required for attendance.

The taxability of stipends, however, in no way alters the relationship between NRSA fellows and sponsoring institutions. NRSA stipends are not considered salaries. In addition, fellows supported under the NRSA are not considered to be in an employee-employer relationship with the NIH or the sponsoring institution. It must be emphasized that the interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

g. Form 1099

Since stipends are not considered salaries, for the purposes of income tax reporting, stipend payments should be reported on the IRS Form 1099, Statement of Miscellaneous Income. The business office of the sponsoring institution will be responsible for the annual preparation and issuance of the IRS Form 1099 for fellows paid through the institution. NIH will issue

the subject form for all fellows paid directly by them (e.g., fellows training at Federal or foreign laboratories).

h. Employee Benefits

Since NRSA awards are not provided as a condition of employment with either the Federal government or the sponsoring institution, it is inappropriate and unallowable for institutions to seek funds for or to charge individual fellowship awards for costs that would normally be associated with employee benefits (for example, FICA, workman's compensation, and unemployment insurance).

2. Other Costs

a. Institutional Allowance

An institutional allowance to help support the costs of training is awarded. Interested applicants should consult the NIH program announcement(s) regarding the specific level of allowance for predoctoral and postdoctoral support, including those individuals training at Federal laboratories, for-profit, or foreign institutions. Allowance levels are published in the NIH Guide for Grants and Contracts. Current institutional allowance levels are found in Appendix 1. Beginning in FY 1997, for postdoctoral fellowships, costs for tuition and fees, where appropriate, will be awarded independent from the institutional allowance. (See Section 2.b for details on tuition reimbursement.)

(1) Allowable Costs for Sponsoring Institutions

The type of sponsoring institution dictates what allowable costs may be charged to this category and how the funds are administered.

(a) Non-Federal public and private nonprofit institutions

The allowance is intended to defray such expenses for the individual fellow as research supplies, equipment, travel to scientific meetings, health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of graduate training. Funds are paid directly to and administered by the sponsoring institution.

(b) Federal laboratories

The allowance is intended to cover the costs of scientific meeting travel, health insurance, or books. Funds are administered by the awarding component and disbursed from OFM.

(c) For-profit institutions

The allowance is intended to cover the costs of scientific meeting travel, health insurance, or books. Funds are paid directly to and administered by the sponsoring institution.

(d) Foreign institutions

The allowance is intended to defray such expenses as research supplies, equipment, travel to scientific meetings, health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of graduate training. Funds are paid directly to and administered by the sponsoring institution.

(2) Guidelines

The following are specific guidelines for the use of the institutional allowance:

(a) Health Insurance

A fellow's health insurance is an allowable cost only if required of all

persons in a similar training status regardless of the source of support. Family health insurance is not an appropriate charge; however, the individual may elect personally to pay the differential between self-only and family health insurance options.

(b) Travel

1) Payment for travel to scientific meetings is appropriate when it is necessary to the individual's training.

2) For fellows at Federal laboratories, reimbursement of travel costs is in accordance with current Government regulations.

3) Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the grantee institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

(c) Extraordinary Costs:

Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for:

1) travel to field sites remote from the sponsoring institution; or

2) accommodations for fellows who are disabled, as defined by the Americans With Disabilities Act.

The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances which are fully justified and explained by the institution.

(3) Expenditure

Except for fellows at Federal training sites, the sponsoring institution authorizes the expenditure of the allowance on behalf of the fellow according to the institutional policy. The institution is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a training status for more than six months of the award year, only one-half of that year's allowance may be charged to the grant. The Notice of Research Fellowship Award will be revised and the balance must be refunded to the PHS.

For fellows at Federal training sites, the awarding component authorizes the expenditure of the allowance. Payment is made through the OFM.

b. Tuition and Fees

Tuition and fees for postdoctoral fellows are limited to those for specific courses required by the training program and must receive prior approval from the awarding component. For the purposes of calculating this budget item, health insurance is not included since it is still awarded as part of the institutional allowance.

For predoctoral fellows, reimbursement of tuition and fees (including health insurance) varies depending on the policy of the NIH awarding component. Specific programmatic guidelines should be consulted for reimbursement guidance. Reimbursement of tuition and fees changed with awards competing in FY97. See [Appendix 1](#) for details.

c. Travel to Foreign Training Sites

For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers

must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference.

H. Reporting Procedures

The following documents are critical to the process of establishing the payment of stipends and other costs, as well as the determination of possible payback service.

1. Activation Notice (Form PHS 416-5, See [Appendix 3](#))

Immediately upon the initiation of training, the individual completes and signs the Activation Notice, obtains the signature of the designated sponsoring institution officials, and forwards the notice along with the Payback Agreement (postdoctoral fellows in their first 12 months of NRSA support only) to the NIH awarding component. An Activation Notice is enclosed with all competing awards.

For fellows paid directly by NIH, the Activation Notice is required at the start of each award year. The forms should not be submitted before he or she actually begins training. Stipend checks are issued when both the Activation Notice and the Payback Agreement (postdoctoral fellows in their first 12 months of NRSA support only) are received by the awarding component.

For fellows whose stipend is paid through the institution, the Activation Notice is required for the initial year only. The Notice may be submitted up to 30 days before the individual begins training if necessary for payroll purposes. However, the institution must not release any funds until the individual has actually started training. Furthermore, if the individual does not begin research training on the day indicated, the institution must notify

the NIH awarding component immediately. Continuation awards must be activated on the day following termination of the previous award period.

Upon receipt of the Activation Notice, the awarding component enters the activation date into the NIH system. The original is retained in the official file.

2. Payback Agreement (Form PHS 6031, See [Appendix 5](#))

A National Research Service Award Payback Agreement must be signed by each person who is to receive an individual postdoctoral fellowship that covers their initial 12 months of NRSA postdoctoral support. This form is retained along with the Activation Notice in the official file. If the individual has already received 12 months of postdoctoral NRSA support under any grant or award, this form is not required.

For detail on NRSA payback, see [Section IV](#).

3. Termination Notice (Form PHS 416-7, See [Appendix 6](#))

a. Request

The Termination Notice (along with the Activation Notice and the Notice of Research Fellowship Award) is the basis for establishing the amount of payback obligation for each NRSA fellow. For individual fellowships, a Termination Notice is sent to the fellow by the awarding component prior to the scheduled termination date. For early terminations, the forms will be issued immediately upon receipt of notification from the fellow or an authorized institutional official. This form must be completed and returned to the awarding component immediately. The lack of timely and accurate information on this form could adversely affect the payback process.

b. Termination Follow-up

If the awarding component has not received a Termination Notice within 30 days of termination, follow-up should be done through the fellowship sponsor. The sponsor should be requested to have the fellow complete the Termination Notice within a second 30-day period. If the individual cannot be located, the sponsor is requested to complete the Termination Notice immediately and return it to the awarding component. All items are to be completed except in the latter situation, the section titled Signature of Fellow/Trainee. In this section, the sponsor should indicate "Fellow Unavailable for Signature." The best available address for the fellow should be included.

c. "Proxy" Termination Notice

If it is impossible to obtain a Termination Notice from either the fellow or the sponsoring institution, a "proxy" Termination Notice should be prepared by the awarding component. Thorough documentation regarding the efforts made to secure the Termination Notice should be maintained. The form should be completed with as much information as possible and appropriately annotated to substantiate the circumstances. Using the last known address, a copy of the Termination Notice should be mailed with a covering letter to the fellow. The letter should explain the future actions and responsibilities in fulfilling the payback obligation, if any.

d. Validation and Distribution of the Termination Notice

(1) The awarding component reviews each Termination Notice for accuracy and completeness and verifies the amount of stipend support and the number of months of support. If inaccuracies are found in a Termination Notice it should be returned to the sponsoring institution for revision. Such inaccuracies can include improper signatures, lack of initialed corrections, incorrect stipend amounts and/or incorrect period of support.

(2) After assuring completeness and accuracy of all information, the awarding component:

(a) may send a validated copy of the Termination Notice to the fellow.

If the individual received NRSA support prior to June 10, 1993 and had a total of 12 months or less of NRSA support, he or she must be informed that there is no payback obligation. If a payback obligation does exist and the fellow did not complete the notice, a letter accompanies the validated copy indicating that a payback obligation has been established based on NIH records and the Termination Notice which was prepared in conjunction with the sponsoring institution.

(b) enters the data from the Termination Notice into the IMPAC I/II File.

By entering the Termination Notice information, a mailer is automatically generated and mailed by staff in the Office of Extramural Research (OER) to each fellow acknowledging receipt of the Termination Notice and requesting that any change in name, address or social security number be reported to the cognizant awarding component.

(c) maintains the validated original Termination Notice in the individual payback record.

This file may include the Payback Agreement and Activation Notice as well as other documents relevant to the payback process.

(3) The validation and distribution of copies should be completed within a maximum of 90 days after termination.

4. Consecutive Support

a. If a fellow switches from one NRSA grant mechanism to another, including from one awarding component to another, the requirement for

payback service incurred is deferred until the total NRSA support is completed. All fellowship applications are reviewed to determine if previous NRSA support has been provided. Previous NRSA support can be verified by checking the NRSA record in IMPAC. When consecutive support is provided by a different awarding component, that component updates the record in the IMPAC system. As additional verification, the Data Integrity Unit (DIU), OER notifies both awarding components of consecutive support when a subsequent Termination Notice is entered into the IMPAC I/II File.

b. The original awarding component provides the pertinent original of the Statement of Appointment or Activation Notice, Payback Agreement, Termination Notice, and Fellowship Award Notice, when applicable, as well as any validated APACs to the gaining awarding component. That component is responsible for monitoring the payback obligation for the fellow's total period of support even if all the obligation was incurred while supported by the original awarding component.

I. Progress Reports, Financial Status Reports, Changes in the Project

1. Progress Reports

Progress reports must be submitted with all applications for non-competing continuation support in accordance with the instructions accompanying the application forms. Inadequate or incomplete progress reports may be returned to the fellow for revision and may result in a delay of continued support. For individual awards the final progress report is required as part of the Termination Notice.

2. Financial Status Report

An annual or final Financial Status Report is not required on individual

awards. In the event of early termination, the stipend will be prorated according to the amount of time spent in training and the Notice of Research Fellowship Award will be revised. The balance of any institutional allowance (at least 1/2) must be refunded if the training has been for six months or less.

3. Changes in the Project

Individual awards are made for training at a specific institution under the guidance of a particular sponsor. A transfer of the award to another institution or a change in sponsor and/or project requires the approval of the NIH awarding component. As part of that approval process, if a fellow sponsored by a domestic non-Federal institution requests a transfer to another domestic non-Federal institution before the end of the current award year, the initial institution may be requested to continue to pay the stipend until the end of the current year. Disposition of the institutional allowance is negotiable between the two sponsoring institutions.

Transfers involving Federal or Foreign sponsoring institutions require unique administrative procedures and approvals. Regardless of the type of sponsoring institution involved, since each transfer varies depending upon individual circumstances, the NIH awarding component should be contacted for specific guidance.

Any proposed change in the individual's specified area of research training must be reviewed and approved in writing by the awarding component to assure that the training continues to be an area that falls within the scientific area of the original peer reviewed application.

An interim sponsor must be named by the institution and approved in writing by the awarding component when the sponsor is going to be absent for a period of more than three months.

J. Other Terms and Conditions

1. Leave

a. Vacations and Holidays

Fellows may receive the same vacations and holidays available to individuals in comparable training positions at the grantee or sponsoring institution. Fellows shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters is generally considered an active part of the training period.

b. Sick Leave and Other Leave

Fellows may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the awarding component in r esponse to a written request from the sponsor, countersigned by an authorized institutional official. Sick leave may be used for the medical conditions related to pregnancy and childbirth pursuant to the Pregnancy Discrimination Act (42 USC 2000 e(k)).

c. Parental Leave

Fellows may also receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee or sponsoring institution have access to paid leave for this purpose. Either parent is eligible for parental leave. In the case of individual fellowships, the use of parental leave requires approval by the sponsor.

A period of terminal leave is not permitted and payment may not be made from grant funds for leave not taken.

d. Unpaid Leave

Individuals requiring extended periods of time away from their research training experience, which could include more than 15 calendar days of sick leave or more than 30 calendar days of parental leave must seek approval for an unpaid leave of absence. Approval for a leave of absence must be requested in advance from the awarding component. Fellows must provide a letter of support from the sponsor, countersigned by an authorized institutional official, and must advise the awarding component of the dates of the leave of absence. Upon approval of the request, the awarding component will issue a revised Notice of Research Fellowship Award extending the termination date of the current budget period by the number of months of the leave. A restriction will be included in the Terms and Conditions of the award precluding the expenditure of funds from the fellowship during the period of the leave of absence.

During a leave of absence, documentation to suspend the award and/or the accrual of service for calculating the payback obligation must be completed.

2. Termination

An individual award may be terminated prior to its normal expiration date at the written request of the recipient, or by the Director, NIH, if it is found that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. In the event an award is terminated for cause, the Director shall notify the awardee in writing of this determination, the reasons therefore, the effective date, and the right to appeal the decision.

3. Publications

Fellows are encouraged to submit reports of their findings for publication to

the journals of their choice. Responsibility for direction of the project should not be ascribed to NIH. Awarding component support must be acknowledged by a footnote in language similar to the following: "This Investigation was supported by National Institutes of Health, National Research Service Award (number) from the (awarding component) ." In addition, it is now mandated that all grantees funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Grantees are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

4. Copyright

Except as otherwise provided in the conditions of the award, when publications or similar copyrightable materials are developed from work supported by NIH the author is free to arrange for copyright without awarding component approval. Any such copyrighted material shall be subject to royalty-free, nonexclusive, and irrevocable license to the Government to reproduce them, translate them, publish them, use and dispose of them, and to authorize others to do so for Government purposes.

5. Patents

No fellowship grant made by PHS primarily to an awardee for educational purposes will contain any provision giving PHS any rights to inventions made by the awardee.

6. Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other

comparable activities performed pursuant to the purpose of the award may not be retained by the fellow. Such fees will be assigned to the sponsoring institution for disposition in accordance with PHS policy on grant related income. The term professional fees does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private nonprofit organizations. These fees, if within institutional policy, may be retained by the awardee.

7. Human Subjects/Animal Welfare/Recombinant DNA

a. Human Subjects

The DHHS regulations for the protection of human subjects provides a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that the sponsoring institution, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that the sponsoring institution file a written Assurance of Compliance with the Office of Protection for Research Risks (OPRR).

If a project involves nonexempt human subjects, certification that an appropriate Institutional Review board has reviewed and approved the proposed activity is also required.

b. Vertebrate Animals

The PHS Policy on Humane Care and Use of Laboratory Animals requires that sponsoring institutions (foreign or domestic) proposing to use vertebrate animals file a written Animal Welfare Assurance with the OPRR, establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities

supported by PHS. Verification of the date the Institutional Animal Care and Use Committee approved the project is also required.

For additional information on either Human Subjects or Vertebrate Animals please refer to the Individual NRSA application kit or contact the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd., Bethesda, Maryland 20892, Telephone: (301) 496-7163.

c. Recombinant DNA

The current NIH Guidelines for Research Involving Recombinant DNA Molecules and announcements of modifications and changes to the Guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20892. All research involving recombinant DNA techniques that is supported by the DHHS must meet the requirements of these Guidelines.

III. Institutional National Research Service Awards (Training Grants)

A. General

The National Institutes of Health (NIH) will award National Research Service Award (NRSA) Institutional Training Grants (T32s, T34s, & T35s) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical and behavioral research. The purpose of the NRSA program is to help ensure that highly trained scientists are available in adequate numbers and in the appropriate research areas and fields to carry out the Nation's biomedical and behavioral research agenda. The NRSA program supports both predoctoral and postdoctoral research training as well as limited specialized support at the prebaccalaureate

level. Note, all NIH awarding components except the Fogarty International Center (FIC) and the National Library of Medicine (NLM) make institutional awards under NRSA. FIC & NLM have unique funding authorities for training grants that are not under the NRSA.

1. Eligibility

a. Applicant Eligibility

A domestic, non-profit public or private institution may apply for a grant to support a research training program in a specified area(s) of research. Support for predoctoral, postdoctoral, or a combination of trainees may be requested. (Specific program announcements should be referred to for awarding component guidelines.) Support for short-term training positions for students in health-professional degree programs may also be requested as indicated under 2.c. below. Each applicant institution must submit an application according to instructions, using the appropriate forms (see Section B).

b. Research Areas

National Research Service Awards may be made for research training in areas which fall within the mission of the NIH awarding components. Applications which do not fit these areas will be returned. An increased emphasis has been placed on the research training of physicians. The Secretary, DHHS is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of two consecutive years of biomedical and behavioral research training.

The applicant institution must have a strong research program in the area(s) proposed for research training and must have the requisite staff and facilities required to carry out the proposed program. The research

training program director at the grantee institution will be responsible for the selection and appointment of trainees and the overall direction of the training program. In selecting trainees, the program director must make certain that individuals receiving support meet the eligibility requirements set forth in these guidelines.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical or behavioral research with the primary objective of developing or extending their research skills and knowledge in preparation for a research career.

c. Research Training Program

The National Research Service Award must be used to support a program of research training. The NRSA may not support studies leading to the M.D., D.O., D.D.S., D.V.M., or other clinical, health professional degrees; nor to support residencies, the primary purpose of which is the attainment of a medical or nursing specialty. Research trainees in clinical areas are expected to devote full time to the proposed research training. During the 40 hours per week required for research training, any clinical duties should be confined to those which are part of the research training.

2. Degree Requirements

a. Predoctoral Training

Predoctoral research training is for individuals who have a baccalaureate degree and are enrolled in a doctoral program leading to the either the Ph.D. degree, a comparable research doctoral degree, or the combined M.D./Ph.D. Students enrolled in health-professional programs that are not part of a formal, combined program (i.e., M.D./Ph.D.) and who wish to postpone their professional studies in order to gain research experience, may also be appointed to a T32 grant. Predoctoral research training must

emphasize fundamental training in areas of basic biomedical and behavioral sciences.

b. Postdoctoral Training

Postdoctoral research training is for individuals who have received a Ph.D., an M.D., or comparable doctoral degree from an accredited domestic or foreign institution. Research training at the postdoctoral level must emphasize specialized training to meet national research priorities in the biomedical and behavioral sciences.

Research training grants are a desirable mechanism for the postdoctoral training of physicians and other health professionals who may have had extensive clinical training but limited research experience. For such individuals, the training may be a part of a research degree program. In all cases, health-professional postdoctoral trainees should agree to engage in at least 2 years of research, research training, or comparable experiences beginning at the time of appointment since the duration of training has been shown to be strongly correlated with post-training research activity.

c. Short-Term Research Training

Students in Health Professional Schools NIH offers two short-term training programs; those which are part of a traditional institutional training grant (T32) and those which exclusively support short-term trainees (T35). These short-term research training experiences of two to three months are available to students in health professional schools. All short-term training must be full-time. Unless otherwise stated, provisions for institutional training grants apply. See [Appendix 1](#) for current stipend levels.

(1) T32

T32 applications may include a request for short-term positions reserved

specifically to train medical or other health-professional students on a full-time basis during the summer or other "off-quarter" periods. Short-term appointments are intended to provide health-professional students with opportunities to participate in biomedical and/or behavioral research in an effort to attract these individuals into research careers.

To be eligible for short-term research training positions, health-professional students must have completed at least one quarter at an accredited health-professional school leading to a clinical doctorate prior to participating in the program. Trainees need not be enrolled at the applicant institution.

Individuals matriculated in a formal research degree program, or those holding an M.S., a Ph.D., an M.D./Ph.D. or an equivalent graduate level research degree are not eligible. Within schools of pharmacy, only individuals who are candidates for the Pharm. D. degree are eligible.

Short-term positions should be longer than 2 months but may not last longer than 3 months. Students should be encouraged to obtain two or more periods of short-term research training during their studies leading to a health-professional degree. Such appointments may be consecutive or may be reserved for summers or other "off-quarter" periods.

Since some NIH institutes support short-term research training positions on a limited basis, applicants are strongly urged to contact the appropriate NIH awarding component before requesting short-term research training positions as part of a T32 application.

(2) T35

Several NIH awarding components provide short-term research using a separate training grant mechanism (T35). The program intent and student eligibility requirements are similar to those indicated above. However,

since this NRSA funding mechanism is used by only a few NIH awarding components, interested applicants are encouraged to contact specific awarding components for details.

d. Prebaccalaureate Training

Under the auspices of the institutional undergraduate NRSA (T34) two distinct programs for prebaccalaureate training are offered. Both programs are designed to support students from institutions with a substantial minority enrollment.

(1) The National Institute of General Medical Sciences (NIGMS) administers the MARC Undergraduate Student Training and Research (U*STAR) program.

Formerly know as Honors Undergraduate Research Training Program (HURT), this training program is designed to support selected junior/senior undergraduate honors students at baccalaureate colleges and universities.

The NIGMS recognizes that because of the heterogeneity at minority institutions there are differences in institutional missions. Therefore, the emphasis of this program will be on the specific objectives and measurable goals which the applicant institution sets for itself as being achievable. For more information on this program, contact:

MARC Program, NIGMS
Room 2AS.37D
45 Center Drive MSC 6200
Bethesda, Maryland 20892-6200

Phone: (301) 594-3900

Fax: (301) 480-2753

(2) The National Institute of Mental Health (NIMH) administers the Career Opportunities in Research (COR) Education and Training Program.

The intent of this program is to strengthen research and research training experiences in scientific disciplines related to mental health. An applicant institution (a four-year college or university) must propose a two-year COR Honors Undergraduate Program for which six to ten highly talented third and fourth-year undergraduate students will be selected. Students will be provided with special research training experiences designed to improve their qualifications for entry into advanced research training programs leading to the doctoral-level or M.D. research career degrees. For more information on this program contact:

COR Program Office of Special Populations/NIMH
Parklawn Building, Room 17C14
Rockville, Maryland 20852

Ph: (301) 443-2847

3. Citizenship

The individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. A non-citizen national is a person, who, although not a citizen of the United States, owes permanent allegiance to the U.S. They are generally persons born in outlying possessions of the United States (e.g.; American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must be in possession of a currently valid Alien Registration Receipt Card (I-551), or must be in possession of other legal verification of such status. For example, if an individual is in possession of the proper validation on their passport, a notarized photocopy of the passport could suffice. Since there

is a six-month limitation on this validation, it is the responsibility of the grantee institution to follow-up and assure that the individual received the I-551 prior to the six month expiration date.

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment Form (PHS Form 2271). Individuals on temporary or student visas are not eligible for support from the NRSA.

B. Applications and Receipt Dates

1. Application

The application for the institutional training grant is Form PHS 398. It contains special instructions for Institutional National Research Service Awards. Application kits containing forms, instructions, and related information may be obtained from:

The Division of Extramural Outreach and Information Resources, OER, NIH
6701 Rockledge Drive, MSC 7910
Bethesda, MD 20892-7910

Phone: (301)-435-0714

E-mail: asknih@odrockm1.od.nih.gov

2. Receipt Dates

Many of the NIH awarding components receive training grant applications three times each year. Some awarding components have only one or two receipt date(s). Information on receipt dates is available in the NIH-wide T32 Information Statement or in RFAs issued by the individual awarding components. See Appendix 2 for a complete listing of the current receipt

dates and review cycle. Applicants are encouraged to contact appropriate NIH staff before preparing and submitting an application.

C. Review

1. Overall

Each initial and competing continuation application will be evaluated for scientific merit by a NIH peer review group. Institutional applications must also be reviewed by the appropriate Council or Board of the awarding component whose activities relate to the proposed research training. Institutional applications will be evaluated using criteria such as: a) past research training record of both the program and the designated preceptors; b) objectives, design, and direction of the research training program; c) caliber of preceptors as researchers including successful competition for research support; d) recruitment and selection plans for trainees and the availability of high quality candidates; and e) the institutional training environment including the level of institutional commitment, quality of the facilities, availability of appropriate courses, and the availability of research support.

In addition, where appropriate, the record of the research training program in retaining health-professional postdoctoral trainees for at least two years in research training or other research activities; and the concomitant training of health-professional postdoctorates (e.g., individuals with the M.D., D.O., D.D.S.) with basic science postdoctorates (e.g., individuals with a Ph.D., Sc.D.) or linkages with basic science departments will receive special consideration.

While overall criteria are described above, applicants are encouraged to consult the PHS 398 application kit, the NIH T32 program announcement and/or specific awarding component program announcements for specific

details.

2. Short-Term Research Training Positions

In addition to the overall program criteria described above, applications that request short-term research training positions in conjunction with full-time positions will also be assessed using specific criteria. The NIH T32 program announcement and/or specific awarding component program announcements should be consulted for details.

3. Minority Recruitment Plan

The NRSA institutional training grant program must provide for the recruitment and retention of individuals from underrepresented minority groups including, but not limited to, African Americans, Hispanics Americans, Native Americans, Alaskan Natives and Pacific Islanders. All competing applications for institutional NRSA research training grants must include a specific plan to recruit minorities, and competing continuation applications also must include a report on the recruitment and retention record during the previous award period. If an application is received without a plan, or without a report on the previous award period, the application will be considered incomplete and may be returned to the applicant without review. Additional information on this requirement is available in the NIH T32 Program Announcement.

Competing continuation applications for research training grants must include a detailed section on the outcomes of the minority recruitment plan proposed in the previous competing application. Information must be included on successful and unsuccessful recruitment strategies. The report should provide information on the racial/ethnic distribution of:

students and/or postdoctorates in the department(s) relevant to the training

grant;

individuals who applied for research training;

individuals who were offered admission; and

individuals who were appointed to the research training grant.

For those trainees who were appointed to the grant, the report should include information about the duration of research training and whether those trainees have finished their training in good standing.

Peer reviewers will examine and evaluate the minority recruitment plan and any record of recruitment and retention after the overall educational and technical merit of an application has been assessed so that the quality of the plan will not be a factor in determining the priority score. For competing continuation applications, the reviewers will examine and evaluate the record of the program in recruiting and retaining underrepresented minority trainees during the previous award period. The panel also will consider whether the experience in recruitment during the previous award period has been incorporated into the formulation of the recruitment plan for the next award period.

The findings of the panel will be included in an administrative note in the summary statement. If the minority recruitment plan of the application is judged to be unacceptable, funding will be withheld until a revised plan that addresses the deficiencies is received. Staff within the NIH awarding component, with guidance from the appropriate national advisory committee or council, will determine whether amended plans and reports submitted after the initial review are acceptable.

Information on the recruitment and retention of underrepresented minority trainees appointed during the previous period must also be provided in

progress reports included in all non-competing applications.

4. Training in the Responsible Conduct of Research Training

All competing NRSA institutional training grant applications must include a description of the formal and informal activities related to instruction on the responsible conduct of research that will be incorporated into the proposed research training program. Every prebaccalaureate, pre and postdoctoral NRSA trainee must receive instruction on the responsible conduct of research. Applications must include a description of a program to provide formal or informal instruction in scientific integrity and/or the responsible conduct of research. Applications without plans for instruction in the responsible conduct of research will be considered incomplete and may be returned to the applicant without review.

Although the NIH does not establish specific curricula or formal requirements, all programs are encouraged strongly to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management. Within the context of training in scientific integrity it is also beneficial to discuss the mutual responsibilities of the institution and the trainees participating in the program.

Plans must address the subject matter of the instruction, the format of the instruction, the degree of faculty participation, trainee attendance requirements, and the frequency of instruction.

The rationale for the proposed plan of instruction must be provided.

Program reports on the type of instruction provided, topics covered, and other relevant information, such as attendance by trainees and faculty participation, must be included in future competing continuation and

noncompeting applications.

The NIH encourages institutions to provide instruction in the responsible conduct of research to all individuals in a training program or department, regardless of the source of support.

NIH initial review groups will assess the applicant's plans on the basis of the appropriateness of topics, format, amount and nature of faculty participation, and the frequency and duration of instruction. The plan will be discussed after the overall determination of merit, so that the quality of the plan will not be a factor in the determination of the priority score. Plans will be judged as acceptable or unacceptable. The acceptability of the plan will be described in an administrative note on the summary statement. Regardless of the priority score, applications with unacceptable plans will not be funded until a revised, acceptable plan is provided by the applicant. The acceptability of the revised plan will be judged by staff within the NIH awarding component.

Following initial review, applications undergo a second level review by the appropriate NIH institute or center council, board, or other advisory group. These advisory groups will consider, in addition to the assessment of the scientific and educational merit of the research training grant application, the initial review group's comments on the recruitment of individuals from underrepresented minority groups into the research training program and the plan for instruction in the responsible conduct of research.

Information on the nature of the instructions in the responsible conduct of science and the extent of trainee and faculty participation must also be provided in progress reports included in all non-competing applications.

D. Notification of Action

Shortly after the initial review meeting, each applicant will be sent a mailer

that includes the SRG recommendation/priority score and the name of a program official in the assigned NIH awarding component. The awarding component automatically forwards a copy of the summary statement to the applicant as soon as possible after receipt from the SRG. The applicant will be notified by letter concerning the final review recommendation. A Notice of Grant Award will be issued to applicants selected for funding. Any questions about initial review recommendations and funding possibilities should be directed to the appropriate awarding component program official, not the scientific review administrator of the SRG.

E. Period of Support

1. Institutional Grants

Grants may be made for competitive segments of up to five years and are renewable. Awards within an approved competitive segment are normally made in 12-month increments with support for additional non-competitive years dependent upon satisfactory progress and availabilityof funds.

2. Trainees

a. Trainees are customarily appointed for full-time 12-month continuous periods. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding component. All trainees are required to pursue their research training on a full-time basis, normally defined as 40 hours per week or as specified by the grantee institution in accordance with its own policies. The amount of the stipend, tuition and fees for each full period of appointment must be obligated from funds available at the time the individual begins training unless other instructions are furnished by the awarding component.

b. With the exception of specifically designated short-term research training positions, no trainee may be appointed under a regular institutional

grant for a period of less than nine months except with the prior written approval of the awarding component and then usually only to complete a planned program of training. An initial appointment of less than nine months may be allowed as long as an assurance is included that the individual will be immediately reappointed in the subsequent year so that the cumulative continuous training period is at least nine months.

3. NRSA Limitations

No individual trainee may receive more than five years of aggregate NRSA support at the predoctoral level and three years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional and individual awards. Any exception to this requires a waiver from the Director of the awarding component or designee based on review of justification from the individual and grantee institution. The for approving extensions of support are as follows:

a. Physicians/Clinicians

Individuals requiring additional time to complete training, either as a participant in a combined M.D.-Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon certification of the recipient's good academic standing and justified need for the exception to policy.

b. Interruptions (Break-in-Service)

Requests for additional time will also be considered if an event unavoidably has altered the planned course of the research training; the interruption has significantly detracted from the nature or quality of the planned research training; and if a short extension would permit

completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation which prevents a trainee from pursuing research training in an effective manner for a significant period of time. Requests for extension of support will also be considered if a short additional period would provide the trainee an opportunity to use an exceptional training resource directly related to the approved research training program.

c. Other Exceptions

Requests that do not arise from circumstances considered in 3.a or 3.b above will be considered if they are accompanied by an exceptionally strong justification. Requests must be made in writing to the NIH awarding component by the trainee. The trainee's program director and an authorized institutional official, must endorse the request certifying the need for additional support. The request must include a sound justification and specify the amount of additional support for which approval is sought.

Requests must be approved by the Director of the awarding component or designee.

F. Initiation of Support

A Notice of Grant Award is issued to the grantee institution, normally with a budget period of 12 months. A predoctoral or postdoctoral trainee may be appointed at any time during the course of the budget period for an appointment period of 9 to 12 months, without prior approval by the awarding component. At the time of the initial appointment and subsequent reappointments, the training program director must submit a Statement of Appointment Form to the awarding component. Additionally, a signed Payback Agreement must be submitted for each postdoctoral trainee who is in his/her first 12 months of NRSA postdoctoral support. (See Sections H.1. and 2 for specific information on required forms). The Statement of

Appointment Form includes biographical data on the trainee and the stipend level for the period of appointment. The stipend is paid by the grantee institution directly to the trainee.

G. Financial Provisions

1. Stipends

A stipend is provided as a subsistence allowance for trainees and fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal Government or the grantee institution. Changes in stipend levels are published in the NIH Guide for Grants and Contracts. Stipends must be paid in accordance with stipend levels set by this policy. No departure from the standard stipend schedule, as provided from the grant, may be negotiated by the grantee institution with the trainee. For appointments of less than 12 months, the stipend will be prorated.

a. Levels (Current annual stipend amounts are detailed in [Appendix 1](#))

(1) Prebaccalaureate

Two separate levels are provided for trainees: Freshman/Sophomore or Junior/Senior.

(2) Predoctoral

One stipend level is used for all predoctoral individuals regardless of the level of experience.

(3) Postdoctoral

The stipend level for the entire first year of support i s determined by the number of full years of relevant postdoctoral experience at the time of

appointment. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health related field beyond that of the qualifying doctoral degree.

Once the appropriate stipend level has been determined, the trainee must be paid at that level for the entire period of appointment. The stipend for each additional year of NRSA support is the next level in the stipend structure and does not change mid-year.

b. Stipend Supplementation

Trainees are supported for 12-month full-time training appointments for which they receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation is without obligation to the trainee. An institution can determine what amount of stipend supplementation, if any, will be provided according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar training status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. An individual may make use of Federal educational loan funds or V.A. benefits when permitted by those programs as described below in Section G.1.d & e.

Under no circumstances may Public Health Service (PHS) funds be used for supplementation.

c. Student Compensation

It is recognized that trainees as students may seek part-time employment coincidental to their training program in order to further offset their expenses. In circumstances of actual employment, the funds provided as

compensation (salary or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation. Funds characterized as compensation may be paid to trainees when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in the PHS Grants Policy Statement. Under these conditions trainees may be compensated for actual employment on Federal grants, including PHS research grants. However, it is expected that compensation from research grants will occur on a limited part-time basis for employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant which supports the same research that is part of the trainee's planned training experience as approved in the training grant application. Institutional training grant program directors must approve all instances of employment on research grants in order to verify that the circumstances will not detract from or prolong the approved training program.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved NRSA training program. Additionally, compensation must be in accordance with institutional policies applied consistently to both federally and non-federally supported activities and supported by acceptable accounting records determined by the employer-employee relationship agreement.

d. Concurrent Benefits

A National Research Service Award may not be held concurrently with another Federally-sponsored fellowship or similar Federal award which

provides a stipend or otherwise duplicates provisions of the NRSA.

e. Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the Veterans Administration (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation. In the case of the MARC-USTAR program, funds from a PELL grant may be accepted as well. f. Taxability of Stipends Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. The Tax Reform Act of 1986, Public Law 99-514, impacts on the tax liability of all individuals supported under the NRSA program. New statutory requirements were effective as of January 1, 1987.

Degree candidates may now exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are now required to report as gross income all stipends and any monies paid on their behalf for course tuition and fees required for attendance.

The taxability of stipends, however, in no way alters the relationship between NRSA trainees and institutions. NRSA stipends are not considered salaries. In addition, trainees supported under the NRSA are not considered to be in an employee-employer relationship with the NIH or the grantee institution.

It must be emphasized that the interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to

their situation and for information on their tax obligations.

g. Form 1099

Since stipends are not considered salaries, for the purposes of income tax reporting, stipend payments should be reported on the IRS Form 1099, Statement of Miscellaneous Income. The business office of the grantee institution will be responsible for the annual preparation and issuance of the IRS Form 1099 for trainees.

h. Employee Benefits

Since NRSA awards are not provided as a condition of employment with either the Federal government or the grantee institution, it is inappropriate and unallowable for institutions to seek funds for or to charge institutional training grants awards for costs that would normally be associated with employee benefits (for example, FICA, workman's compensation, and unemployment insurance).

2. Other Direct Costs

a. Training Related Expenses

Funds are provided to defray such training costs as staff salaries, consultant costs, equipment, research supplies, staff travel, and other expenses directly related to the training program. Funds are requested and awarded as a lump sum on the basis of the predetermined amount per predoctoral and postdoctoral trainee approved for support. Levels are published in the NIH Guide for Grants and Contracts. Current levels are found in Appendix 1. Interested applicants should be advised to consult the program announcement regarding the specific level for programs such as the short-term training program, the MARC program, or the COR

program.

Under exceptional circumstances, which can include accommodating the disabilities of a trainee, it is possible to request institutional costs above the standard rate. Requests for additional costs must be explained in detail and carefully justified in the application. Consultation with NIH program staff in advance of such requests is strongly advised.

b. Trainee Tuition and Fees

Tuition, fees, and health insurance are allowable trainee costs only if such charges are required of all persons in a similar training status at the institution, without regard to their source of support. Family health insurance is not an appropriate charge. However, the trainee may elect personally to pay the differential between self and family health insurance options. Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires prior approval of the awarding component. For the purposes of award, tuition, fees and health insurance are awarded together in a single budget category. Funds are awarded based on a formula applied to the requested level. The formula is described in [Appendix 1](#).

c. Trainee Travel Costs

If requested by the institution, the awarding component may award grant funds to cover the costs of trainee travel including attendance at scientific meetings which the institution determines to be necessary to the individual's training. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution, except that the grantee institution may authorize a one-way travel allowance in an individual case of extreme hardship.

In addition, support for travel to a research training experience away from

the grantee institution may be permitted. Research training experiences away from the parent institution must be justified considering the type of opportunities for training available, how these opportunities differ from those offered at the parent institution, and the relationship of the proposed experience to the trainee's career stage and career goals. This type of research training requires prior approval from the awarding component. Letters requesting such training may be submitted to the awarding component at any time during the award period.

d. Short-term

The institution may receive up to $125 per month to offset the costs of tuition, fees, travel, supplies, and other expenses for each short-term, health-professional research training position.

3. Rebudgeting of Funds

a. Trainee Related Expenses

Expenditure and rebudgeting of funds awarded in lump sum for trainee related expenses do not require awarding component prior approval.

b. Trainee Costs

For the purposes of rebudgeting, trainee costs include stipends and tuition and fees (including health insurance). These costs may not be used for other purposes except under unusual circumstances and then only with the prior written approval of the awarding component. Rebudgeting into or within the stipends and tuition/fees categories is allowable without awarding component prior approval.

c. Trainee Travel

For the purposes of rebudgeting, trainee travel is not considered a trainee

cost and, therefore, may be rebudgeted into any other budget category without prior approval.

4. Expenditure of Funds

Policies governing expenditure of all training grant funds are those permitted under the PHS Grants Policy Statement and applicable cost principles, unless otherwise indicated in the Notice of Grant Award.

5. Facilities and Administrative (F&A) Costs

Previously referred to as indirect costs, in FY96 NIH received a deviation from DHHS policy regarding the reimbursement of these costs for institutional training grants. The institution will receive F&A costs based solely on 8% of total direct costs exclusive of tuition and fees and health insurance, and expenditures for equipment.

Applications from State and local government agencies, except State universities or hospitals, may receive full F&A cost reimbursement.

6. Program Income

Policy requires applicants for PHS research grants, including training grants, to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. The specific policies that govern the treatment of program income are set forth in the PHS Grants Policy Statement.

H. Reporting Procedures

The following documents are critical to the process of establishing the payment of stipends and other costs, as well as the determination of possible payback service. Failure to submit the required forms in a timely

manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

1. Statement of Appointment (Form PHS 2271, See [Appendix 4](#))

a. Grantee Submission

The institution must submit this form to the NIH awarding component prior to or at the start of each trainee's appointment or reappointment. No stipend or other allowance may be paid until the appointment form has been submitted. If the support covers the individual's initial 12 months of postdoctoral support, a signed Payback Agreement must also be submitted.

It is important to note that the information on the Statement of Appointment and the Termination Notice is the basis for determination of the length or amount of an individual's payback requirement. An accurate social security number should be included on the Statement of Appointment and all other documents. The program director and the institutional financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating costs (stipends) which later are reflected on the Termination Notice and as part of the total costs in the Financial Status Report. A supply of Statement of Appointment Forms (PHS 2271) is provided to the program director by the awarding component. In FY96, NIH began piloting the electronic receipt of the information on the PHS 2271. A number of grantee institutions are currently testing this system.

b. Awarding Component

Processing All records relating to NRSA support and payback are maintained in a centralized NIH computer system. This system is now interactive, thus most awarding components are responsible for

establishing and maintaining these computer records. No changes are to be made to the computer record without supporting documentation.

When the awarding component receives Statement of Appointment Forms (Form 2271), the forms are reviewed for accuracy and completeness. Upon receipt and acceptance of each completed Form 2271, the awarding component establishes a computer record for each NRSA recipient by entering the data into the interactive NIH IMPAC I/II FILE. The actual form is retained as part of the official file.

c. Interim Revisions

Any changes or corrections involving a trainee appointment under an institutional grant, such as, name, permanent mailing address, period of training, stipend support, must be reported by the training program director to the awarding component on an amended PHS-2271 at the time of the change.

2. Payback Agreement (Form PHS 6031, See [Appendix 5](#))

A National Research Service Award Payback Agreement must be signed by each postdoctoral individual for whom the appointment covers his/her initial 12 months of postdoctoral NRSA support.

If the individual has already received 12 months of postdoctoral support under any NRSA grant or award, this form is not required. No Payback Agreement is required for predoctoral or prebaccalaureate trainees. The Payback Agreement is retained along with the Statement of Appointment Form as part of the official file. For detail on NRSA payback, see [Section IV](#).

3. Termination Notice (Form PHS 416-7, See [Appendix 6](#))

The Termination Notice (Form 416-7) is the basis (along with the Statement of Appointment Form) for validating the total period of NRSA support and the amount of payback obligation (if any) for each NRSA trainee.

a. Requesting the Termination Notice

For an institutional award, the awarding component sends the program director a supply of Termination Notices on an annual basis. The program director is responsible for the submission of a Termination Notice on each trainee immediately upon the termination of his/her support. If an awarding component has not received a Statement of Appointment Form indicating reappointment within 30 days of the appointment anniversary, awarding component staff should determine if the trainee has terminated support or received consecutive support (see Section H.4 below) by contacting the program director. In the case of termination, a Termination Notice is requested from the program director.

b. Termination Follow-up

If an awarding component has not received a Termination Notice within 30 days of termination, follow-up should be done through training grant program director.

The program director is requested to have the trainee complete the Termination Notice within a second 30-day period, or if the individual cannot be located, the program director is requested to complete the Termination Notice immediately and return it to the awarding component. All items are to be completed except in the latter situation, the section titled Signature of Fellow/Trainee. In this section, the program director should indicate "Trainee Unavailable for Signature."

The best available address for the trainee should be included.

c. "Proxy" Termination Notice

If it is impossible to obtain a Termination Notice from either the trainee or the grantee institution, a "proxy" Termination Notice should be prepared by the awarding component. Thorough documentation regarding the efforts made to secure the Termination Notice should be maintained. The form should be completed with as much information as possible and appropriately annotated to document the circumstances.

Using the last known address, a copy of the Termination Notice should be mailed with a covering letter to the trainee. The letter should explain the future actions and responsibilities in fulfilling the payback obligation, if any.

d. Validation and Distribution of the Termination Notice

(1) The awarding component reviews each Termination Notice for accuracy and completeness and verifies the amount of stipend support and the number of months of training. If inaccuracies are found in a Termination Notice it should be returned to the institution for revision. Such inaccuracies can include improper signatures, lack of initialed corrections, incorrect stipend amounts and/or incorrect periods of appointment.

(2) After assuring completeness and accuracy of all information, the awarding component:

(a) may send a validated copy of the Termination Notice to the trainee.

If the individual received NRSA support prior to June 10, 1993 and had a total of 12 months or less of NRSA support, he/she should be informed that there is no payback obligation. If a payback obligation does exist and if the trainee did not complete the notice, a letter accompanies the

validated copy indicating that the payback obligation has been established based on NIH records and the Termination Notice which was prepared in conjunction with the grantee institution.

(b) enters the data from the Termination Notice into the IMPAC I/II File.

By entering the Termination Notice information, a mailer is automatically generated and mailed by OPERA staff to each trainee acknowledging receipt of the Termination Notice and requesting that any change in name, address or social security number be reported to the cognizant awarding component.

(c) maintains the validated original Termination Notice in the individual payback record.

his file may include the Payback Agreement and original of the Statement of Appointment as well as other documents relevant to the payback process.

(3) The validation and distribution of copies should be completed within a maximum of 90 days after termination.

4. Consecutive Support

a. If a trainee switches from one NRSA grant mechanism to another, including from one awarding component to another, the requirement for payback service incurred is deferred until the total NRSA support is completed. All Statement of Appointment forms are reviewed to determine if previous NRSA support has been provided.

Previous NRSA support can be verified by checking the NRSA record in IMPAC. When consecutive support is provided by a different awarding component, that component updates the record in the IMPAC system. As

additional verification, the Data Integrity Unit (DIU), OER notifies both components of consecutive support when a subsequent Termination Notice is entered into the IMPAC I/II File.

b. The original awarding component provides the pertinent original of the Statement of Appointment or Activation Notice, Payback Agreement, Termination Notice, and Fellowship Award Notice, when applicable, as well as any validated APACs to the gaining awarding component. That component is responsible for monitoring the payback obligation for the trainee's total period of support even if all the obligation was incurred while supported by the original awarding component.

5. Verification Reports

Upon awarding component request to the DIU, a computer list identifying trainees for whom a Statement of Appointment has been received by the NIH will be mailed to program directors 60 days after the budget period end date of each institutional grant. The list must be verified by the program director and an appropriate business official and returned to the DIU within 30 days after receipt.

I. Progress Reports, Financial Status Reports, and Changes in the Project

1. Progress Reports

Progress reports must be submitted with all applications for non-competing continuation support in accordance with the instructions accompanying the application forms. Incomplete or inadequate progress reports may be returned for revision and may result in a delay of continued support. In addition, a final progress report must be submitted to the awarding component within 90 days after the end of a final competing segment of a

project period.

2. Financial Status Report (FSR)

An FSR is required for all institutional grants no later than 90 days after the close of each budget period. This report will document the financial status of the grant according to the official accounting records of the grantee institution. Trainee stipends and tuition are obligated for the full 12-month appointment from the budget period in which the appointment is initiated. Portions of stipends and tuition that extend beyond the budget period are carried over as unliquidated obligations. However, the report for the final budget period must have no unliquidated obligations and must indicate the exact balance of unobligated funds.

3. Changes in the Project

a. Changes in the program objectives as they relate to the area of research training for which the grant was approved require prior approval from the NIH awarding component.

b. Where absence of the program director is expected to exceed a continuous period of more than three months, plans for the conduct of the program during his or her absence must be approved in writing by the awarding component. Any proposed change of program director must be requested by the grantee institution and be approved in writing by the awarding component following review of the nominee's qualifications and re-evaluation of the project in the light of the proposed change.

c. Institutional grants are not transferred from one domestic institution to another except under most unusual circumstances. Such a change will generally be approved only if all of the major benefits attributable to the original grant can be transferred and there is no negative impact on

trainees active in the program.

J. Other Terms and Conditions

1. Leave

a. Vacations and Holidays

Trainees may receive the same vacations and holidays available to individuals in comparable training positions at the grantee or sponsoring institution. Trainees shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters is generally considered an active part of the training period.

b. Sick Leave and Other Leave

Trainees may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the awarding component in response to a written request from the training program director or the sponsor. Sick leave may be used for the medical conditions related to pregnancy and childbirth pursuant to the Pregnancy Discrimination Act (42 USC 2000 e(k)).

c. Parental Leave

Trainees may also receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee or sponsoring institution have access to paid leave for this purpose. Either parent is eligible for parental leave. For trainees, the use of parental leave must be approved by the training program director.

A period of terminal leave is not permitted and payment may not be made

from grant funds for leave not taken.

d. Unpaid Leave

Individuals requiring extended periods of time away from their research training experience, which could include more than 15 calendar days of sick leave or more than 30 calendar days of parental leave must seek approval from the awarding component for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by the training grant program director and be countersigned by an authorized institutional official.

During a leave of absence, documentation to suspend the period of appointment must be completed by submitting an amended Statement of Appointment Form and a Termination Notice. These forms should be submitted to the awarding component at the beginning of the leave. At the resumption of NRSA support, the reappointment must be documented on another Statement of Appointment Form.

2. Termination

A training grant may be terminated prior to its normal expiration date at the written request of the recipient, or by the Director, NIH, if it is found that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. In the event an award is terminated for cause, the Director shall notify the awardee in writing of this determination, the reasons therefore, the effective date, and the right to appeal the decision.

3. Publications

Trainees are encouraged to submit reports of their findings for publication to the journals of their choice. Responsibility for direction of the project

should not be ascribed to NIH. However, awarding component support must be acknowledged by a footnote in language similar to the following: "This Investigation was supported by National Institutes of Health, National Research Service Award (number) from the (awarding component) ."

In addition, it is now mandated that all grantees funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Grantees are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

4. Copyright

Except as otherwise provided in the conditions of the award, when publications or similar copyrightable materials are developed from work supported by NIH the author is free to arrange for copyright without awarding component approval. Any such copyrighted material shall be subject to royalty-free, nonexclusive, and irrevocable license to the Government to reproduce them, translate them, publish them, use and dispose of them, and to authorize others to do so for Government purposes.

5. Patents

No training grant made by PHS primarily to an awardee for educational purposes will contain any provision giving PHS any rights to inventions made by the awardee.

6. Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other

comparable activities performed pursuant to the purpose of the award may not be retained by the trainee/fellow. Such fees will be assigned to the grantee institution for disposition in accordance with PHS policy on grant related income. The term professional fees does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private nonprofit organizations.

These fees, if within institutional policy, may be retained by the awardee.

7. Human Subjects/Animal Welfare/Recombinant DNA

a. Human Subjects

The DHHS regulations for the protection of human subjects provides a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. If the applicant organization has an approved Assurance of Compliance on file with OPRR but, at the time of application, plans for the involvement of human subjects are so indefinite that Institutional Review Board (IRB) review and approval are not feasible, the grantee should check "Yes" and insert "Indefinite" on the face page of the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB review is already completed or an exemption is already designated. This review or exemption designation is sufficient, providing the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRG review dates or exemption designation.

b. Vertebrate Animals

The PHS Policy on Humane Care and Use of Laboratory Animals requires that grantee institutions (foreign or domestic) proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Protection from Research Risks (OPRR), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by PHS. If the applicant organization has an approved Assurance of Compliance on file with OPRR but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that Institutional Animal Care and Use Committee (IACUC) review and approval are not feasible, the grantee should check "Yes" and insert "Indefinite" on the face page of the application. If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IACUC review is already completed. This review is sufficient, providing the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. For additional information on either Human Subjects or Vertebrate Animals please refer to the PHS 398 application kit or contact the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd. Bethesda, Maryland 20892, Telephone: (301) 496-7163.

c. Recombinant DNA

The current NIH Guidelines for Research Involving Recombinant DNA Molecules and announcements of modifications and changes to the

Guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20892. All research involving recombinant DNA techniques that is supported by the DHHS must meet the requirements of these Guidelines.

IV. Payback Reporting Requirements for Recipients

A. Purpose and Background

The National Research Service Award (NRSA) legislation requires some recipients of support to pay back the Federal Government by engaging in health-related biomedical or behavioral research including the direct administration or review of health-related research, health-related teaching, or any combination of these activities. Recent policy changes have significantly broadened the definition of "health-related." See Section C.1.a.(3) for a complete interpretation.

The National Institutes of Health (NIH) Revitalization Act of 1993, signed into law on June 10, 1993, includes provisions in Section 1602 that substantially modify the service payback requirement for individuals supported by the NRSA. For research training grants, these new provisions are applicable to all new appointments or reappointments on or after June 10, 1993. For individual fellowships, these provisions apply to all fellowship awards beginning on or after June 10, 1993. For competing fellowships, the award beginning date refers to the award activation date.

An individual who was appointed to a research training grant or who had a fellowship award activated before June 10, 1993 would be governed by the service payback provisions in effect at the time of the appointment or award until the end of that appointment or budget period.

B. Implementation

The incurrence of a payback obligation for an NRSA recipient is solely dependent upon when NRSA support was received.

1. Prior to August 13, 1981 (enactment of the Omnibus Reconciliation Act), a payback obligation existed for all prebaccalaureate, predoctoral, and postdoctoral support received.

2. Effective August 13, 1981, a 12-month legislative allowance waiving payback obligation for the first 12 months of support was enacted for all predoctoral and postdoctoral trainees/fellows. This legislation provided that all trainees/fellows who were not in delinquent status on that date received the allowance (this was retroactive to the beginning of the NRSA program).

Individuals in delinquent status continued to have a payback obligation for all support received. This legislative change also eliminated the payback obligation for prebaccalaureate recipients. Historically, short-term trainees supported by the T35 mechanism (NRSA Short-Term Training) incurred no payback obligation. However, for short-term trainees supported within a T32 program, the period(s) of support accrued and ultimately counted toward the total NRSA support.

3. Effective June 10, 1993 (NIH Revitalization Act):

a. Predoctoral Recipients

For predoctoral trainees beginning appointments and for predoctoral fellows activating awards on or after June 10, 1993, no payback obligation is incurred. Thus a Payback Agreement Form (PHS 6031) is no longer required.

b. Postdoctoral Recipients

For postdoctoral recipients, a payback obligation is incurred for the first 12 months of NRSA support with the 13th and subsequent months of postdoctoral support serving to pay back this obligation on a month by month basis. A Payback Agreement Form (PHS 6031) is still required but only for the initial 12-month postdoctoral support period.

The requirements established by the Revitalization Act also provide that the 13th and subsequent months of postdoctoral NRSA supported research training will be used to discharge any PRIOR postdoctoral NRSA service payback obligation. See Section IV.C.1.c Initiation of Payback Service for detailed changes effective with the Act.

c. Short-term Training

Any predoctoral short-term training would not incur a payback obligation. Postdoctoral short-term training would incur a payback obligation. Any support would accrue along with any subsequent postdoctoral support until the first twelve months was established. At that point, the 13th and subsequent months of support would serve to offset the obligation on a month-by-month basis. In the event that subsequent postdoctoral support was not received, the individual would have an obligation which would have to be paid back in the traditional manner.

C. Payback

The NIH awarding component, generally assumes responsibility for handling payback activities once the Termination Notice has been submitted and accepted.

For some awarding components, the NIH NRSA Payback Service Center assumes this responsibility. Established in the National Institute of General Medical Sciences effective October 1, 1995, the Payback Service Center personnel represent the NIH's experts in the NRSA Payback arena. For

those awarding components participating in the Center, the authorities normally delegated to the awarding component are automatically delegated to the Chief, NRSA Payback Service Center. Most NRSA recipients eventually fulfill their payback obligation by engaging in activities which are determined to be acceptable service. Some recipients fulfill their obligation via financial payback. On rare occasions waivers of the payback obligation are granted.

As indicated in Section IV.B above, the amount of a payback obligation incurred is solely dependent upon when NRSA support was received. Timing of NRSA support is also a factor on the type of service that qualifies as acceptable payback.

1. Service Payback

a. Definitions

For the purpose of fulfilling the NRSA service payback obligation, the following definitions apply:

(1) Research

Research is defined as an activity which involves the design of experiments, development of protocols, and collection and interpretation of data. In addition, review of original research or administration of original research which includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government, commercial or other environment in either a foreign or domestic setting.

In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions which

involve analytic or other technical activities conducted in direct support of research, as defined above, will also satisfy the service payback obligation.

(2) Teaching

Teaching is an instructional activity that takes place in an organized educational or other instructional environment. Activities classified as teaching are generally carried out in a formal didactic setting but other activities will be considered if they are consistent with the certifying institution's policy on the definition of teaching responsibilities. Such teaching can be conducted at universities, professional schools, research institutes, teaching hospitals, primary schools, secondary schools or colleges. When calculating hours of teaching per week, it is permissible to include three hours of preparation time for each hour of direct instruction.

Acceptable teaching activities must have a biomedical or health-related relevance.

(3) Health-Related

This incorporates a broad range of activities related to the description, diagnosis, prevention or treatment of disease from the most basic biomedical or behavioral research to the most applied or clinical research. In addition to fields usually considered to be directly related to human disease, activities in other fields such as agriculture, environmental sciences, biotechnology, and bioengineering will also be considered health related.

b. Time Commitment

All acceptable activities must be undertaken for periods that average at least 20 hours per week. Total employment in such activities averaging

less than 20 hours per week cannot be counted towards fulfilling the obligation except in cases of disability or other pressing personal or family circumstances such as child care or elder care responsibilities. It is not permissible for individuals otherwise engaged in full-time employment to engage in service payback activities at effort levels below 20 hours per week.

If less than 20 hours commitment per week is permitted, the total period of service obligation will be prorated. For example, an individual who owes 12 months of service and can devote only 10 hours per week to service payback activities due to a disability will be required to engage in such service for 24 months. These exceptions are rare and must receive prior approval from the awarding component.

c. Initiation of Payback Service

(1) Support Received Prior to NIH Revitalization Act

For NRSA recipients who incurred a payback obligation from support received prior June 10, 1993, payback service must be performed following completion of NRSA support. No amount or type of activity prior to or during the period of NRSA support will satisfy the NRSA service payback obligation. However, payback service may be initiated immediately after termination from NRSA if the research or teaching activities meet the criteria cited above.

(2) Support Received Post NIH Revitalization Act

Beginning with awards operating under the NIH Revitalization Act (appointments on or after June 10, 1993), service payback obligations for postdoctoral recipients may be discharged in the following ways:

(a) By receiving an equal number of months of postdoctoral NRSA support

beginning in the 13th month of such postdoctoral NRSA support;

(b) By engaging in an equal number of months of health-related research, training and/or teaching averaging more than 20 hours per week.

(c) Trainees and fellows beginning appointments for the 13th and subsequent month of POSTDOCTORAL NRSA support on or after June 10, 1993 will be engaging in service which will also satisfy prior postdoctoral NRSA service payback obligation. Post-award service in non-NRSA supported health-related research, training, and/or teaching, is creditable toward any NRSA service payback obligation.

(d) Individuals who have completed their predoctoral NRSA training and have an existing NRSA service payback obligation are still required to engage in service payback or make financial repayment. Postdoctoral NRSA support may not be used to satisfy an existing predoctoral payback obligation.

d. Source of Funding

The source of funds supporting an individual's service payback activity is not restricted beyond the fact that for predoctoral payback activities it must not be supported by NRSA. An individual could be supported by a PHS grant or from any non-NRSA Federal or non-Federal source. Unpaid service is also permitted.

e. Timing of Service Obligation

An individual must begin to undertake the payback service requirement within two years after the termination date of the individual's NRSA support unless an extension of time to begin payback has been approved by the awarding component (see Section IV.C.4.a).

2. Alternative Service

a. Policy

Alternative service in lieu of research and teaching was deleted by the Omnibus Budget Reconciliation Act of 1981. Individuals who entered the NRSA program on or after August 13, 1981, the date the Act was signed, are not eligible for alternative service. Individuals who entered the NRSA before August 13, 1981, are governed by the alternative service provisions in effect when their appointment started. The Deputy Director for Extramural Research, NIH must authorize alternative service and make a determination that no suitable research or teaching positions are available to the individual.

The types of permissible alternative service are as follows:

(1) If the individual is a physician, dentist, nurse or other person trained to provide health care directly to individual patients, he or she may:

(a) serve as a member of the National Health Service Corps for a period equal to the period of NRSA support; or

(b) provide services in his or her specialty for a health maintenance organization to which payments must be made under Section 1876 of Title XVIII of the Social Security Act and which serves an underserved population (as defined in Section 1302(7) of the Public Health Service Act); or

(2) If the individual is not trained to provide health care directly to patients, he or she may engage in a health related activity appropriate to his or her education or training.

b. Process

The individual must submit a written request for Alternative Service. The request from the trainee/fellow should describe the effort made to secure a research or teaching position and any specific constraints under which the search for employment has been conducted. If a request relates to the inability of a former trainee/fellow to find an acceptable position, rejection letters or other documentation supporting a reasonable effort to find a suitable position must be provided.

The awarding component, preferably through its Associate Director for Extramural Programs or equivalent, forwards the trainee/fellow's request along with a recommendation to approve (or not approve), through the Research Training Officer (RTO), to the DDER. The RTO evaluates the request. If approval is recommended the RTO prepares a letter from the DDER, NIH to the former NRSA trainee/fellow granting the request. If the request is disapproved, the Associate Director for Extramural Programs in the awarding component will be informed in writing by the RTO. The letter of disapproval sent to the former trainee/fellow will be signed by the Director of the awarding component or a designee.

All recommendations for alternative service must include information on: (1) the grant number(s) of the award(s) under which support was received, (2) the total months of support (predoctoral or postdoctoral), (3) the total amount owed before interest; and (4) whether any payback service was credited. The awarding component should also clearly state the reason for the request and include any documentation provided by the individual.

3. Financial Payback

a. Policy and Principal Calculation

If any individual to whom the requirement for service is applicable fails to undertake or perform such services, the United States Government shall

be entitled to recover from the individual the amount determined in accordance with the following formula plus interest:

$$A = \frac{O (t-s)}{(t)}$$

Where "A" is the amount the United States is entitled to recover, "O" is the sum of total amount paid to the individual under the National Research Service Award support; "t" is the total number of months in service obligation, and "s" is the number of months of such obligation served .

The total paid to the individual under institutional grants and individual awards at domestic, non-federal sponsoring institutions is considered to be the stipend only. The total paid an individual under a fellowship award at a foreign sponsoring institution includes the payment for the round trip travel costs. The total paid an individual under a fellowship award at a Federal sponsoring institution includes any money expended from the institutional allowance provided for such purposes as health insurance, travel, tuition, and fees.

OFM establishes Account Receivable-Interest Receivable account for the principal and interest amounts the United States is entitled to recover.

b. Interest & Interest Rate Calculation

OFM computes interest on the principal amount beginning on the date the U.S. became entitled to recover stipends. The interest rate is the rate fixed by the Secretary of the Treasury after taking into consideration prevailing consumer rates of interest. Accordingly, interest may be accruing on any NRSA obligation if the two-year grace period has passed, or if deferment has expired, or if service has terminated before completion of the payback obligation. The Department of the Treasury certifies NRSA interest rates on a quarterly basis. Interest is computed on a 360 day-a-year basis and is

applied through the date of receipt. Any outstanding amount will continue to bear interest at the initial rate set by the Secretary of the Treasury until financial payback is complete.

Determination of the "date" which sets the applicable rate of interest is dependent upon the type of NRSA account received for collection. If Financial Payback is Voluntary (see Section C.3.c.), the signature date of the notification of voluntary payback is the "date" that determines the interest rate as well as the initiation of the three year repayment period. If Financial Payback is Involuntary (see Section C.3.d.), the "date" which determines the interest rate and the three-year repayment period is the date of expiration of the two-year period following the termination of NRSA support. For example, if during June 1991, the OFM received an account reflecting January 31, 1989, as the termination date of NRSA support, the Government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 1991. The rate of interest applicable is determined based on the February 1, 1991, date and the total NRSA obligation is required to be fulfilled by January 31, 1994.

The amount to be recovered financially, as determined from the Termination Notice plus applicable interest, shall be paid to the United States within the three-year period following such date.

c. Voluntary Financial Payback Process

In the event that the trainee/fellow voluntarily elects financial payback, the awarding component immediately:

(1) acknowledges the trainee/fellow's decision to payback financially;

(2) sends the following information to the Office of Financial Management (OFM) official when financial payback is indicated:

(a) a copy of all trainee/fellow's APACs and/or letter electing to pay back financially;

(b) a copy of the awarding component's acknowledgment to the trainee/fellow;

(c) a copy of the Termination Notice(s) reflecting the trainee/fellow's complete NRSA support record; and Statements of Appointment (2271) and/or Activation Notices;

(d) a copy of the NRSA Payback Agreement(s) executed by the trainee/fellow.

d. Delinquency/Involuntary Financial Payback

(1) A trainee/fellow is considered delinquent if he or she has not initiated payback service within the 24 months following the date of termination of NRSA support and has not initiated a request for a waiver of obligation, extension, or voluntary financial payback. Delinquent status may become evident in two ways:

(a) a second year APAC is returned by a trainee/fellow but does not indicate that acceptable payback service has been initiated by the end of the 24 month period and there is no request for waiver, extension, or voluntary financial payback; or

(b) there has not been a second year APAC returned by the trainee/fellow and contact procedures have failed (See Section IV.D.1.d.)

(2) If the second year APAC is returned as in d.(1) above, the awarding component sends a certified letter which explains that the trainee/fellow is considered in delinquent status and is responsible for financial payback unless the trainee/fellow requests, within a 30 day period:

(a) a delay in undertaking payback service; or

(b) a waiver of payback obligation (see Section IV.C.5.).

(3) In the event of delinquent status, (no acceptable APAC, no request for waiver or extension, or no contact) involuntary financial payback is initiated and the awarding component immediately refers the case for collection to OFM.

e. Procedure for Notifying OFM

The OFM is assigned the responsibility for receiving any amount owed to the U.S. Government. The awarding component notifies the General Ledger, Reports and Reconciliation Branch, OFM of financial payback as soon as it is aware of a situation of either voluntary financial payback or involuntary payback.

The awarding component should provide to OFM:

(1) the Special Action/Change Notice which indicates the trainee/fellow's social security number, most recent address, and date of birth in the Other Changes portion of the form;

(2) Statement of Appointment Form(s), Payback Agreement(s), and Termination Notice(s);

(3) a copy of the trainee/fellow's APAC indicating either partial service or failure to respond; and

(4) copies of the last correspondence sent to and received from the trainee/fellow, including the unclaimed envelope or returned receipt with which the final APAC was mailed. This is considered sufficient documentation in the event of involuntary payback action.

The NIH will report the claim to the appropriate credit bureau, if the trainee/fellow does not respond to the third demand letter from OFM.

f. Notification to Recipient

OFM sends a letter, a basic data record, and instructions for financial payback to the NRSA trainee/fellow explaining the total amount the U.S. is entitled to recover as of the particular date.

g. Payment Method

The trainee/fellow may elect to make payment in lump sum or installments (monthly, quarterly, annually, or otherwise). The OFM sends a statement to the individual after each payment is received reflecting the amount of principal and interest paid plus the outstanding balance. Each payment is first applied against accrued interest with the remaining balance to principal.

Individuals have 3 years in which to complete the repayment.

h. Receipts

The OFM receives the checks for repayment directly from the trainee/fellow. Checks are made payable to "DHHS, National Institutes of Health" with the fellowship or grant number recorded on them. The checks are mailed to:

National Institutes of Health
Office of Financial Management
General Ledger, Reports, & Reconciliation Branch
Building 31, Room B1B47
9000 Rockville Pike
Bethesda, Maryland 20892

i. Request for Waivers/Exemptions

Once the financial payback process has been initiated, Trainee/Fellow requests for waiver or exemptions are referred back to the appropriate awarding component for review and consideration. A copy of the response and all other correspondence pertinent to financial payback is sent to the OFM at the address shown above.

j. Extension of the Three-Year Period to Complete Financial Payback

The Chief, General Ledger, Reports and Reconciliation Branch, Office of Financial Management may approve or disapprove a request to extend the financial payback period. Decisions to extend the period are based on the criteria described in Section IV.C.4. below.

k. Completion

The OFM notifies the trainee/fellow and the awarding component when financial payback has been completed. Upon receipt of this notification, the awarding component enters the appropriate code in the computer file. The physical file is retained for one year and then forwarded to the Federal Records Center.

4. Extensions of Payback

The National Research Service Award legislation and the promulgating regulation (42 CFR Part 66) authorize the Secretary to make exceptions to certain requirements under the Act. The Secretary has delegated this authority through the Assistant Secretary for Health to the Director, NIH, for NIH-supported NRSA grants and awards. The Director in turn has redelegated to the Deputy Director for Extramural Research (DDER) and the awarding component Directors certain of these authorities for making exceptions. In the case of extensions to initiate or complete payback,

awarding component Directors have the authority to approve.

a. Extensions of the Two-Year Period to Initiate Payback

Frequently, an APAC is returned requesting an extension of the two-year period to initiate payback. Indication of valid plans to initiate payback soon after the two-year grace period may be good reason to grant an extension.

Upon approval of requests for extension, the awarding component signs off on the APAC and updates the IMPAC file directly.

b. Basis for Extensions

The Associate Director for Extramural Programs of the awarding component may extend the period for undertaking payback service or permit breaks in continuous service. These determinations are based on the following criteria:

(1) an extension or break in service is necessary so the individual may complete his or her research or clinical training;

(2) the individual is unable to complete the requirements within the specified period because of a temporary disability; or

(3) completion by the individual of the requirement within the specified period would involve substantial hardship to the individual and that failure to extend the period would be against equity and good conscience.

Reasons for an extension or break in service include such things as completing residency training, where clinical teaching or research are not an integral part of their training, or individuals seeking employment that would fulfill the payback requirements.

Requests must be made in writing (separate letter or Annual Payback

Activities Certification (APAC)) to the awarding component, specifying the need for additional time and the length of the required extension.

c. Extension to Complete Payback Service

The awarding component Director or designee may approve or disapprove requests to extend the period of payback service or permit breaks in continuous service. Decisions to permit breaks in service are based on the criteria described in Section IV.C.4.b above.

5. Waiver

a. Policy

The National Research Service Award legislation and the promulgating regulation (42 CFR Part 66) authorize the Secretary to make exceptions to certain requirements under the Act. The Secretary has delegated this authority through the Assistant Secretary for Health to the Director, NIH, for NIH-supported NRSA grants and awards. The Director in turn has redelegated to the Deputy Director for Extramural Research (DDER) and the awarding component Directors certain of these authorities for making exceptions. For waiver requests, only the Deputy Director for Extramural Research, NIH may waive, in whole or in part, the payback obligation, upon determination that compliance by the individual is impossible, or would involve substantial hardship, and enforcement of the obligation to that individual would be against equity and good conscience.

b. Waiver Criteria

Requests for waivers should be made in writing to the awarding component and explain the need for the waiver according to the following criteria:

(1) Compliance by an individual will be deemed impossible if the individual is permanently and totally disabled;

(2) In determining whether compliance would involve substantial hardship to the individual and would be against equity, the Director, NIH shall take into consideration:

(a) the individual's financial resources and obligations at the time of request for a waiver;

(b) the individual's estimated future financial resources and obligations; In rare cases, the following might also be considered:

c) the reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(d) the extent to which the individual has engaged in payback activities;

(e) whether the individual has received sufficient training to be qualified to perform such activities;

(f) the lack of employment opportunities appropriate to the individual's education and training; and

(g) any other extenuating circumstances.

(3) Any obligation of any individual toward payback will be canceled upon death of the individual.

c. Process

The awarding component, preferably through its Associate Director for Extramural Programs or equivalent, forwards the trainee/fellow's request along with their recommendation for a waiver, through the Research

Training Officer (RTO), to the DDER. The trainee/fellow's request and the recommendation are based on the criteria described in Section IV.C.5.b.. The RTO evaluates the waiver case. If approval is recommended the RTO prepares a letter from the DDER, NIH to the former NRSA trainee/fellow granting the waiver. If a waiver is disapproved, the Associate Director for Extramural Programs in the awarding component will be informed in writing by the RTO.

The letter of disapproval sent to the former trainee/fellow will be signed by the Director of the awarding component or a designee.

All requests for waiver must include information on:

(1) the grant number(s) of the award(s) under which support was received;

2) the total months of support (predoctoral or postdoctoral);

3) the total amount owed before interest; and

(4) whether any payback service was credited. The awarding component should also clearly state the reason for waiver. Whenever possible, appropriate documentation should be provided, such as tax forms, if a financial hardship waiver is requested, or a letter from a licensed health care provider if permanent and total disability is grounds for waiver.

If a waiver request relates to the inability of a former trainee/fellow to find an acceptable position, rejection letters or other documentation supporting a reasonable effort to find a suitable position must be provided.

d. Record Closure

Upon receipt of notification that the waiver has been approved, the awarding component enters the appropriate code in the computer file. The physical file will be retained for one year and then forwarded to the Federal

Records Center.

D. Certification of Payback Activities

1. Annual Payback Activities Certification (Form PHS 6031-1, See [Appendix 7](#))

a. Annual Certification

Entering the Termination Notice data into the IMPAC I/II File establishes the basis for the payback cycle. Payback service is certified through the use of the Annual Payback Activities Certification (APAC) form (PHS 6031-1). Individuals with an outstanding payback obligation, must complete an APAC annually until their payback obligation is fulfilled.

The APAC is sent by DMCS, OER approximately one year after the completion of NRSA support, if an individual has incurred a payback obligation. Payback service may be initiated within the first 12 months of termination even though trainees/fellows have up to 24 months to initiate payback. There is no penalty to those individuals who do not initiate payback within the first 12 months; however, it is critical that they complete an APAC form to ensure contact is maintained and addresses are current.

On this form, the individual will report the activity in which he or she was engaged for the preceding 12 months, within the specified "reporting period". These forms are to be returned within 30 days of the reporting period end date to:

Data Management Control Section, OER
National Institutes of Health
Rockledge II, Room 1010
6701 Rockledge Drive
MSC 7715

Bethesda, MD 20817

Forms are then forwarded by DMCS to the awarding component who will then review the activity and make a decision on its acceptability and inform the former trainee/fellow of the decision. This process will continue annually until the individual's total payback obligation is satisfied. See IV.D.1.d. for individuals who do not submit an APAC or cannot be located.

b. Change of Address

Any change in the mailing address of a NRSA recipient must be reported promptly to the awarding component until the service obligation is fully discharged.

c. Payback Validation

(1) When a returned APAC indicates payback service, the awarding component validates the service acceptability based on the description of duties and the criteria for acceptable payback (see Section IV.C.1.). Staff of the awarding component indicates the number of months of acceptable service on the APAC, signs and dates the form. This should be accomplished within 45 days of receipt.

(2) The original APAC and the trainee/fellow's payback record are maintained in the awarding component.

(3) The awarding component enters all appropriate data from the APAC into the IMPAC system. This includes appropriate credit for months of acceptable service, breaks in service, extensions, financial payback election, and address changes.

(4) One copy of the signed APAC is sent to the trainee/fellow, with a letter referencing the number of months of remaining payback obligation. If

payback service is complete, the trainee/fellow is notified in writing.

(5) If the payback service is not approved, a letter of explanation is sent to the trainee/fellow with a copy of the APAC. A copy of the letter is maintained with the original APAC in the official payback file and the trainee/fellow's file is marked accordingly.

d. Contact Procedures

(1) General

The problems incurred in receiving a valid APAC form are generally two types; one is the lack of any response at all which usually indicates that the trainee/fellow received the information but did not return it; and, second, that the material is returned "address unknown" indicating that an address correction is necessary. DIU produces a mailer to the Trainee/Fellow which acknowledges receipt of the Termination Notice and requests that any change in address, name, or Social Security number be sent to the awarding component.

The following procedures are directed at making contact with the trainee/fellow and receiving a valid APAC form or establishing a proper financial collection claim.

(2) First Annual Report on Payback

(a) The DIU sends the first APAC form by regular mail to the NRSA trainee/fellow on the first anniversary of termination. When the APAC is returned the form is sent to the awarding component for validation. Payback credit and updated information is entered into the IMPAC system.

(b) If the first APAC is not returned within 45 days, DIU automatically sends a second (follow-up) APAC to the individual.

(c) If the second APAC is not returned within 45 days, the name of the individual and an APAC form will be sent by DIU to the awarding component. They use official file information and contacts with training grant program directors or fellowship sponsors to re-establish contact with the trainee/fellow and send the APAC to the most current address. This third APAC is sent by certified mail to verify the correct address and receipt of the APAC.

(d) If the third APAC is not returned within 45 days, the awarding component notes the type of response and the best available address and updates the record in the payback system. A further follow-up is not required until the second year APAC is sent to the trainee/fellow.

(3) First year APAC - "Address Unknown"

(a) If the first annual APAC is returned "address unknown", it is directed to the awarding component which uses official file information as well as contacts with training program directors and fellowship sponsors to obtain a current address.

If these contacts fail to produce a current address, the awarding component utilizes services such as the TRW credit bureau location service to obtain a valid address. This address should be entered into the interactive system by the awarding component. Using this new address, a second APAC is sent by regular mail to the trainee/fellow by DIU.

(b) If the second APAC is also returned "address unknown," the documents are sent to the awarding component for verification. If a substantial number of follow-up APACs have been returned "address unknown", and all efforts by the awarding component have failed to produce a current address, DIU may initiate an address verification process with the Internal Revenue Service (IRS). These requests are

batch processed and submitted to the IRS through the Claims Office.

Upon receipt of a new address, an APAC is prepared by DIU and sent to the trainee/fellow.

(c) The third APAC is sent by certified mail by the awarding component in order to confirm the address. If the APAC is not returned, no further action is required until the second year.

(4) Second Annual Report on Payback

(a) The DIU sends the second year APAC on the second anniversary of termination. Forms are sent to all trainees/fellows, even if the first annual APAC was not returned. In the event that an APAC was not obtained from an individual for the first twelve-month period, the APAC is mailed to the best available address. If the follow-up APAC for the second year is either not returned or returned "address unknown," the procedures outlined in Section d.(3) above are followed with these exceptions:

(1) A final, follow-up APAC together with a letter explaining that the trainee/fellow is considered to be in delinquent status and responsible for financial payback will be sent.

(2) If within 30 days this final APAC is not returned or there has not been a request for an extension or waiver, the trainee/fellow is considered to be in delinquent payback status. The awarding component will then forward a financial collection claim to the Office of Financial Management (OFM).

2. Continuing Payback Service

An APAC form is sent each year by DIU near the termination anniversary to trainees/fellows who have continuing payback obligations. The validation process as specified in Section IV.D.1.c. is followed for each

APAC. When the total payback obligation is satisfied, the DIU sends the awarding component the report, "Fellows/Trainees Having Completed Payback." The awarding component closes the automated payback record and sends a formal acknowledgment of completion of payback and a copy of the final APAC to the trainee/fellow.

3. Breaks in NRSA Support

Sometimes a trainee/fellow will have a period of non-NRSA support between two NRSA awards. An appropriate activity performed during this period of time may count for payback purposes toward the first NRSA award. If the non-support period is six months or longer, the individual receives an Annual Payback Activities Certification (APAC) form through the regular mechanism. However, if the break is less than six months, an APAC will not be automatically mailed by DIU. If acceptable payback service was performed during the break, the individual may complete an APAC, which can be obtained from the awarding component, to document the payback service. The completed APAC is validated as in Section IV.D.1.c.

4. National Health Service Corp

Occasionally, an NRSA recipient will have previously been a National Health Service Corps (NHSC) scholar. Legislation provides authority for holders of both awards to pay back the obligation of the two sources of support concurrently. Therefore, activities which qualify as NRSA payback will also serve as payback for the NHSC obligation. However, no Legislative Allowance is provided for NHSC service; e.g., 36 months of NRSA support (prior to June 10, 1993) and 36 months of NHSC support would require 24 months of NRSA payback service and 36 months of NHSC service respectively. The awarding component monitors both obligations until they are both satisfactorily completed. A listing of

individuals who have received both awards is provided by the NHSC monitoring office.

Once these individuals have terminated NRSA support, the APACs generated and mailed by OER should reflect both obligations. Across the top of each APAC the statement "NHSC Obligation Outstanding" should appear. It should also show the number of months of NHSC obligation in addition to the NRSA obligation in the section marked "Total Months of NRSA support". An individual will continue to receive an APAC each year until both obligations have been fulfilled. Most often the NRSA obligation is fulfilled before the NHSC. However, each year APACs should continue to be validated until the NHSC obligation is also complete. It is the obligation of the recipient to report any action to the NHSC. The validated APAC is considered the official document. However, it is advisable for the awarding component payback monitor to send a copy of the validated APAC to the NHSC.

When recipients have completed their total obligation to both NRSA and NHSC, send the following documentation to the NHSC contact:

a) a copy of the completed validated APAC and;

b) a copy of the awarding component letter addressed to the recipient.

The awarding component letter to the recipients should indicate that after they submit a copy of their APAC to the NHSC, they will receive a letter of completion from the NHSC.

NHSC Contact:

Division of Scholarship & Loan Repayments
Scholarship Programs Branch
4350 East-West Highway, 10th Floor

Bethesda, MD 20814

Phone: (301) 594-4403

5. Payback Record Retention and Disposal

All physical records must be retained in accordance with standard policy for individual grant files. Records relating to the individual's payback obligation are retained for one year after the individual has fulfilled or has been excused from fulfilling the payback obligation. After the one-year period, closed files are transferred to the Federal Record Center.

6. Reports

Interim reports on the individuals who have terminated NRSA support and their payback status are available through the interactive system. The reports include information concerning individuals who received 12 months or less of NRSA support. These reports may be requested by the awarding component via the computer by accessing the NRSA Reporting System. A listing of available reports is provided along with print options.

Appendix 1 – NRSA Financial Provisions

[**Please refer to paper copy for some appendix information.**]

Costs are normally provided based on a 12-month budget period. Awards for less than 12 months are prorated accordingly.

A. Stipends

Reference: NIH Guide, Volume 25, Number 41, November 29, 1996

Effective October 1, 1996, the following annual stipend levels apply to all

individuals receiving support through Institutional or Individual NRSA grants made with FY 1997 and subsequent fiscal year funds. These levels also apply to Minority Access to Research Career (MARC) and Career Opportunities in Health (COR)programs. Supplementation, or retroactive adjustments, with NRSA funds for awards made prior to October 1, 1996, is unallowable. Note, the annual level for postdoctoral postdoctoral experience at the time of the appointment/award.

Career Level Stipend for FY 97 (and subsequent years, until revised) MARC/COR Honors Undergraduates:

- Freshmen/Sophomores $6,276

- Juniors/Seniors $8,796

- Predoctoral $11,496

- Postdoctoral Years of Experience.

    o less than 1 $20,292

    o greater than or equal to 1 but less than 2 $21,420

    o greater than or equal to 2 but less than 3 $25,600

    o greater than or equal to 3 but less than 4 $26,900

    o greater than or equal to 4 but less than 5 $28,200

    o greater than or equal to 5 but less than 6 $29,500

    o greater than or equal to 6 but less than 7 $30,800

    o greater than or equal to 7 $32,300

- Senior Fellows $32,300

B. Training Related Expenses (TRE) -Institutional

Training Grants

Sometimes referred to as "Above the Line Costs" or "Other Expenses", TRE funds are awarded to help defray the costs of other training related expenses such as staff salaries, consultant costs, equipment, research supplies and staff travel. TRE is generally requested in a lump sum, based on the number of trainees requested in the application, and entered on the budget page without further stipulation.

Current levels are up to $1,500 per year for each predoctoral trainee, and up to $2,500 per year for each postdoctoral trainee. The training related expenses for specialized programs such as MARC & COR are referenced in the specific program announcements.

C. Institutional Allowance - Individual Fellowships

Reference: NIH Guide, Vol. 26, No. 1, January 10, 1997

Provided annually to help defray the costs for the individual fellow. Section II.G.2.a.(1) describes in detail what are considered acceptable costs for individual fellowships depending on the training site. Note however, beginning in FY97, for postdoctoral fellowships, tuition & fees (except health insurance), when applicable, are no longer included as part of the institutional allowance. That cost will be awarded in accordance with the tuition policy described below. The cost of self-only health insurance itself will continue to be charged to the Institutional Allowance.

1. For new, competing fellowships funded in FY97 and henceforth, institutional allowance will be provided for all years as follows:

Predoctoral:

Up to $4,000. Note, many awarding components provide individual predoctoral fellowships with a reduced institutional allowance (usually

$2,000) since costs for tuition, fees and health insurance are awarded separately. Specific program announcements and/or awarding components should be contacted for guidance.

Postdoctoral:

- Up to $4,000 (For fellows at non-federal, non-profit, or foreign institutions)

- Up to $3,000 (For fellows at Federal laboratories or for-profit institutions)

2. For non-competing fellowships funded in FY97, institutional allowance will continue to be awarded at levels previously determined. For those grants involving tuition & fees (including health insurance), these costs will continue to be paid under the previous policy guidelines. For postdoctoral fellows these costs will continue to be part of the institutional allowance. For predoctoral fellows, specific programmatic guidelines should be consulted.

Predoctoral: Up to $4,000

Postdoctoral: Up to $3,000

D. Tuition and Fees

References:

- NIH Guide, Vol. 25, No. 2, February 2, 1996

- NIH Guide, Vol. 25, No. 31, September 20, 1996

- NIH Guide, Vol. 26, No. 1, January 10, 1997

Beginning in FY96, the NIH announced a new policy for the

reimbursement of tuition costs. This new policy is being implemented beginning with competing institutional awards. Note, applicant institutions are instructed to continue to request the full amount of these costs in competing applications. Awarding component staff will apply the reimbursement formula at the time of an award.

1. Institutional Grants

a. For competing awards issued in FY96 and henceforth, combined costs of tuition, fees and self-only health insurance are reimbursed at the following per trainee rate: 100% of all costs up to $2,000 and 60% of costs above $2,000. Future years provide no escalation.

b. Non-competing awards funded in FY96 will continue to be reimbursed at established levels until such time as they recompete.

2. Individual Postdoctoral Fellowships

a. For competing awards issued in FY97 and henceforth, when applicable, tuition and fees (excluding health insurance) is reimbursed at the following rate: 100% of all costs up to $2,000 and 60% of costs above $2,000. Future years provide no escalation.

b. Non-competing awards funded in FY97 will continue to be reimbursed at previously established levels.

3. Individual Predoctoral Fellowships

Reimbursement of tuition and fees (including health insurance) varies among the NIH awarding components. Therefore, specific program announcements and/or awarding components should be contacted for guidance.

a. When tuition, fees and health insurance is awarded as a separate cost,

for competing awards issued in FY97 and henceforth, this cost will be reimbursed at the following rate: 100% of all costs up to $2,000 and 60% of costs above $2,000. Future years provide no escalation

b. Non-competing awards funded in FY97 will continue to be reimbursed at previously established levels.

E. Short-Term Training - Students in Health Professional School

Most short-term trainees are funded at the predoctoral stipend level. The current monthly level is $958. Up to $125 per month for each participating student may be requested to defray other costs of training such as staff salaries, consultant costs, research supplies, tuition, travel etc. Some NIH awarding components provide short-term training at the postdoctoral level as well. Specific program announcements and awarding components should be contacted for guidance.

Appendix 2 – Receipt, Review & Award Schedule

Application Receipt Dates	Review and Award Schedule	ALL Institutional Research Service Awards (*)	Scientific Merit Review	Advisory Council Review	Earliest Award
January 10	June/July	September/ October	December	May 10	October/ November
January/ February	April	September 10	February/ March	May/June	July

Individual National Research Service Awards (Fellowships)	Initial Review Dates	Range of Likely Start Dates
April 5	June/July	September - Dec
August 5	October/November	January - March

December 5	February/March	May - July

*Some Institutes have only 1 or 2 receipt dates for Institutional Training Grants. They are:

Institute/Center	Application Receipt Date(s)
NIA	May 10
NIAAA	May 10
NIAID	September 10
NIAMS	May 10
NICHD	May 10
NIDCD	May 10
NIDR	September 10
NEI (beginning FY 1998)	May 10
NIEHS	May 10
NHLBI	January 10 & May 10
NHGRI	May 10
NIMH (except Office of AIDS)	May 10
NINDS	May 10
NINR	May 10

Applicants are encouraged to confirm the application receipt dates by calling the appropriate Institute or Center Review Office. Specific NRSA programs may change their receipt dates to complement Institute workloads.

Appendix 3 – Research Fellowship Activation Notice (PHS 416-5)

Research Fellowship Activation Notices (PHS 416-5) are automatically mailed with applicable Notice of Grant Awards. Additional forms are

available from the Grants Management Office of the awarding component.

Appendix 4 – Statement of Appointment Form (PHS 2271)

Statement of Appointment Forms (PHS 2271) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding component.

Appendix 5 – NRSA Payback Agreement (PHS 6031)

NRSA Payback Agreements (PHS 6031) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding component.

Appendix 6 – NRSA Termination Notice (PHS 416-7)

NRSA Termination Notices (PHS 416-7) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding component.

Appendix 7 – NRSA Annual Payback Activities Certification (PHS 6031-1)

NRSA Annual Payback Activities Certifications (PHS 6031-1) are automatically mailed annually to applicable recipients.

NIH POLICY MANUAL

54815 Implementation of Cooperative Agreements

Issuing Office: OEP/OER/OD 301-435-2690

Release Date: 08/17/09

1. **Explanation of Material Transmitted:** This chapter contains revised policy and procedures for implementation of cooperative agreements. Due to the length of the chapter, subsections are numbered to assist in making citations and finding information. This chapter defines the types of substantial NIH scientific and/or programmatic involvement after award. Substantial involvement occurs when NIH Scientific or Program staff provides technical assistance, advice, coordination, and/or other functions above and beyond the usual level of program stewardship for grants. These include the following four distinct roles: "Project Scientist," "Project Coordinator," "Project Collaborator," and "NIH Intramural Scientist."

2. **Filing Instructions:**

   Remove: NIH Manual 54815, Implementation of Cooperative Agreements: Initiation, Review, Award, and Administration, dated 10/01/93.

   Insert: NIH Manual 54815, Implementation of Cooperative Agreements, dated 08/17/09.

PLEASE NOTE:

- For questions on this chapter, contact the issuing office listed above.

- For on-line information on the NIH Manual System, go to
  http://oma.od.nih.gov/manualchapters/.

- To sign up for email notification of future changes, please go to the NIH Manual Chapters LISTSERVE Web Page.

- For Cooperative Agreement Conference Grants, please see [NIH Manual Chapter 54105](#).

- For additional information on Cooperative Agreements, go to the [Cooperative Agreement Kiosk](#) (see: http://odoerdb2-2.od.nih.gov/oer/programs/coop/).

A. Purpose

This issuance establishes NIH policy for initiation, review, award, and administration of cooperative agreements for conducting extramural research and development projects. For additional information on Cooperative Agreements, go to the [Cooperative Agreement Kiosk](#).

B. Background

The Federal Grant and Cooperative Agreement Act of 1977, P.L. 95-224 (FGCA) as amended by P.L. 97-258 (31 U.S.C. § 6301 et. seq.), established Government-wide criteria to distinguish between Federal acquisition and assistance relationships with other parties. The Act emphasizes that the choice of award instrument should be based on the purpose of the agency-recipient relationship, characteristics of the legal instruments, and related standards and conditions. Under the Act:

- The Federal Government shall use a contract mechanism when the principal purpose of the transaction is the acquisition of property or services for its direct benefit or use.

- The Federal Government shall use an assistance mechanism when the principal purpose of the transaction is to transfer money, property, or services to a recipient to accomplish a public purpose of support or stimulation authorized

by law.

1. Grants are used when no substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity.

2. Cooperative agreements are used when substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity.

In 1978 the Office of Management and Budget (OMB) published Government-wide guidance to implement the FCGA. HHS has implemented the FCGA in its grants administration regulations at 45 C.F.R. Part 74 and 45 C.F.R. Part 92, and NIH manual issuances have expanded on that guidance. See NIH Manual Chapter 1820, "Selection of Extramural Award Instrument – Grant, Cooperative Agreement, or Contract" and NIH Grants Administration (GAM) Chapter 4.2.02.202 "Determining Appropriate Award Instrument", which provide NIH policy for selecting appropriate award instruments. This Manual Chapter provides NIH guidance for procedures to initiate, review, award, and administer cooperative agreements.

C. Policy

NIH Institutes and Centers (ICs) must use a cooperative agreement whenever an assistance award is made and need is demonstrated for the substantial involvement of scientific-programmatic staff during the performance of the activity. A cooperative agreement is not intended as a means to exercise greater control over a recipient or a project than would be the case under a grant or to allow for involvement that exceeds that which is permissible under a contract. When the substantial involvement is the collaboration of an NIH Intramural scientist in an extramurally-funded assistance project, the IC must fund the project as a cooperative agreement. The IC must have a process to manage concern about bias (see D.8 and D.9 below) involving staff with

substantial involvement in cooperative agreement awards. For additional information on Cooperative Agreements, go to the [Cooperative Agreement Kiosk](#).

NIH implements cooperative agreements through policies and procedures appropriate for grants, and assigns an NIH activity code in the "U" series. In general, ICs announce their intentions to make "U" awards for special projects or programs in Funding Opportunity Announcements (FOA). ICs must pay particular attention to special requirements for program planning and advisory group recommendations, scientific peer review of applications, award terms and conditions, and corresponding administrative details. Cooperative Agreement Terms and Conditions of Award (COA) shall reflect the terms and conditions approved in the OEP review (see note below) and ensure preservation of the authorities and responsibilities of awardee investigators to control and direct the development, conduct, and publication of their studies, and of IC staff to assist those processes. NIH staff involvement is limited to those activities listed on the Notice of Award (NoA).

Note: The IC Extramural Program Management Committee (EPMC) member or designee submits the planned use of the cooperative agreement to the Office of Extramural Programs (OEP), Office of Extramural Research (OER) official designated by the Deputy Director for Extramural Research (DDER), NIH, for review and approval and conformance with this Manual Chapter (For additional details, see Sections F.2 and F.4).

D. Definitions

D.1. Assistance: The award of money, property, services, or anything of value by the Federal Government to a recipient to accomplish a public purpose of support or stimulation authorized by Federal statute. Assistance relationships are generally expressed less formally and in less detail than acquisitions.

D.2. Acquisition: The purchase, lease, or barter of property or services for the direct benefit or use of the Federal Government, including dissemination to third parties or the public. Acquisition establishes a procurement relationship and defines the rights and duties of the Government as buyer, and of the performer as seller.

D.3. Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

D.4. Cooperative Agreement: An award instrument of financial assistance where "substantial involvement" is anticipated between the NIH and the recipient during performance of the contemplated project or activity. "Substantial involvement" means that the recipient can expect Federal programmatic collaboration or participation in managing the award.

Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Consistent with this concept, the dominant role and prime responsibility for the activity reside with the awardee(s) for the project as a whole, although specific tasks and activities in carrying out the studies will be shared among the awardees and the IC Project Scientist and/or Program Official/Collaborator/Coordinator. The IMPAC activity code "U" is assigned to these awards.

D.5. Program Official

The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement that involves normal program stewardship of the award.

D.5.1. Normal *Program Official* Stewardship

Usually the Program Official is a separate staff member from the substantially involved staff member. Normal Program Official stewardship includes:

- Enforcement of general statutory, regulatory, or policy requirements;

- Approval of awardee plans prior to award and review of performance after completion;

- Evaluation of progress by reviews of technical or fiscal reports, site visits, or external consultants, to determine that performance is consistent with the terms and conditions of the award;

- Technical assistance requested by awardees, or unanticipated procedures to correct programmatic or financial deficiencies in awardees' performance;

- Scientific/technical discussions with awardees, or actions to facilitate or expedite interactions between awardees, e.g., organizing and holding meetings of investigators;

See also detailed information on http://odoerdb2-2.od.nih.gov/oer/programs/coop/po_responsibilities.htm, including several examples of normal program stewardship functions in the administration of PHS grants.

D.6. Substantial Involvement

Substantial involvement occurs when NIH scientific or program staff provides technical assistance, advice, coordination, and/or other functions above and beyond the usual level of programmatic and/or scientific stewardship for grants. This level of staff involvement does not alter the awardee's dominant role and prime authority in conducting the activity (see [NIH Manual 1820](#)).

D.6.1. Substantial *Programmatic* Involvement: NIH program staff provides

technical assistance, advice, coordination, and other program actions supporting recipients of cooperative agreements during the conduct of an activity, above and beyond the levels required normally for program stewardship of grants, but without dominating the relationship.

D.6.2. Substantial *Scientific* Involvement: NIH program staff provides scientific technical assistance and advice to recipients of cooperative agreements during the conduct of an activity, above and beyond the levels required normally for program stewardship of grants, but without dominating the relationship.

D.7. Types of Substantial Involvement

1. *Project Scientist:* Substantial scientific involvement by NIH extramural staff or substantial scientific and programmatic involvement by NIH extramural staff. (See Section D.7.1 below for additional details)

2. *Project Coordinator:* Substantial programmatic involvement by NIH extramural staff. (See Section D.7.2 below for additional details)

3. *Project Collaborator:* Substantial scientific and/or programmatic involvement combined with the normal Program Official role. (See Section D.7.3 below for additional details)

4. *NIH Intramural Scientist:* Substantial scientific involvement as a key co-investigator in the extramural research project. (See Section D.7.4 below for additional details)

   When the substantial involvement involves the collaboration of an NIH Intramural Scientist in an extramurally funded assistance project, the IC may fund the project as a cooperative agreement (see: [Collaborations of NIH Scientists with Extramural Scientists](#)). The Intramural Scientist cannot receive extramural funds for participation in the cooperative agreement award.

Examples of substantial involvement include activities such as:

D.7.1. Substantial SCIENTIFIC Involvement (e.g., Project Scientist)

- Cooperation or coordination with, or assistance to, awardees in performing project activities, e.g., development of research protocols; data collection, analyses, and interpretations; re-establishment of objectives during the course of a project; or holding FDA Investigational New Drugs (INDs) for investigational drugs;

- Providing for an option to halt a project activity if technical performance requirements are not met or if program objectives have already been met;

- Specifying under the terms and conditions of award that the project be structured in stages and that NIH staff review and approve each stage before work may begin on such stage, e.g. concepts for research projects;

- Assistance with the selection of contractors or sub-awardees under the assistance award, and in the selection of key project personnel other than principal investigators of projects or sub-projects;

- Technical monitoring to permit specific direction of the project, including recommending approval of changes in experimental approaches;

- Participation on committees (other than peer review, see below) as a voting member as needed (the chairperson will be someone other than an IC staff member) or in other functions responsible for helping to guide the course of long-term projects or activities; and

- Participation in the presentation of research results, including publications from the project;

- Generally not involved in normal programmatic stewardship of the project;

- Has defined procedure for management of concern about bias (see D.8 and D.9) by NIH staff, developed by the IC;

- May not attend peer review meetings of Renewal or Revision applications unless IC waiver obtained per IC procedures for management of concern about bias.

D.7.2. Substantial PROGRAMMATIC Involvement (e.g., Project Coordinator)

- Cooperation or coordination with, or assistance to, awardees in performing project activities, e.g., coordination of research networks; providing access to NIH supported research resources; identifying other researchers/resources for the project; assistance in processing FDA INDs for investigational drugs;

- Participation on committees as a voting member as needed (the chairperson will be someone other than an IC staff member) or in other functions responsible for helping to guide the course of long-term projects or activities, e.g., annual meetings of awardees, Chair and/or member of project oversight committees composed of NIH officials;

- Not involved in normal program stewardship;

- May not attend peer review meetings of Renewal or Revision applications unless IC waiver obtained per IC procedures for management of concern about bias.

D.7.3. Program Official plus Substantial Scientific and/or Programmatic Involvement (e.g., Project Collaborator)

- Provides normal program stewardship;

- Selected activities for scientific and/or programmatic substantial involvement, as set forth in Sections D.7.1. and/or D.7.2. of this Manual Chapter;

- Has defined procedure for management of concern about bias by NIH staff, developed by the IC;

- May not attend peer review meetings of Renewal or Revision applications or the

closed session of IC Council/Board, unless an IC waiver is obtained per IC procedures for management of concern about bias.

D.7.4. Substantial Scientific Involvement by an NIH Intramural Scientist

- The NIH Intramural Scientist with substantial scientific involvement is designated as an NIH Intramural Scientist in the cooperative agreement terms and conditions of award.

- The NIH Intramural Scientist is not involved in normal program stewardship. A separate Extramural Program Official is assigned to the award for normal program stewardship.

- The NIH Intramural Scientist will not attend a Peer Review meeting of the same project conducted by extramural Scientific Review Officers (SROs).

Examples of Intramural Scientific Staff Activities that Constitute Substantial Involvement http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/coop-agr.htm:

- Acting as the director of a project within a program project (P01) grant.

- Having primary responsibility for a specific aim within a regular research project grant (R01).

- Development of a major data base for an extramural collaborator.

- Participation in a multi-institutional collaborative arrangement with extramural researchers for clinical, prevention or epidemiological studies.

Notes:

1. Involvement may initially be un substantial, but evolve over time to become substantial, thus requiring reconsideration of the appropriate mechanism of award.

2. Certain kinds of involvement, such as acting as consultant to provide occasional advice or providing occasional sample analyses, likely do not constitute

substantial involvement.

3. It is acknowledged that gray areas may arise that will require determination on a case-by-case basis to be resolved by OEP, the IC, or both.

D.8. Concern about Bias (formerly Conflict of Interest) in Programmatic Administration of Cooperative Agreements

In addition to the criminal statutes and government-wide and NIH-specific Standards of Ethical Conduct with which all NIH staff must comply, NIH management exercises its inherent authority to assign work in a manner that protects the perceived integrity of administration of cooperative agreements. The participation of an NIH employee who is substantially involved under a cooperative agreement in the normal programmatic stewardship of the award could raise concerns regarding the integrity of agency operations. As a result of the substantial involvement with the award, the staff role as a partner may appear to be similar to that of a co-investigator on the award, which could result in a real or apparent bias about the project that prohibits independent evaluation of the progress of the award; the Project Scientist/Collaborator also may publish with the awardee in accordance with NIH publication policy. Accordingly, employees who are substantially involved in such a project are prohibited from participating in the normal programmatic stewardship of the award, unless the IC has an appropriate procedure in place to reduce or address any such concern about bias.

D.9. IC Management of Concern about Bias

ICs must establish procedures to eliminate or mitigate any concerns about the integrity of awards or bias if a Program Official for an award also is substantially involved in an award. Relevant approaches may include:

- A waiver procedure from the immediate supervisor AND next higher level supervisor OR EPMC member (if applicable) or designee to allow attendance at

the peer review meeting (IC or CSR) and the closed session of an IC Council/Board meeting that includes review of the relevant Renewal applications and Revisions. A justification for why a Program Official cannot cover the Peer Review meeting or IC Council/Board meeting is required. Staff roles should be considered (see [NIH Policy Manual 4204-204B, Peer Review Process](#)).

- Clarification of budgetary or programmatic lines of authority for an award to manage, reduce, or eliminate concern about bias.

- Establishment of an independent IC or NIH oversight committee to assist the designated Program Official in monitoring performance.

- Clarification of IC measures used to manage concern about bias when multiple program staff (including, but not limited to Project Scientists/Coordinators/Collaborators) within an IC, or from multiple ICs, are substantially involved in complex projects, e.g., Roadmap Initiatives, Clinical Cooperative Groups, and Networks. Generally, the attendance at Peer Review meetings will need justification and any waiver will be limited to the named lead person on the complex project.

- Clarification of intent for IC staff to publish with the awardee consistent with the NIH publication policy (see also [NIH Manual Chapter 1184](#)).

E. Responsibilities

E.1. Office of the Director, NIH

The Deputy Director for Extramural Research (DDER) establishes NIH grant policies including determining the adequacy of procedures for implementing cooperative agreements, and maintaining an overview of IC practices in carrying out pertinent policies and procedures, through solicitation procedures outlined below and through occasional program and review evaluations.

The DDER appoints a senior OEP official responsible for approving the use of

the cooperative agreement mechanism for NIH projects. This person evaluates IC requests to use cooperative agreements based on compliance with NIH policies and procedures for using this award instrument. The senior OEP official provides additional instructions, procedures, and advice to ensure that the cooperative agreement mechanism is the proper award instrument to use for the IC's purpose. The OEP official may obtain advice from senior NIH program, grants policy, and acquisition policy staff experienced with the use of the cooperative agreement mechanism to assist in the evaluation of IC requests.

E.2. NIH Awarding ICs

IC Directors define procedures by which their staffs implement cooperative agreements under the provisions of this Manual.

IC Official: A single IC official is designated to clear requests from an IC for use of the cooperative agreement mechanism and is responsible for the quality of the submission. This IC official is generally the Extramural Program Management Committee (EPMC) member, although the IC may designate a different official for this purpose.

IC program, review, and grants management officials implement established policies and procedures to initiate, review, award, and administer cooperative agreement awards.

The IC Grants Management Officer (IC GMO) is responsible for certifying the proper choice of the assistance award instrument.

F. Procedures

F.1. Institute/Center (IC) Development and Internal Clearance of Activity

F.1.1. Decision to use a cooperative agreement mechanism: IC Program Officials are responsible for planning programs and activities and for

determining the appropriate funding mechanism (grant, cooperative agreement, or contract). To utilize the cooperative agreement mechanism, the IC must obtain the following advice and recommendations:

- Program staff must obtain concept review through recommendations from public discussion (e.g. Councils, Boards, workshops) on the purpose, relevance, scope, priority, and need for the activity when proposed as an FOA. The recommendations should be documented in the form of minutes or other official documents and retained in accordance with the NIH Manual Chapter 1743, Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

- Program staff must seek technical and procedural advice on the development of the cooperative agreement activity from review, grants management, and contracting officials, according to NIH and IC policies and procedures.

F.1.2. Preparation of the FOA: The FOA shall follow the requirements in NIH Manual Chapter 54110, "Program Announcements and Requests for Applications," and shall use the templates and standard language provided by OEP/OER, including the specific sections of the templates and standard language relating to cooperative agreements. See Format for FOAs for Cooperative Agreements for specific text recommended by the OEP. The Cooperative Agreement Kiosk (see: http://odoerdb2-2.od.nih.gov/oer/programs/coop/) will also have *examples of previously approved cooperative agreement announcements.* The FOA should describe any plans to continue the cooperative agreement project beyond the initial period of award and any other possible post-award changes (for example, plans to convert the awards to grants or contracts after the initial award period), consistent with the "Preparation of Justification Memorandum." (see Section F.3).

F.2. Cooperative Agreement Terms and Conditions (Section VI.2.A. of FOA

template)

ICs shall use the following standard subheadings for cooperative agreement terms and conditions of award.

F.2.1. Cooperative Agreement Mechanism: Add the following statement that clarifies the special terms and conditions of the cooperative agreement award:

"The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, and NIH grant administration policies."

"The administrative and funding instrument used for this program will be the cooperative agreement Uxx, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below."

A one or two sentence description of the project should be included when a group of awards or components have the same cooperative agreement terms and conditions of award, e.g., for a network or multi-site/multi-component project. ("The xxx Network consists of the number of Clinical Sites, a Data Coordinating Center, a Steering Committee, etc").

F.2.2. Awardee Rights and Responsibilities: Describe the primary authorities

and responsibilities of awardees to define objectives and approaches, and to plan, conduct, analyze, share, and publish results, interpretations, and conclusions of their studies. Describe the responsibilities of multiple awardees in collaborating on common protocols, etc., including methods and requirements for joint participation and collaboration, and the handling of data, including the appropriate sharing of methods and data among collaborating organizations. For multi-award clinical trials, include separate responsibilities for major components: e.g., clinical sites, data coordinating centers, etc.

Awardees should be advised that they will retain custody of and primary rights to their data developed under the award, subject to current Government policies regarding rights of access.

F.2.3. NIH Responsibilities

"An NIH IC Project Scientist/Coordinator/Collaborator will be substantially involved in this project above and beyond the normal stewardship of an NIH IC Program Official as follows:"

Describe the nature, character, and extent of the IC Project Scientist/Coordinator/Collaborator's scientific-programmatic involvement (i.e., the NIH "partner") during conduct of the activity, as set forth in Section D.7 above. Staff involvement must reflect that the dominant role and prime responsibility for the activity reside with the awardee(s) for the project as a whole, but not necessarily for each task.

Optional: ICs may identify the IC staff who will be scientifically-programmatically involved in the activity as the NIH IC Project Scientist, or Project Coordinator, or Project Collaborator, by project/program-specific functional title.

In most circumstances, an IC will identify two different program staff members involved with the cooperative agreement - one is the IC Project Scientist/Coordinator/Collaborator, and the other is the IC Program Official

responsible for normal program stewardship of awards. The roles and responsibilities (i.e., different staff functions) for IC program staff involved in the activity should be appropriately reflected in the Terms and Conditions of the NoA.

F.2.4. Collaborative Responsibilities: Where applicable, describe membership, responsibilities, and operations of any committees, such as a Steering/Executive Committee and other central coordinating components in which there is substantial scientific-programmatic involvement.

F.2.5. Dispute Resolution (formerly Arbitration): Using standard template language if possible, describe pertinent dispute resolution mechanisms applicable to scientific disagreements *between awardees and the IC,* related to programmatic decisions on scientific/technical matters. Add the following statement to assure that resolution of differences will not affect the appeals process: "These special dispute resolution procedures in no way affect the awardee's right to appeal an adverse action in accordance with PHS regulations at 42 CFR Part 50, Subpart D, and HHS regulations at 45 CFR Part 16."

In some cases, a separate dispute resolution mechanism may be described and encouraged for disagreements among awardees.

F.3. Preparation of Justification Memorandum to the Office of Extramural Programs/Office of Extramural Research (OEP/OER)

A justification memorandum should be prepared that addresses the following items, using the following format:

F.3.1. Description of Project: Provide a very brief description of the project in a short paragraph. A detailed description of and scientific rationale for the project are not required in this memorandum.

F.3.2. Need for an Assistance Mechanism: Briefly explain the rationale and

need for an assistance mechanism (e.g., for a general public purpose or good) rather than acquisition (primarily for direct Federal Government benefit or use). This explanation should discuss how the activity will assist, stimulate, or support recipients to define and conduct their project activities, and should mention how project results or products will be used and disseminated (see NIH Manual 1820 and NIH GAM 4.2.02.202.B.2 for further description of the award selection criteria).

When a project involves aspects of both acquisition and assistance, and it is not practical to divide the activity into separate acquisition and assistance transactions, then the award instrument should reflect the principal purpose of the activity. Once that decision has been made, however, the degree of control and other terms of the award must be consistent with the funding mechanism (either acquisition or assistance). (NIH GAM 4.2.02.202.C)

F.3.3. Need for Substantial Involvement: Provide the rationale and need for substantial scientific-programmatic involvement (see NIH GAM 4.2.02.202.B.2 and NIH Manual 1820 for considerations involved in the use of cooperative agreements). Provide a brief description of the proposed substantial involvement by the Project Scientist/Coordinator/Collaborator. If more than one IC staff member is involved as a Project Scientist/Coordinator/Collaborator, the need for and nature of each of their involvements must be clearly explained. The specific involvement must be described in the "Cooperative Agreement Terms and Conditions of Award" in the NoA.

A Program Official is designated in the NoA. Routine Program Official post-award responsibilities (i.e., normal program stewardship of awards) described in the NIH GAM Chapter 4.1.04.204, "Responsibilities of Grants Administration Staff" (June 24, 2002) (see http://odoerdb2-2.od.nih.gov/oer/programs/coop/po_responsibilities.htm) are not adequate justifications for use of the cooperative agreement mechanism.

F.3.4. Maintaining Program Integrity: As noted in section D.8, substantial involvement in a cooperative agreement award while also serving as the designated Program Official for normal stewardship of the award can raise concerns about program integrity. Nevertheless, there may be situations where this dual service is warranted. In such cases, the IC must have internal procedures and policies in place to ensure that any concern about bias is successfully managed. The roles and responsibilities (i.e., different staff functions) for IC Project Scientist/Collaborator/Coordinator involved in the activity should also be appropriately reflected in the Cooperative Agreement Terms and Conditions of the NoA.

Include the IC procedures for managing the situation in the justification memo when one individual is substantially involved and also serves as the Program Official for stewardship (i.e., the Project Collaborator).

F.3.5. Concept Approval and IC Clearances: Provide assurance that the planned activity received concept review by an external advisory committee or workgroup.

Provide assurance that appropriate grants management, acquisition, and review officials concur in the selection of the cooperative agreement mechanism. Review and grants management officials are also responsible for ensuring that the information in the FOA is in compliance with applicable grant and cooperative agreement statutes, regulations, policies and procedures.

Explain any planned change of award instrument after the initial award period, consistent with the "Mechanism of Support" section below, including:

- If the awards will become grants, why substantial staff involvement will no longer be necessary;
- If contracts are planned, how the projects will become primarily for the direct benefit or use for the Government.

Deviations: Describe and justify any proposed deviations from applicable OMB administrative guidelines or HHS, PHS, and NIH grant administration regulations and policies. Those deviations must receive appropriate OER (or higher level) approvals as described in [NIH GAM 4.1.03.203](#), "Applicability." This includes, for example, a request for approval of a seven-year project period under an RFA as a single-case deviation ([NIH GAM 4204-204D](#) limits this to five years).

F.4. Submission of Cooperative Agreement Package to OEP

F.4.1. IC Submission of Request to OEP: The IC Extramural Program Management Committee (EPMC) member, or other designated official, will submit the initial or revised request package for the planned use of the cooperative agreement (via email) to the appointed OEP official for review and approval of its conformance with NIH policy and procedures, the appropriateness of NIH programmatic involvement and the terms and conditions of award. A detailed explanation of the submission process is available at http://odoerdb2.od.nih.gov/oer/policies/pol_coopagree_process_20000113.htm).

For FOAs, the request should be submitted as part of the submission to the [NIH Guide Publishing System](#). For new or complex initiatives, it may be helpful to seek advice from the designated OEP official in advance of the NIH Guide submission date to avoid delays if modifications are needed.

The request package comprises:

a. The justification memorandum, as described above in Section F.3, including assurances of appropriate concept review and review by IC officials; and

b. The planned FOA or Terms and Conditions for conversion to cooperative agreement. The submitting IC is responsible for ensuring that the FOA is in compliance with [NIH Manual 54110](#) and the required FOA templates and

standard language described in Section F.1 of this Chapter.

F.4.2. OEP/OER Evaluation and Approval Process

- The designated OEP official reviews and evaluates the IC request package for the appropriateness of the activity, the rationale and need for an assistance mechanism, the need for substantial scientific-programmatic involvement (see G.1.c above), and those sections of the FOA or proposed Terms and Conditions that specifically relate to the cooperative agreement mechanism.

- The OEP official approves or provides feedback to the IC official regarding requested additions, modifications, and/or clarifications within eight working days. This process is repeated until all cooperative agreement issues are resolved and use of the cooperative agreement mechanism is approved.

- If revisions are necessary, the EPMC member/IC official communicates them by e-mail to the submitting program staff to resolve the issues.

- When issues are resolved, the OEP official will provide an E-mail notification approval of the final documents for cooperative agreement use, with a copy to the NIH GUIDE staff.

- The IC is responsible for ensuring that the cooperative agreement approval is in the official file and retained in accordance with the [NIH Manual Chapter 1743](#), "Keeping and Destroying Records" (See Section I. Records Retention and Disposal for details).

- The assigned IC grants management official will incorporate, verbatim, the approved Terms and Conditions of Award into the NoA.

F.4.3. Publication of IC Policy Intent to Use Cooperative Agreements: An IC may wish to publish in the NIH Guide a policy indicating its intent to use cooperative agreements for certain kinds of unsolicited assistance awards. For example, an IC may wish to issue a policy indicating its intent to use cooperative agreements when supporting scientific meetings, consistent with

NIH Manual Chapter 54105, "NIH Grant Support of Scientific Meetings." OEP/OER, NIH shall review and approve any such announcement, along with the terms and conditions for such awards, following the procedures described above. OEP/OER shall consult with OGC, as necessary, when conducting such review and approval.

F.4.4. Conversion of an Unsolicited Grant Application or Contract Proposal to a Cooperative Agreement: IC staff may determine, on a case by case basis, that pending applications or proposals submitted for other funding mechanisms should be converted to "U" awards. Following peer review, an IC may also wish to consider converting an unsolicited application to a cooperative agreement. An SRG or Advisory Council may similarly recommend that certain applications or proposals be converted to cooperative agreements.

- After peer review, if IC staff judges that the "U" mechanism is valid and appropriate, they shall prepare a justification memorandum (see Section F.3.) and develop appropriate terms and conditions for awardee and staff responsibilities and authorities, reflecting staff judgments, advisory recommendations, and pertinent policies and procedures.

- Advisory recommendations, staff decisions, and terms and conditions shall be communicated to the OEP Official for review and approval. This includes requests for approval as a single-case deviation (see above).

- The IC must discuss the proposed Cooperative Agreement Terms and Conditions with the institution, and obtain agreement from the institution, before final award.

F.4.5. Conversion of Awarded Grant or Contract to Cooperative Agreement

- In cases where IC staff judges that the "U" mechanism is valid and appropriate for an ongoing grant or contract activity, the staff shall prepare a justification memorandum and develop appropriate terms and conditions for awardee and

staff responsibilities and authorities, reflecting staff judgments, advisory recommendations, and pertinent policies and procedures. NIH Office of Acquisitions staff shall follow FAR requirements for award termination when converting a contract to a cooperative agreement.

- Advisory recommendations, staff decisions, and terms and conditions shall be communicated to the OEP Official for review and approval.

- Ownership of, and access to, data should be defined consistent with applicable statutes and regulations when converting to or from an assistance mechanism.

- The IC must discuss the proposed Cooperative Agreement Terms and Conditions with the institution, and obtain agreement from the institution, before final award.

F.4.6. Changes to Substantial Involvement by Program Staff: If there is a change in the level of program staff involvement after award, the IC must submit the proposed revised terms and conditions to the OEP for review and approval. The IC must discuss the proposed terms and conditions with the institution, and obtain agreement from the institution, before issuing a revised NoA. The revised terms and conditions must be documented in the official file and must be retained in accordance with the [NIH Manual Chapter 1743](#), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

F.4.7. Conversion of Cooperative Agreement Awards to Grants or Contracts: If program intentions have changed since the issuance of an NoA and the cooperative agreement mechanism is no longer appropriate, program staff shall submit to the IC EPMC member or other responsible official a memorandum identifying the awards affected and explaining the reasons for the proposed change. The IC must also submit proposed revised terms and conditions to the OEP for review and approval. The IC must discuss the proposed terms and conditions with the institution, and obtain agreement from the institution, before issuing a revised NoA. The revised terms and conditions

must be documented in the official file and must be retained in accordance with the [NIH Manual Chapter 1743](#), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

For conversions to contracts, staff must follow the FAR. Staff must also follow the Justification Other than Full and Open Competition (JOFOC) procedures, if appropriate.

The IC EPMC member or other responsible official ensures that the shift of award instrument is appropriate and, after approving the change, sends copies of the justification and approval to the OEP/OER, NIH along with a Request for Assignment Change (Form NIH 901-1 "Grant/Application Change Notice" or electronic equivalent), to the Director, Division of Receipt and Referral (DRR), CSR, for necessary action. The documentation: (a) verifies that the IC approves the conversion, (b) becomes part of records for the awards and (c) indicates to CSR that pertinent applications or proposals are anticipated. The above officials communicate with the awarding IC and with one another if the shift to another award instrument needs clarification. Retain all records in accordance with the [NIH Manual Chapter 1743](#), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

F.5. Receipt, Review, Award, and other Administrative Components

F.5.1. Receipt and Referral of Applications: Applications responding to a cooperative agreement FOA are assigned the appropriate "U" activity code by the OEP, NIH.

Unsolicited applications are assigned an appropriate grant activity code without regard to the possibility of their becoming a "U" award. After the required peer review, if an IC wishes to fund such an application as a cooperative agreement, a request for conversion to a cooperative agreement mechanism is submitted to OEP following the procedures described above. After written (email) approval of

the conversion by OEP, the IC grants management official can change the activity code to the appropriate cooperative agreement activity code in IMPAC II following standard procedures.

F.5.2. Review of Cooperative Agreement Applications: Most applications for cooperative agreements respond to FOAs that specify the terms and conditions of award and other requirements.

F.5.3. Scientific Review Officer (SRO) Management of Conflict of Interest for the Initial Peer Review Meeting

See also [NIH GAM 4204-204B](#), Peer Review Process.

- SROs are responsible for managing COI or appearances of COI during the initial peer review process. This includes: 1) screening potential SRG members and assigned reviewers for COI or appearances of COI, 2) instructing those selected to identify to them situations that constitute a COI or appearance of a COI, and 3) avoiding or minimizing such situations. Procedures and measures to be taken by the SRO and the SRG members in advance of, during, and after scientific review meetings in relation to COI and appearance of COI are based on the peer review regulations at 24 CFR 52h (http://grants.nih.gov/grants/policy/fed_reg_peer_rev_20040115.pdf).

F.5.4. Award of Cooperative Agreements: ICs will make cooperative agreement awards using the same funding criteria and procedures as for grants.

- At the time of award, the IC must notify the awardee of the name(s) and title(s) of the program staff who have substantial scientific-programmatic involvement in the project, as well as the name(s) and title(s) of the IC program official responsible for normal stewardship of the award. The NoA shall identify, by titles only (i.e., Project Scientist/Coordinator/Collaborator), any program, extramural or intramural staff involved in the cooperative agreement.

F.5.5. Administration of Cooperative Agreements: Administration of cooperative agreements shall be consistent with all applicable statutory and regulatory requirements, including the HHS Grants Administration Regulations set forth at 42 CFR Part 74 (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, or Other Nonprofit Organizations, and Commercial Organizations) or 45 CFR Part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments), as well as applicable OMB Circulars and HHS and NIH grant administration policies and procedures.

Because substantial NIH program/scientific staff involvement is an integral component of "U" awards, adequate documentation of that participation constitutes an important program management tool.

The official cooperative agreement file, as maintained by grants management, will document the names of substantially involved IC program staff, as well as the nature of IC staff involvement. IC program staff shall prepare an annual summary of IC staff involvement in the award, and shall send the summary to the grants management officer/specialist upon the receipt, review and acceptance of the annual and/or final progress report, for inclusion in the official file. All records must be retained in accordance with the [NIH Manual Chapter 1743](#), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

F.5.6. Renewal and Revision Applications: IC program staff's written communication should advise awardees submitting Renewal (Type 2) and Revision (Type 3) applications to describe, along with other progress, how they have met the terms and conditions of their awards, including, where appropriate, any terms and conditions related to their interaction with the IC staff collaborators. If Type 2 or 3 applications do not include this information, SROs will obtain it from awardee-applicants to ensure adequate review.

If current projects will continue as "U" awards with the same parameters as before, the IC should invite Type 2 applications from awardees through individual written communications. If this is intended to limit competition, follow NIH GAM 4204-204A - Requirements for Maximum Competition under Assistance Programs.

If the IC plans significant changes in award objectives, approaches, or costs, or intends to reissue the FOA to seek new "U" awardees to add to or replace current ones, IC staff should follow the same procedures as for new "U" FOAs.

G. References

1. Public Law 95-224, Federal Grant and Cooperative Agreement Act of 1977, as amended by Public Law 97-258, 31 U.S.C. § 6301 et seq...

2. Office of Management and Budget — Implementation of Federal Grant and Cooperative Agreement Act of 1977 —Final OMB Guidance (43 CFR 36860-65, August 18, 1978).

3. NIH GAM 4.1.04.204 — Responsibilities of NIH Grants Administration Staff.

4. NIH GAM 4.2.02.202 — Determining Appropriate Award Instrument.

5. NIH GAM 4204-204A — Requirements for Maximum Competition under Assistance Programs.

6. NIH GAM 4204-204B — Peer Review Process.

7. NIH GAM 4.2.01.201 — Special Award Conditions, Departmental Alert List, and Debarment.

8. NIH GAM 4204-204C — Notification of Funding.

9. NIH GAM 4204-204D — Project Period System of Awarding Grants and Duration of Recommended Grant Support.

10. NIH Manual 54110 — Program Announcements (PAs) and Requests for

Applications (RFAs).

11. [NIH Manual 54513](#) — Management and Procedures of National Advisory Councils and Boards in their Review of Extramural Activities.

12. [NIH Manual 1743](#) — Keeping and Destroying Records.

13. Intramural/Extramural Collaborations — Collaborations of NIH Scientists with Extramural Scientists. http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/irp-erp-Cover-Memo-10-27-99.htm and http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/fund-irp-erp-3-00.htm. Intramural Scientists cannot receive Extramural Funds when participating in a cooperative agreement award; their support is provided by the IC Intramural Program.

14. [NIH Manual 54105](#) — NIH Support of Scientific Meetings and Conferences by Grants and Cooperative Agreements.

15. [NIH Manual 1184](#) — Scientific, Technical, and Other Professional Information Presented by NIH Employees: Review, Approval, and Distribution. See, in particular, Section H. NIH Staff (Co-) Authorship of Publications from NIH Extramural Awards.

H. Additional Information

Format for FOAs for Cooperative Agreements includes examples of language for use to implement an announcement for a cooperative agreement. In addition, OEP can provide further information on this Manual, and advice on generic issues and specific questions regarding current or planned "U" awards.

I. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to the processes described in this chapter must be maintained (e.g. retained and/or disposed of) under the authority of NIH Manual 1743, "Keeping and Destroying Records", NIH Records Control Schedule, Section 1100 - General Administration and Section 4000

Grants and Awards.

NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of the Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

J. Management Controls

The purpose of this section is to provide guidance to OEP for the implementation of the cooperative agreement award instrument at NIH.

J.1. Office Responsible for Reviewing Management Controls Related to this Chapter: Responsibility for monitoring compliance with this chapter resides with the OEP/OER. The Office of Policy for Extramural Research Administration (OPERA) is responsible for reviewing management controls relative to the grants management issues involved in this chapter.

J.2. Frequency of Review: On-going review, no less than every five years.

J.3. Method of Review: Other review: OEP will use several methods of review, including the ongoing review of new cooperative agreement requests from IC Officials, in which new issues may arise that need to be incorporated into the chapter, and in which feedback from IC Officials on current procedures is obtained; periodic sampling of electronic notices of grant awards via the IMPAC II system; feedback from periodic extramural staff training programs on cooperative agreements; and feedback from the Program Leadership Committee (PLC), including working groups to evaluate cooperative agreement use. In addition, OPERA will be routinely apprised of any difficulties in the implementation of this policy. Reports of findings and recommendations resulting from these types of reviews will be issued to assess compliance with the policy stated in this chapter. Common issues will be brought to the PLC and the Extramural Program Management Committee (EPMC) for resolution and corrective action. Depending upon the nature and the extent of problems found, if any, the DDER may recommend additional review, policy guidance, and/or training of staff.

J.4. Review Reports: Reports are sent to the DDER and OPERA. Reports should also be sent to the Deputy Director for Management. Reports should indicate that controls are in place and working well or indicate any internal management control issues that should be brought to the attention of the report recipient(s).

NIH POLICY MANUAL

54815 Implementation of Cooperative Agreements

Issuing Office: OEP/OER/OD 301-435-2690

Release Date: 08/17/09

1. **Explanation of Material Transmitted:** This chapter contains revised policy and procedures for implementation of cooperative agreements. Due to the length of the chapter, subsections are numbered to assist in making citations and finding information. This chapter defines the types of substantial NIH scientific and/or programmatic involvement after award. Substantial involvement occurs when NIH Scientific or Program staff provides technical assistance, advice, coordination, and/or other functions above and beyond the usual level of program stewardship for grants. These include the following four distinct roles: "Project Scientist," "Project Coordinator," "Project Collaborator," and "NIH Intramural Scientist."

2. **Filing Instructions:**

   Remove: NIH Manual 54815, Implementation of Cooperative Agreements: Initiation, Review, Award, and Administration, dated 10/01/93.

   Insert: NIH Manual 54815, Implementation of Cooperative Agreements, dated 08/17/09.

PLEASE NOTE:

- For questions on this chapter, contact the issuing office listed above.

- For on-line information on the NIH Manual System, go to http://oma.od.nih.gov/manualchapters/.

- To sign up for email notification of future changes, please go to the NIH Manual Chapters LISTSERVE Web Page.

- For Cooperative Agreement Conference Grants, please see [NIH Manual Chapter 54105](#).

- For additional information on Cooperative Agreements, go to the [Cooperative Agreement Kiosk](#) (see: http://odoerdb2-2.od.nih.gov/oer/programs/coop/).

A. Purpose

This issuance establishes NIH policy for initiation, review, award, and administration of cooperative agreements for conducting extramural research and development projects. For additional information on Cooperative Agreements, go to the [Cooperative Agreement Kiosk](#).

B. Background

The Federal Grant and Cooperative Agreement Act of 1977, P.L. 95-224 (FGCA) as amended by P.L. 97-258 (31 U.S.C. § 6301 et. seq.), established Government-wide criteria to distinguish between Federal acquisition and assistance relationships with other parties. The Act emphasizes that the choice of award instrument should be based on the purpose of the agency-recipient relationship, characteristics of the legal instruments, and related standards and conditions. Under the Act:

- The Federal Government shall use a contract mechanism when the principal purpose of the transaction is the acquisition of property or services for its direct benefit or use.

- The Federal Government shall use an assistance mechanism when the principal purpose of the transaction is to transfer money, property, or services to a recipient to accomplish a public purpose of support or stimulation authorized

by law.

1. Grants are used when no substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity.

2. Cooperative agreements are used when substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity.

In 1978 the Office of Management and Budget (OMB) published Government-wide guidance to implement the FCGA. HHS has implemented the FCGA in its grants administration regulations at 45 C.F.R. Part 74 and 45 C.F.R. Part 92, and NIH manual issuances have expanded on that guidance. See [NIH Manual Chapter 1820](#), "Selection of Extramural Award Instrument – Grant, Cooperative Agreement, or Contract" and [NIH Grants Administration (GAM) Chapter 4.2.02.202 "Determining Appropriate Award Instrument"](#), which provide NIH policy for selecting appropriate award instruments. This Manual Chapter provides NIH guidance for procedures to initiate, review, award, and administer cooperative agreements.

C. Policy

NIH Institutes and Centers (ICs) must use a cooperative agreement whenever an assistance award is made and need is demonstrated for the substantial involvement of scientific-programmatic staff during the performance of the activity. A cooperative agreement is not intended as a means to exercise greater control over a recipient or a project than would be the case under a grant or to allow for involvement that exceeds that which is permissible under a contract. When the substantial involvement is the collaboration of an NIH Intramural scientist in an extramurally-funded assistance project, the IC must fund the project as a cooperative agreement. The IC must have a process to manage concern about bias (see D.8 and D.9 below) involving staff with

substantial involvement in cooperative agreement awards. For additional information on Cooperative Agreements, go to the [Cooperative Agreement Kiosk](#).

NIH implements cooperative agreements through policies and procedures appropriate for grants, and assigns an NIH activity code in the "U" series. In general, ICs announce their intentions to make "U" awards for special projects or programs in Funding Opportunity Announcements (FOA). ICs must pay particular attention to special requirements for program planning and advisory group recommendations, scientific peer review of applications, award terms and conditions, and corresponding administrative details. Cooperative Agreement Terms and Conditions of Award (COA) shall reflect the terms and conditions approved in the OEP review (see note below) and ensure preservation of the authorities and responsibilities of awardee investigators to control and direct the development, conduct, and publication of their studies, and of IC staff to assist those processes. NIH staff involvement is limited to those activities listed on the Notice of Award (NoA).

Note: The IC Extramural Program Management Committee (EPMC) member or designee submits the planned use of the cooperative agreement to the Office of Extramural Programs (OEP), Office of Extramural Research (OER) official designated by the Deputy Director for Extramural Research (DDER), NIH, for review and approval and conformance with this Manual Chapter (For additional details, see Sections F.2 and F.4).

D. Definitions

D.1. Assistance: The award of money, property, services, or anything of value by the Federal Government to a recipient to accomplish a public purpose of support or stimulation authorized by Federal statute. Assistance relationships are generally expressed less formally and in less detail than acquisitions.

D.2. Acquisition: The purchase, lease, or barter of property or services for the direct benefit or use of the Federal Government, including dissemination to third parties or the public. Acquisition establishes a procurement relationship and defines the rights and duties of the Government as buyer, and of the performer as seller.

D.3. Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

D.4. Cooperative Agreement: An award instrument of financial assistance where "substantial involvement" is anticipated between the NIH and the recipient during performance of the contemplated project or activity. "Substantial involvement" means that the recipient can expect Federal programmatic collaboration or participation in managing the award.

Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Consistent with this concept, the dominant role and prime responsibility for the activity reside with the awardee(s) for the project as a whole, although specific tasks and activities in carrying out the studies will be shared among the awardees and the IC Project Scientist and/or Program Official/Collaborator/Coordinator. The IMPAC activity code "U" is assigned to these awards.

D.5. Program Official

The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement that involves normal program stewardship of the award.

D.5.1. Normal *Program Official* Stewardship

Usually the Program Official is a separate staff member from the substantially involved staff member. Normal Program Official stewardship includes:

- Enforcement of general statutory, regulatory, or policy requirements;

- Approval of awardee plans prior to award and review of performance after completion;

- Evaluation of progress by reviews of technical or fiscal reports, site visits, or external consultants, to determine that performance is consistent with the terms and conditions of the award;

- Technical assistance requested by awardees, or unanticipated procedures to correct programmatic or financial deficiencies in awardees' performance;

- Scientific/technical discussions with awardees, or actions to facilitate or expedite interactions between awardees, e.g., organizing and holding meetings of investigators;

See also detailed information on http://odoerdb2-2.od.nih.gov/oer/programs/coop/po_responsibilities.htm, including several examples of normal program stewardship functions in the administration of PHS grants.

D.6. Substantial Involvement

Substantial involvement occurs when NIH scientific or program staff provides technical assistance, advice, coordination, and/or other functions above and beyond the usual level of programmatic and/or scientific stewardship for grants. This level of staff involvement does not alter the awardee's dominant role and prime authority in conducting the activity (see [NIH Manual 1820](#)).

D.6.1. Substantial *Programmatic* Involvement: NIH program staff provides

technical assistance, advice, coordination, and other program actions supporting recipients of cooperative agreements during the conduct of an activity, above and beyond the levels required normally for program stewardship of grants, but without dominating the relationship.

D.6.2. Substantial *Scientific* Involvement: NIH program staff provides scientific technical assistance and advice to recipients of cooperative agreements during the conduct of an activity, above and beyond the levels required normally for program stewardship of grants, but without dominating the relationship.

D.7. Types of Substantial Involvement

1. *Project Scientist:* Substantial scientific involvement by NIH extramural staff or substantial scientific and programmatic involvement by NIH extramural staff. (See Section D.7.1 below for additional details)

2. *Project Coordinator:* Substantial programmatic involvement by NIH extramural staff. (See Section D.7.2 below for additional details)

3. *Project Collaborator:* Substantial scientific and/or programmatic involvement combined with the normal Program Official role. (See Section D.7.3 below for additional details)

4. *NIH Intramural Scientist:* Substantial scientific involvement as a key co-investigator in the extramural research project. (See Section D.7.4 below for additional details)

   When the substantial involvement involves the collaboration of an NIH Intramural Scientist in an extramurally funded assistance project, the IC may fund the project as a cooperative agreement (see: [Collaborations of NIH Scientists with Extramural Scientists](#)). The Intramural Scientist cannot receive extramural funds for participation in the cooperative agreement award.

Examples of substantial involvement include activities such as:

D.7.1. Substantial SCIENTIFIC Involvement (e.g., Project Scientist)

- Cooperation or coordination with, or assistance to, awardees in performing project activities, e.g., development of research protocols; data collection, analyses, and interpretations; re-establishment of objectives during the course of a project; or holding FDA Investigational New Drugs (INDs) for investigational drugs;

- Providing for an option to halt a project activity if technical performance requirements are not met or if program objectives have already been met;

- Specifying under the terms and conditions of award that the project be structured in stages and that NIH staff review and approve each stage before work may begin on such stage, e.g. concepts for research projects;

- Assistance with the selection of contractors or sub-awardees under the assistance award, and in the selection of key project personnel other than principal investigators of projects or sub-projects;

- Technical monitoring to permit specific direction of the project, including recommending approval of changes in experimental approaches;

- Participation on committees (other than peer review, see below) as a voting member as needed (the chairperson will be someone other than an IC staff member) or in other functions responsible for helping to guide the course of long-term projects or activities; and

- Participation in the presentation of research results, including publications from the project;

- Generally not involved in normal programmatic stewardship of the project;

- Has defined procedure for management of concern about bias (see D.8 and D.9) by NIH staff, developed by the IC;

- May not attend peer review meetings of Renewal or Revision applications unless IC waiver obtained per IC procedures for management of concern about bias.

D.7.2. Substantial PROGRAMMATIC Involvement (e.g., Project Coordinator)

- Cooperation or coordination with, or assistance to, awardees in performing project activities, e.g., coordination of research networks; providing access to NIH supported research resources; identifying other researchers/resources for the project; assistance in processing FDA INDs for investigational drugs;

- Participation on committees as a voting member as needed (the chairperson will be someone other than an IC staff member) or in other functions responsible for helping to guide the course of long-term projects or activities, e.g., annual meetings of awardees, Chair and/or member of project oversight committees composed of NIH officials;

- Not involved in normal program stewardship;

- May not attend peer review meetings of Renewal or Revision applications unless IC waiver obtained per IC procedures for management of concern about bias.

D.7.3. Program Official plus Substantial Scientific and/or Programmatic Involvement (e.g., Project Collaborator)

- Provides normal program stewardship;

- Selected activities for scientific and/or programmatic substantial involvement, as set forth in Sections D.7.1. and/or D.7.2. of this Manual Chapter;

- Has defined procedure for management of concern about bias by NIH staff, developed by the IC;

- May not attend peer review meetings of Renewal or Revision applications or the

closed session of IC Council/Board, unless an IC waiver is obtained per IC procedures for management of concern about bias.

D.7.4. Substantial Scientific Involvement by an NIH Intramural Scientist

- The NIH Intramural Scientist with substantial scientific involvement is designated as an NIH Intramural Scientist in the cooperative agreement terms and conditions of award.

- The NIH Intramural Scientist is not involved in normal program stewardship. A separate Extramural Program Official is assigned to the award for normal program stewardship.

- The NIH Intramural Scientist will not attend a Peer Review meeting of the same project conducted by extramural Scientific Review Officers (SROs).

Examples of Intramural Scientific Staff Activities that Constitute Substantial Involvement http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/coop-agr.htm:

- Acting as the director of a project within a program project (P01) grant.

- Having primary responsibility for a specific aim within a regular research project grant (R01).

- Development of a major data base for an extramural collaborator.

- Participation in a multi-institutional collaborative arrangement with extramural researchers for clinical, prevention or epidemiological studies.

Notes:

1. Involvement may initially be un substantial, but evolve over time to become substantial, thus requiring reconsideration of the appropriate mechanism of award.

2. Certain kinds of involvement, such as acting as consultant to provide occasional advice or providing occasional sample analyses, likely do not constitute

substantial involvement.

3. It is acknowledged that gray areas may arise that will require determination on a case-by-case basis to be resolved by OEP, the IC, or both.

D.8. Concern about Bias (formerly Conflict of Interest) in Programmatic Administration of Cooperative Agreements

In addition to the criminal statutes and government-wide and NIH-specific Standards of Ethical Conduct with which all NIH staff must comply, NIH management exercises its inherent authority to assign work in a manner that protects the perceived integrity of administration of cooperative agreements. The participation of an NIH employee who is substantially involved under a cooperative agreement in the normal programmatic stewardship of the award could raise concerns regarding the integrity of agency operations. As a result of the substantial involvement with the award, the staff role as a partner may appear to be similar to that of a co-investigator on the award, which could result in a real or apparent bias about the project that prohibits independent evaluation of the progress of the award; the Project Scientist/Collaborator also may publish with the awardee in accordance with NIH publication policy. Accordingly, employees who are substantially involved in such a project are prohibited from participating in the normal programmatic stewardship of the award, unless the IC has an appropriate procedure in place to reduce or address any such concern about bias.

D.9. IC Management of Concern about Bias

ICs must establish procedures to eliminate or mitigate any concerns about the integrity of awards or bias if a Program Official for an award also is substantially involved in an award. Relevant approaches may include:

- A waiver procedure from the immediate supervisor AND next higher level supervisor OR EPMC member (if applicable) or designee to allow attendance at

the peer review meeting (IC or CSR) and the closed session of an IC Council/Board meeting that includes review of the relevant Renewal applications and Revisions. A justification for why a Program Official cannot cover the Peer Review meeting or IC Council/Board meeting is required. Staff roles should be considered (see [NIH Policy Manual 4204-204B, Peer Review Process](#)).

- Clarification of budgetary or programmatic lines of authority for an award to manage, reduce, or eliminate concern about bias.

- Establishment of an independent IC or NIH oversight committee to assist the designated Program Official in monitoring performance.

- Clarification of IC measures used to manage concern about bias when multiple program staff (including, but not limited to Project Scientists/Coordinators/Collaborators) within an IC, or from multiple ICs, are substantially involved in complex projects, e.g., Roadmap Initiatives, Clinical Cooperative Groups, and Networks. Generally, the attendance at Peer Review meetings will need justification and any waiver will be limited to the named lead person on the complex project.

- Clarification of intent for IC staff to publish with the awardee consistent with the NIH publication policy (see also [NIH Manual Chapter 1184](#)).

E. Responsibilities

E.1. Office of the Director, NIH

The Deputy Director for Extramural Research (DDER) establishes NIH grant policies including determining the adequacy of procedures for implementing cooperative agreements, and maintaining an overview of IC practices in carrying out pertinent policies and procedures, through solicitation procedures outlined below and through occasional program and review evaluations.

The DDER appoints a senior OEP official responsible for approving the use of

the cooperative agreement mechanism for NIH projects. This person evaluates IC requests to use cooperative agreements based on compliance with NIH policies and procedures for using this award instrument. The senior OEP official provides additional instructions, procedures, and advice to ensure that the cooperative agreement mechanism is the proper award instrument to use for the IC's purpose. The OEP official may obtain advice from senior NIH program, grants policy, and acquisition policy staff experienced with the use of the cooperative agreement mechanism to assist in the evaluation of IC requests.

E.2. NIH Awarding ICs

IC Directors define procedures by which their staffs implement cooperative agreements under the provisions of this Manual.

IC Official: A single IC official is designated to clear requests from an IC for use of the cooperative agreement mechanism and is responsible for the quality of the submission. This IC official is generally the Extramural Program Management Committee (EPMC) member, although the IC may designate a different official for this purpose.

IC program, review, and grants management officials implement established policies and procedures to initiate, review, award, and administer cooperative agreement awards.

The IC Grants Management Officer (IC GMO) is responsible for certifying the proper choice of the assistance award instrument.

F. Procedures

F.1. Institute/Center (IC) Development and Internal Clearance of Activity

F.1.1. Decision to use a cooperative agreement mechanism: IC Program Officials are responsible for planning programs and activities and for

determining the appropriate funding mechanism (grant, cooperative agreement, or contract). To utilize the cooperative agreement mechanism, the IC must obtain the following advice and recommendations:

- Program staff must obtain concept review through recommendations from public discussion (e.g. Councils, Boards, workshops) on the purpose, relevance, scope, priority, and need for the activity when proposed as an FOA. The recommendations should be documented in the form of minutes or other official documents and retained in accordance with the NIH Manual Chapter 1743, Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

- Program staff must seek technical and procedural advice on the development of the cooperative agreement activity from review, grants management, and contracting officials, according to NIH and IC policies and procedures.

F.1.2. Preparation of the FOA: The FOA shall follow the requirements in NIH Manual Chapter 54110, "Program Announcements and Requests for Applications," and shall use the templates and standard language provided by OEP/OER, including the specific sections of the templates and standard language relating to cooperative agreements. See Format for FOAs for Cooperative Agreements for specific text recommended by the OEP. The Cooperative Agreement Kiosk (see: http://odoerdb2-2.od.nih.gov/oer/programs/coop/) will also have *examples of previously approved cooperative agreement announcements.* The FOA should describe any plans to continue the cooperative agreement project beyond the initial period of award and any other possible post-award changes (for example, plans to convert the awards to grants or contracts after the initial award period), consistent with the "Preparation of Justification Memorandum." (see Section F.3).

F.2. Cooperative Agreement Terms and Conditions (Section VI.2.A. of FOA

template)

ICs shall use the following standard subheadings for cooperative agreement terms and conditions of award.

F.2.1. Cooperative Agreement Mechanism: Add the following statement that clarifies the special terms and conditions of the cooperative agreement award:

"The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, and NIH grant administration policies."

"The administrative and funding instrument used for this program will be the cooperative agreement Uxx, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below."

A one or two sentence description of the project should be included when a group of awards or components have the same cooperative agreement terms and conditions of award, e.g., for a network or multi-site/multi-component project. ("The xxx Network consists of the number of Clinical Sites, a Data Coordinating Center, a Steering Committee, etc").

F.2.2. Awardee Rights and Responsibilities: Describe the primary authorities

and responsibilities of awardees to define objectives and approaches, and to plan, conduct, analyze, share, and publish results, interpretations, and conclusions of their studies. Describe the responsibilities of multiple awardees in collaborating on common protocols, etc., including methods and requirements for joint participation and collaboration, and the handling of data, including the appropriate sharing of methods and data among collaborating organizations. For multi-award clinical trials, include separate responsibilities for major components: e.g., clinical sites, data coordinating centers, etc.

Awardees should be advised that they will retain custody of and primary rights to their data developed under the award, subject to current Government policies regarding rights of access.

F.2.3. NIH Responsibilities

"An NIH IC Project Scientist/Coordinator/Collaborator will be substantially involved in this project above and beyond the normal stewardship of an NIH IC Program Official as follows:"

Describe the nature, character, and extent of the IC Project Scientist/Coordinator/Collaborator's scientific-programmatic involvement (i.e., the NIH "partner") during conduct of the activity, as set forth in Section D.7 above. Staff involvement must reflect that the dominant role and prime responsibility for the activity reside with the awardee(s) for the project as a whole, but not necessarily for each task.

Optional: ICs may identify the IC staff who will be scientifically-programmatically involved in the activity as the NIH IC Project Scientist, or Project Coordinator, or Project Collaborator, by project/program-specific functional title.

In most circumstances, an IC will identify two different program staff members involved with the cooperative agreement - one is the IC Project Scientist/Coordinator/Collaborator, and the other is the IC Program Official

responsible for normal program stewardship of awards. The roles and responsibilities (i.e., different staff functions) for IC program staff involved in the activity should be appropriately reflected in the Terms and Conditions of the NoA.

F.2.4. Collaborative Responsibilities: Where applicable, describe membership, responsibilities, and operations of any committees, such as a Steering/Executive Committee and other central coordinating components in which there is substantial scientific-programmatic involvement.

F.2.5. Dispute Resolution (formerly Arbitration): Using standard template language if possible, describe pertinent dispute resolution mechanisms applicable to scientific disagreements *between awardees and the IC,* related to programmatic decisions on scientific/technical matters. Add the following statement to assure that resolution of differences will not affect the appeals process: "These special dispute resolution procedures in no way affect the awardee's right to appeal an adverse action in accordance with PHS regulations at 42 CFR Part 50, Subpart D, and HHS regulations at 45 CFR Part 16."

In some cases, a separate dispute resolution mechanism may be described and encouraged for disagreements among awardees.

F.3. Preparation of Justification Memorandum to the Office of Extramural Programs/Office of Extramural Research (OEP/OER)

A justification memorandum should be prepared that addresses the following items, using the following format:

F.3.1. Description of Project: Provide a very brief description of the project in a short paragraph. A detailed description of and scientific rationale for the project are not required in this memorandum.

F.3.2. Need for an Assistance Mechanism: Briefly explain the rationale and

need for an assistance mechanism (e.g., for a general public purpose or good) rather than acquisition (primarily for direct Federal Government benefit or use). This explanation should discuss how the activity will assist, stimulate, or support recipients to define and conduct their project activities, and should mention how project results or products will be used and disseminated (see NIH Manual 1820 and NIH GAM 4.2.02.202.B.2 for further description of the award selection criteria).

When a project involves aspects of both acquisition and assistance, and it is not practical to divide the activity into separate acquisition and assistance transactions, then the award instrument should reflect the principal purpose of the activity. Once that decision has been made, however, the degree of control and other terms of the award must be consistent with the funding mechanism (either acquisition or assistance). (NIH GAM 4.2.02.202.C)

F.3.3. Need for Substantial Involvement: Provide the rationale and need for substantial scientific-programmatic involvement (see NIH GAM 4.2.02.202.B.2 and NIH Manual 1820 for considerations involved in the use of cooperative agreements). Provide a brief description of the proposed substantial involvement by the Project Scientist/Coordinator/Collaborator. If more than one IC staff member is involved as a Project Scientist/Coordinator/Collaborator, the need for and nature of each of their involvements must be clearly explained. The specific involvement must be described in the "Cooperative Agreement Terms and Conditions of Award" in the NoA.

A Program Official is designated in the NoA. Routine Program Official post-award responsibilities (i.e., normal program stewardship of awards) described in the NIH GAM Chapter 4.1.04.204, "Responsibilities of Grants Administration Staff" (June 24, 2002) (see http://odoerdb2-2.od.nih.gov/oer/programs/coop/po_responsibilities.htm) are not adequate justifications for use of the cooperative agreement mechanism.

F.3.4. Maintaining Program Integrity: As noted in section D.8, substantial involvement in a cooperative agreement award while also serving as the designated Program Official for normal stewardship of the award can raise concerns about program integrity. Nevertheless, there may be situations where this dual service is warranted. In such cases, the IC must have internal procedures and policies in place to ensure that any concern about bias is successfully managed. The roles and responsibilities (i.e., different staff functions) for IC Project Scientist/Collaborator/Coordinator involved in the activity should also be appropriately reflected in the Cooperative Agreement Terms and Conditions of the NoA.

Include the IC procedures for managing the situation in the justification memo when one individual is substantially involved and also serves as the Program Official for stewardship (i.e., the Project Collaborator).

F.3.5. Concept Approval and IC Clearances: Provide assurance that the planned activity received concept review by an external advisory committee or workgroup.

Provide assurance that appropriate grants management, acquisition, and review officials concur in the selection of the cooperative agreement mechanism. Review and grants management officials are also responsible for ensuring that the information in the FOA is in compliance with applicable grant and cooperative agreement statutes, regulations, policies and procedures.

Explain any planned change of award instrument after the initial award period, consistent with the "Mechanism of Support" section below, including:

- If the awards will become grants, why substantial staff involvement will no longer be necessary;
- If contracts are planned, how the projects will become primarily for the direct benefit or use for the Government.

Deviations: Describe and justify any proposed deviations from applicable OMB administrative guidelines or HHS, PHS, and NIH grant administration regulations and policies. Those deviations must receive appropriate OER (or higher level) approvals as described in [NIH GAM 4.1.03.203](), "Applicability." This includes, for example, a request for approval of a seven-year project period under an RFA as a single-case deviation ([NIH GAM 4204-204D]() limits this to five years).

F.4. Submission of Cooperative Agreement Package to OEP

F.4.1. IC Submission of Request to OEP: The IC Extramural Program Management Committee (EPMC) member, or other designated official, will submit the initial or revised request package for the planned use of the cooperative agreement (via email) to the appointed OEP official for review and approval of its conformance with NIH policy and procedures, the appropriateness of NIH programmatic involvement and the terms and conditions of award. A detailed explanation of the submission process is available at [http://odoerdb2.od.nih.gov/oer/policies/pol_coopagree_process_20000113.htm]()).

For FOAs, the request should be submitted as part of the submission to the [NIH Guide Publishing System](). For new or complex initiatives, it may be helpful to seek advice from the designated OEP official in advance of the NIH Guide submission date to avoid delays if modifications are needed.

The request package comprises:

a. The justification memorandum, as described above in Section F.3, including assurances of appropriate concept review and review by IC officials; and

b. The planned FOA or Terms and Conditions for conversion to cooperative agreement. The submitting IC is responsible for ensuring that the FOA is in compliance with [NIH Manual 54110]() and the required FOA templates and

standard language described in Section F.1 of this Chapter.

F.4.2. OEP/OER Evaluation and Approval Process

- The designated OEP official reviews and evaluates the IC request package for the appropriateness of the activity, the rationale and need for an assistance mechanism, the need for substantial scientific-programmatic involvement (see G.1.c above), and those sections of the FOA or proposed Terms and Conditions that specifically relate to the cooperative agreement mechanism.

- The OEP official approves or provides feedback to the IC official regarding requested additions, modifications, and/or clarifications within eight working days. This process is repeated until all cooperative agreement issues are resolved and use of the cooperative agreement mechanism is approved.

- If revisions are necessary, the EPMC member/IC official communicates them by e-mail to the submitting program staff to resolve the issues.

- When issues are resolved, the OEP official will provide an E-mail notification approval of the final documents for cooperative agreement use, with a copy to the NIH GUIDE staff.

- The IC is responsible for ensuring that the cooperative agreement approval is in the official file and retained in accordance with the [NIH Manual Chapter 1743](#), "Keeping and Destroying Records" (See Section I. Records Retention and Disposal for details).

- The assigned IC grants management official will incorporate, verbatim, the approved Terms and Conditions of Award into the NoA.

F.4.3. Publication of IC Policy Intent to Use Cooperative Agreements: An
IC may wish to publish in the NIH Guide a policy indicating its intent to use cooperative agreements for certain kinds of unsolicited assistance awards. For example, an IC may wish to issue a policy indicating its intent to use cooperative agreements when supporting scientific meetings, consistent with

NIH Manual Chapter 54105, "NIH Grant Support of Scientific Meetings." OEP/OER, NIH shall review and approve any such announcement, along with the terms and conditions for such awards, following the procedures described above. OEP/OER shall consult with OGC, as necessary, when conducting such review and approval.

F.4.4. Conversion of an Unsolicited Grant Application or Contract Proposal to a Cooperative Agreement: IC staff may determine, on a case by case basis, that pending applications or proposals submitted for other funding mechanisms should be converted to "U" awards. Following peer review, an IC may also wish to consider converting an unsolicited application to a cooperative agreement. An SRG or Advisory Council may similarly recommend that certain applications or proposals be converted to cooperative agreements.

- After peer review, if IC staff judges that the "U" mechanism is valid and appropriate, they shall prepare a justification memorandum (see Section F.3.) and develop appropriate terms and conditions for awardee and staff responsibilities and authorities, reflecting staff judgments, advisory recommendations, and pertinent policies and procedures.

- Advisory recommendations, staff decisions, and terms and conditions shall be communicated to the OEP Official for review and approval. This includes requests for approval as a single-case deviation (see above).

- The IC must discuss the proposed Cooperative Agreement Terms and Conditions with the institution, and obtain agreement from the institution, before final award.

F.4.5. Conversion of Awarded Grant or Contract to Cooperative Agreement

- In cases where IC staff judges that the "U" mechanism is valid and appropriate for an ongoing grant or contract activity, the staff shall prepare a justification memorandum and develop appropriate terms and conditions for awardee and

staff responsibilities and authorities, reflecting staff judgments, advisory recommendations, and pertinent policies and procedures. NIH Office of Acquisitions staff shall follow FAR requirements for award termination when converting a contract to a cooperative agreement.

- Advisory recommendations, staff decisions, and terms and conditions shall be communicated to the OEP Official for review and approval.

- Ownership of, and access to, data should be defined consistent with applicable statutes and regulations when converting to or from an assistance mechanism.

- The IC must discuss the proposed Cooperative Agreement Terms and Conditions with the institution, and obtain agreement from the institution, before final award.

F.4.6. Changes to Substantial Involvement by Program Staff: If there is a change in the level of program staff involvement after award, the IC must submit the proposed revised terms and conditions to the OEP for review and approval. The IC must discuss the proposed terms and conditions with the institution, and obtain agreement from the institution, before issuing a revised NoA. The revised terms and conditions must be documented in the official file and must be retained in accordance with the NIH Manual Chapter 1743, Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

F.4.7. Conversion of Cooperative Agreement Awards to Grants or Contracts: If program intentions have changed since the issuance of an NoA and the cooperative agreement mechanism is no longer appropriate, program staff shall submit to the IC EPMC member or other responsible official a memorandum identifying the awards affected and explaining the reasons for the proposed change. The IC must also submit proposed revised terms and conditions to the OEP for review and approval. The IC must discuss the proposed terms and conditions with the institution, and obtain agreement from the institution, before issuing a revised NoA. The revised terms and conditions

must be documented in the official file and must be retained in accordance with the [NIH Manual Chapter 1743](#), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

For conversions to contracts, staff must follow the FAR. Staff must also follow the Justification Other than Full and Open Competition (JOFOC) procedures, if appropriate.

The IC EPMC member or other responsible official ensures that the shift of award instrument is appropriate and, after approving the change, sends copies of the justification and approval to the OEP/OER, NIH along with a Request for Assignment Change (Form NIH 901-1 "Grant/Application Change Notice" or electronic equivalent), to the Director, Division of Receipt and Referral (DRR), CSR, for necessary action. The documentation: (a) verifies that the IC approves the conversion, (b) becomes part of records for the awards and (c) indicates to CSR that pertinent applications or proposals are anticipated. The above officials communicate with the awarding IC and with one another if the shift to another award instrument needs clarification. Retain all records in accordance with the [NIH Manual Chapter 1743](#), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

F.5. Receipt, Review, Award, and other Administrative Components

F.5.1. Receipt and Referral of Applications: Applications responding to a cooperative agreement FOA are assigned the appropriate "U" activity code by the OEP, NIH.

Unsolicited applications are assigned an appropriate grant activity code without regard to the possibility of their becoming a "U" award. After the required peer review, if an IC wishes to fund such an application as a cooperative agreement, a request for conversion to a cooperative agreement mechanism is submitted to OEP following the procedures described above. After written (email) approval of

the conversion by OEP, the IC grants management official can change the activity code to the appropriate cooperative agreement activity code in IMPAC II following standard procedures.

F.5.2. Review of Cooperative Agreement Applications: Most applications for cooperative agreements respond to FOAs that specify the terms and conditions of award and other requirements.

F.5.3. Scientific Review Officer (SRO) Management of Conflict of Interest for the Initial Peer Review Meeting

See also [NIH GAM 4204-204B](#), Peer Review Process.

* SROs are responsible for managing COI or appearances of COI during the initial peer review process. This includes: 1) screening potential SRG members and assigned reviewers for COI or appearances of COI, 2) instructing those selected to identify to them situations that constitute a COI or appearance of a COI, and 3) avoiding or minimizing such situations. Procedures and measures to be taken by the SRO and the SRG members in advance of, during, and after scientific review meetings in relation to COI and appearance of COI are based on the peer review regulations at 24 CFR 52h (http://grants.nih.gov/grants/policy/fed_reg_peer_rev_20040115.pdf).

F.5.4. Award of Cooperative Agreements: ICs will make cooperative agreement awards using the same funding criteria and procedures as for grants.

* At the time of award, the IC must notify the awardee of the name(s) and title(s) of the program staff who have substantial scientific-programmatic involvement in the project, as well as the name(s) and title(s) of the IC program official responsible for normal stewardship of the award. The NoA shall identify, by titles only (i.e., Project Scientist/Coordinator/Collaborator), any program, extramural or intramural staff involved in the cooperative agreement.

F.5.5. Administration of Cooperative Agreements: Administration of cooperative agreements shall be consistent with all applicable statutory and regulatory requirements, including the HHS Grants Administration Regulations set forth at 42 CFR Part 74 (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, or Other Nonprofit Organizations, and Commercial Organizations) or 45 CFR Part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments), as well as applicable OMB Circulars and HHS and NIH grant administration policies and procedures.

Because substantial NIH program/scientific staff involvement is an integral component of "U" awards, adequate documentation of that participation constitutes an important program management tool.

The official cooperative agreement file, as maintained by grants management, will document the names of substantially involved IC program staff, as well as the nature of IC staff involvement. IC program staff shall prepare an annual summary of IC staff involvement in the award, and shall send the summary to the grants management officer/specialist upon the receipt, review and acceptance of the annual and/or final progress report, for inclusion in the official file. All records must be retained in accordance with the [NIH Manual Chapter 1743](), Keeping and Destroying Records (See Section I. Records Retention and Disposal for details).

F.5.6. Renewal and Revision Applications: IC program staff's written communication should advise awardees submitting Renewal (Type 2) and Revision (Type 3) applications to describe, along with other progress, how they have met the terms and conditions of their awards, including, where appropriate, any terms and conditions related to their interaction with the IC staff collaborators. If Type 2 or 3 applications do not include this information, SROs will obtain it from awardee-applicants to ensure adequate review.

If current projects will continue as "U" awards with the same parameters as before, the IC should invite Type 2 applications from awardees through individual written communications. If this is intended to limit competition, follow NIH GAM 4204-204A - Requirements for Maximum Competition under Assistance Programs.

If the IC plans significant changes in award objectives, approaches, or costs, or intends to reissue the FOA to seek new "U" awardees to add to or replace current ones, IC staff should follow the same procedures as for new "U" FOAs.

G. References

1. Public Law 95-224, Federal Grant and Cooperative Agreement Act of 1977, as amended by Public Law 97-258, 31 U.S.C. § 6301 et seq...

2. Office of Management and Budget — Implementation of Federal Grant and Cooperative Agreement Act of 1977 —Final OMB Guidance (43 CFR 36860-65, August 18, 1978).

3. NIH GAM 4.1.04.204 — Responsibilities of NIH Grants Administration Staff.

4. NIH GAM 4.2.02.202 — Determining Appropriate Award Instrument.

5. NIH GAM 4204-204A — Requirements for Maximum Competition under Assistance Programs.

6. NIH GAM 4204-204B — Peer Review Process.

7. NIH GAM 4.2.01.201 — Special Award Conditions, Departmental Alert List, and Debarment.

8. NIH GAM 4204-204C — Notification of Funding.

9. NIH GAM 4204-204D — Project Period System of Awarding Grants and Duration of Recommended Grant Support.

10. NIH Manual 54110 — Program Announcements (PAs) and Requests for

Applications (RFAs).

11. [NIH Manual 54513](#) — Management and Procedures of National Advisory Councils and Boards in their Review of Extramural Activities.

12. [NIH Manual 1743](#) — Keeping and Destroying Records.

13. Intramural/Extramural Collaborations — Collaborations of NIH Scientists with Extramural Scientists. http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/irp-erp-Cover-Memo-10-27-99.htm and http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/fund-irp-erp-3-00.htm. Intramural Scientists cannot receive Extramural Funds when participating in a cooperative agreement award; their support is provided by the IC Intramural Program.

14. [NIH Manual 54105](#) — NIH Support of Scientific Meetings and Conferences by Grants and Cooperative Agreements.

15. [NIH Manual 1184](#) — Scientific, Technical, and Other Professional Information Presented by NIH Employees: Review, Approval, and Distribution. See, in particular, Section H. NIH Staff (Co-) Authorship of Publications from NIH Extramural Awards.

H. Additional Information

Format for FOAs for Cooperative Agreements includes examples of language for use to implement an announcement for a cooperative agreement. In addition, OEP can provide further information on this Manual, and advice on generic issues and specific questions regarding current or planned "U" awards.

I. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to the processes described in this chapter must be maintained (e.g. retained and/or disposed of) under the authority of NIH Manual 1743, "Keeping and Destroying Records", NIH Records Control Schedule, Section 1100 - General Administration and Section 4000

Grants and Awards.

NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of the Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

J. Management Controls

The purpose of this section is to provide guidance to OEP for the implementation of the cooperative agreement award instrument at NIH.

J.1. Office Responsible for Reviewing Management Controls Related to this Chapter: Responsibility for monitoring compliance with this chapter resides with the OEP/OER. The Office of Policy for Extramural Research Administration (OPERA) is responsible for reviewing management controls relative to the grants management issues involved in this chapter.

J.2. Frequency of Review: On-going review, no less than every five years.

J.3. Method of Review: Other review: OEP will use several methods of review, including the ongoing review of new cooperative agreement requests from IC Officials, in which new issues may arise that need to be incorporated into the chapter, and in which feedback from IC Officials on current procedures is obtained; periodic sampling of electronic notices of grant awards via the IMPAC II system; feedback from periodic extramural staff training programs on cooperative agreements; and feedback from the Program Leadership Committee (PLC), including working groups to evaluate cooperative agreement use. In addition, OPERA will be routinely apprised of any difficulties in the implementation of this policy. Reports of findings and recommendations resulting from these types of reviews will be issued to assess compliance with the policy stated in this chapter. Common issues will be brought to the PLC and the Extramural Program Management Committee (EPMC) for resolution and corrective action. Depending upon the nature and the extent of problems found, if any, the DDER may recommend additional review, policy guidance, and/or training of staff.

J.4. Review Reports: Reports are sent to the DDER and OPERA. Reports should also be sent to the Deputy Director for Management. Reports should indicate that controls are in place and working well or indicate any internal management control issues that should be brought to the attention of the report recipient(s).

NIH POLICY MANUAL

55004 - Activation or Effective Dates of NIH Assistance Awards
(Grants, Cooperative Agreements, & Fellowships)

Issuing Office: OER 496-5967

Release Date: 5/10/85

A. Purpose:

This issuance states the policy covering the activation or effective dates for all assistance awards made by the NIH.

B. Background:

Periodically questions arise concerning the propriety of terms and conditions affecting the activation or effective dates of assistance awards. The questions have usually arisen in connection with the time limitations of the use of fiscal year appropriations and the desirability of issuing awards in advance of the scheduled beginning date.

C. Applicability:

All NIH grants, cooperative agreements and fellowships.

D. References:

1. NIH Manual Chapter 4700, Notice of Grant Award

2. NIH Manual Chapter 4809, Duration of Recommended Grant Support

3. NIH Manual Chapter 4810, National Research Service Awards

4. NIH Manual Chapter 5003, Issuance and Recording of Grant Award

Obligations

E. Policy:

1. All NIH assistance awards shall be obligated and notices of award issued within the fiscal year for which the funds were appropriated. The date specified as the beginning date of the grant must also be within the same fiscal year. Fellowships normally must have an activation date within a 6-month period following the date of award issue.

2. The date of issue of all awards should be as soon as possible after the funding decision has been made and in all cases prior to the beginning date of the budget period.

F. Effective Date:

This policy is effective on date of release..

G. Additional Information:

For further information on this chapter, contact the Grants Policy Office, Office of Extramural Research and Training, 496-5967.

H. Additional Copies:

For copies of this manual chapter send a Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07.

NIH POLICY MANUAL

55005 - Grant Award Adjustments Related to Estimated and
Actual Unobligated Grant Balances

Issuing Office: OD/OFM 496-6101

Release Date: 7/1/89

A. Purpose:

This issuance states the procedure to be followed by awarding units with regard to the disposition of estimated unobligated balances when reported by grantee institutions or organizations in conjunction with a request (application) for noncompeting continuation grant funds. Also stated is the procedure to be followed when a budget period is found to be underfunded because the actual unobligated balance of a grant is less than the estimate of the unobligated balance previously used as an offset (deduction) for that grant.

B. Background:

Since July 1, 1965, both research grants and training grants supported by NIH have been awarded under the project period system of obligating funds for discretionary grants. Within this concept, the funds awarded in support of each budget period (usually 12 months) are intended to remain available for the duration of the project period -- for use in financing annual grant awards. Thus, the use of unobligated balances may become an integral part of the process of negotiating individual awards within a project period.

In 1979 the definition of a project period was significantly revised to consider competing continuations as extensions of the initially recommended project period. Therefore, instead of considering each competitive segment to be a separate and individual project period, it became possible to have project periods lasting five, ten, fifteen, or more years. This revision impacted on a number of grant administration procedures, including those related to the disposition of unobligated balances.

C. Applicability:

This issuance applies to all research and training grants (except individual fellowships) and cooperative agreements awarded by the National Institutes of Health.

D. References:

1. Application for Continuation Grant, PHS Form 2590, Section III Fiscal Data for Current Budget Period
2. Application for Institutional National Research Service Continuation Award, PHS Form 6025-2, Fiscal Data for Current Budget Period (Form Page 4)
3. Financial Status Report, Standard Form 269
4. PHS Grants Administration Manual Chapter 1-85, "The Project Period System of Obligating Funds for Discretionary Project Grants"
5. NIH Manual Chapter 5002, Notice of Disposition of Grant Unexpended Balance
6. NIH Guide for Grants and Contracts, Vol. 9, No. 2, Page 57 January 25, 1980, Changes In The Project Period System For NIH Grants
7. NIH Guide for Grants and Contracts, Vol. 9, No. 4, Page 1 March 14, 1980, Changes in Project Period System for NIH Grants - A

Clarification

E. Definitions:

1. Unobligated Balance - This chapter uses the term "unobligated balance" in the framework of the total Federal funds authorized for a budget period (direct and indirect costs), according to the Notice of Grant Award. In that context, the "unobligated balance" is the portion of the total Federal authorization which was not obligated by the grantee during the stated budget period.
2. Project Period - The total time for which a project is approved for support, including any extensions thereof.
3. Competitive Segment - The initial period of recommended support (1 to 5 years) or each successive competing continuation period of a project period.

F. Policy:

NIH awarding units will not use estimated unobligated balances of less than $2,500 to reduce noncompeting continuation awards. If, after having applied an offset, it is found that the actual unobligated balance plus current funds awarded are insufficient by $250 or more for the approved budget of a current budget period, the awarding unit will issue a revised award notice or a supplemental award for the balance needed to meet the authorized level of the budget as approved. Upon written request from the grantee institution, any amount less than $250 which is required for an approved budget will likewise be provided by the awarding unit.

G. Procedures:

1. When an estimated unobligated balance of less than $2,500 is reported by the grantee institution in the noncompeting continuation application (Type 5), no part of the estimated balance may be used to reduce the

amount of funds awarded for the next noncompeting continuation budget period. When an estimated unobligated balance of $2,500 or more is reported, the awarding unit may use all or any part of the estimated balance as an offset to reduce the amount of funds awarded for the next budget period.

2. When an NIH awarding unit has received a Financial Status Report form the Division of Financial Management, and it is found that the actual unobligated balance from prior budget periods plus current funds awarded are insufficient to equal the already approved budget for the current budget period, then such deficiency will be treated as follows:

a. When the insufficiency is $250 or more, the awarding unit will, within 30 days, issue a revised award notice or a supplemental award for the balance needed to meet the level of the budget as approved on the Notice of Grant Award.

b. When the insufficiency is less than $250, the awarding unit will make a like adjustment only upon written request from the grantee institution or organization.

3. In the event circumstances in a particular case indicate a different action should be considered, the awarding unit will request permission from the Associate Director for Extramural Affairs, NIH, to take such action.

H. Effective Date:

This procedure is effective on date of release.

I. Additional Information:

For further information on this manual chapter, contact the Grants Policy Office, OERT, 496-5967, or the Federal Assistance Accounting Branch,

DFM, 496-6101.

J. Additional Copies:

For copies of this manual chapter, send a completed Form NIH 414-5, "Request for Manual Chapter," to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07.

NIH POLICY MANUAL

55010 - CO-FUNDING ASSISTANCE AWARDS

Issuing Office: OD/OER/OPERA - 301-435-0949

Release Date: 9/19/2011

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1. **Explanation of Material Transmitted:** This issuance revises the policy and procedures for processing assistance awards--grants (including individual fellowships) and cooperative agreements, when two or more NIH Institutes and Centers (ICs), have agreed to co-fund an award with extramural funds. This revision reflects current policy and procedure, particularly with respect to changes in Council/Board review/approval due to the NIH Reform Act of 2006. It also rescinds GMAC Policy and Procedure Announcement 1997-02.

2. **Filing Instructions:**

   Remove: NIH Manual 55010 dated 07/01/1990 in its entirety

   Insert: NIH Manual 55010 dated 09/19/2011

   PLEASE NOTE: For information on:

   - Content of this chapter contact the issuing office listed above.

   - The NIH Manual System, contact the Division of Management Support, OMA, on (301) 496-2832 or enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This issuance updates the policy and procedures for processing

assistance awards--grants (including individual fellowships) and cooperative agreements, when two or more NIH Institutes or Centers (ICs) have agreed to co-fund an award with extramural funds. It also covers assistance awards where the award is administered by an NIH IC while being partially or fully funded by a NIH OD Office. This document does not include the transfer of funds between NIH components; that process is not considered co-funding and thus is outside the scope of this chapter.

B. Policy:

1. **Background**

   ICs and Trans-NIH committees have long recognized that there are certain research and research training activities in which two or more ICs may have a mutual interest in co-funding extramural assistance awards (note, NIH Intramural funds may not be used to co-fund an extramural award). The procedures outlined in this chapter were established to allow for the co-funding of assistance awards.

   Historically intra-agency agreements were the primary tool for documenting co-funding arrangements. However, since Fiscal Year 1999, use of a direct Common Accounting Number (CAN) citation replaced intra-agency agreements in those cases where the ultimate award is a grant, contract, task order, purchase order, or other document where the awarding NIH component may cite the CAN of the NIH component providing the funds. This direct CAN citation policy relates to agreements between or among NIH ICs.

   In order to facilitate the process of co-funding NIH grant awards, the NIH grants management community implemented the *Notification of Co-Funding Commitment Worksheet* http://odoerdb2.od.nih.gov/gmac/download/outlook_forms.html. This

Worksheet is developed as a standard Outlook Template and is the primary tool used when co-funding between NIH ICs. A sample of the Worksheet is found in Appendix 1.

2. **Legal Authority**

It is important to remember that all ICs entering into a co-funding arrangement must have the legal authority to fund the grant under consideration. This is particularly important if considering co-funding a grant that uses special authorities that only select ICs may have.

3. **Council/Board Review**

The NIH Reform Act of 2006 enacted a policy change whereby all applications, regardless of dollar level, now require Council review and approval by the "appropriate Council" before an award can be issued. (Note all references to "Council" in this document refer to both Council and Board review.) This change impacts all co-funding because prior to this Act, NIH Institutes (but not Centers), were permitted to fund research grant applications requesting $50,000 or less in direct costs without Council approval. Now, in order for an IC to contribute any amount of co-funding, the application must be reviewed/approved by the Council of that IC, regardless of whether the IC is the primary or dual assignment to the application. The Council approval of only the administering IC is not sufficient. This requirement is for all applications regardless of the potential source of funding, except for individual fellowships. Individual fellowships can continue to be funded/co-funded without Council approval unless required by IC-specific Council Operating Procedures.

Applications funded by Office of the Director (OD), e.g., Roadmap or Common Fund, must also receive Council review by the IC that receives the primary assignment. All Common Fund/Roadmap

applications automatically receive an "RM" dual assignment. The Electronic Council Book (ECB) feature in eRA automatically includes all RM dual records in the ECB as dual assignments for all ICs. Therefore participating ICs do not need to do anything special to assure Council review/approval of Common Fund/Roadmap applications as long as they use the ECB and assure these records remain in the ECB for Council review.

Similar programming is also in place for the Neurosciences Blueprint (NB) and OppNet (OP) Initiatives. The 16 participating ICs for Neurosciences Blueprint initiative are now constant; thus an NB dual is automatically assigned to these applications and the ECB is programmed to automatically include NB duals in the respective ECB for the participating ICs. For OppNet Initiatives, the ECB is programmed to treat these applications the same as RM duals; any application with an OP dual assignment will appear in the ECB as a dual assignment for all ICs.

For other Trans-NIH initiatives other than Roadmap/Common Fund, Neurosciences Blueprint and OppNet, ICs will need to assure they have a dual assignment on applications prior to the Council meeting or otherwise assure applications receives IC Council review/approval by their own Council before any amount of co-funding is provided.

OD programs that use an OD primary assignment (e.g., NIH Director's Pioneer and New Innovator Awards) receive a secondary level of peer review by either the Advisory Council to the Director or the Council of Councils. Since these are Common Fund/Roadmap programs, they automatically receive an "RM" dual assignment and consequently are automatically included in the ECB for all ICs. Therefore participating ICs do not need to do anything special to

ensure Council review/approval before co-funding an application with an OD Primary assignment; as long as the IC uses ECB and assures the OD records remain in the ECB for Council Review.

If an IC does not use the ECB feature, it is the IC's responsibility to assure that dual RM, NB, and/or OP records receive IC Council review/approval by their own Council before any amount of co-funding is provided.

Ultimately it is the responsibility of each IC to establish an internal process to ensure that a grant application proposed for co-funding has been reviewed by their Council before any co-funding dollars are provided.

The requirement for Council review affects those applications requiring competing peer review but does not affect administrative supplement actions as long as an IC was listed as a primary or dual assignment on the competing application or the competing application had a trans-NIH dual assignment (RM, NB, OP) that provided automatic Council review for all ICs. Administrative supplements are considered additional funding for activities within the current peer-reviewed scope of a project. ICs should continue to work within or develop their own Council operating procedures that establish parameters for reviewing and funding administrative supplements. However, if an IC decides to co-fund an administrative supplement for a grant with a primary assignment at another IC, they must make certain the application received concurrence by their Council by either: 1) assuring their IC was listed as a dual assignment on the competing application so that it received review/approval by their Council during the competing year; or, 2) seeking Council approval of the competing application as a separate/interim action prior to authorizing co-funding of the

administrative supplement. If the IC did not have a primary or dual assignment on the competing application, the administrative supplement cannot be co-funded until Council approval is received.

If the proposed co-funding action is on a non-competing (T-5) year and the IC was not a dual assignment on the applicable competing year, the IC desiring to co-fund will need to take the applicable competing application and summary statement to their Council as a special action. It is not necessary for the IC to have a dual assignment at this stage; however, Council concurrence is needed before the co-funding action can occur. Co-funding during a non-competing year on a grant where an IC was not initially dual could raise questions about whether such an action is actually within the scope of the reviewed/approved project.

ICs are strongly encouraged to think broadly about dual assignments on competing applications to better enable the ability to co-fund any time during a competitive segment.

If at any time an IC anticipates fully funding a grant that has a primary assignment at another IC, then the two ICs should discuss a Change of Institute action prior to awarding the grant.

4. **Inter-agency Agreements**

Interagency Agreements are primarily used when ICs jointly fund contract or grant awards outside of NIH with other federal agencies. Inter-agency agreements involve the movement of money from one organizational component to another and can no longer be used as an obligating document when co-funding. ICs should review NIH Manual Chapter 1165: *Agency Agreements* to determine the proper use of interagency agreements.

5. **Memorandum of Understanding (MOU)**

   When first considering jointly funding a particular program, ICs may develop a written agreement between or among the participating and administering ICs. To formalize preliminary agreements on programs, a Memorandum of Understanding (MOU) could be developed. While the MOU can include basic information about the financial commitment of each party involved, **it cannot be used as an obligating document**. At the time a decision is made to co-fund a particular grant or multiple grants, an obligating document must be executed. In the absence of a MOU, preliminary co-funding commitments may be informally documented between the parties.

6. **Obligating Documents Between NIH ICs**

   Two document options are available to ICs when entering into a co-funding agreement using a Direct CAN Citation: 1) Notification of Co-funding Commitment Worksheet; or 2) the Direct CAN Citation Form. The use of each is dependent upon the parties involved and the legal authorities of each. These two options are described below.

   a. **Notification of Co-funding Commitment Worksheet (Worksheet):** When two or more ICs determine that there is a mutual interest in co-funding an award, in most cases, the Worksheet will serve as the obligating/reimbursable document for all participating ICs. A sample is provided in Appendix 1. The Worksheet includes basic information needed to commit the participating IC(s) to co-fund the project and documents the responsibilities of each party, including the total dollars and CAN(s) for all years. While the worksheet reflects only a Total Cost Commitment, it is understood by the participating and administering ICs that the administering IC will apportion the total

costs between direct and F&A costs using the applicable base/rate calculation. The Worksheet is executed between Grants Management offices and requires the approval of a GMO with the authority to obligate the participating IC's funds and who has the approval from the responsible CGMO or IC Budget Officer to execute the co-funding action.

b. **NIH Direct CAN Citation:** When an NIH Office (outside of a particular IC) co-funds an award; the Direct Can Citation Agreement may serve as the obligating/reimbursable document for the Office and IC. While similar to the Worksheet, the direct CAN citation document generally reflects only the current FY funding commitment and requires the signature of a high level IC/Office official such as the IC/Office Director from both the administering IC and participating ICs/Office. Suggested format for this document can be found in Manual Chapter 1165, *Agency Agreements.*

7. **Award "Count"**

A co-funded award will count as competing for the administering IC, except in those circumstances in which the administering IC is not providing any funds. In that case, the NIH Component contributing the greatest total cost (direct and F&A) obligation of funds to the award will count the award as competing. The same premise will apply in those cases where an official "count" is made during the non-competing years.

8. **Funding/Co-funding OD Common Fund/Roadmap Programs**

When funding a grant for an OD Common Fund/Roadmap Program and only an OD-established CAN is used, the OD Budget Office will provide ICs with the CAN as part of the document that lists which grants have been approved for funding. This documentation is

considered the obligating document and should also include key information; e.g. grant number, the number of fiscal years funding is being provided, dollar amount, CAN and OD contact information should questions arise. No additional co-funding documentation is necessary; i.e., a separate co-funding worksheet for each grant is not required. However, when an IC plans to contribute their IC funds towards a Common Fund/Roadmap award administered by another IC, co-funding documentation through a Worksheet is required.

Note, this does not include OD programs where the grants actually carry an OD primary assignment, are fully funded by the OD, but the awards are serviced by an IC on behalf of the OD. These are not considered co-funded as long as only OD funds are used. However, if any other ICs desires to co-fund a grant with an OD primary assignment, then co-funding documentation through a Worksheet is required. In these cases, the IC servicing the OD grant is considered the administering IC.

C. References:

1. **NIH Manual Chapter 1165**, **Agency Agreements:** Sets forth NIH policy, procedures, and responsibilities for the management and control of agreements (e.g., those to acquire or provide studies, services, supplies, advice, or counsel) between and among NIH ICs, and between NIH and other organizations of the DHHS, or other Federal agencies outside of the DHHS.

2. **NIH Manual Chapter 54513**, **NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities:** States the NIH policy for the management and review of applications by National Advisory Councils or Boards.

3. **GM Infonet Resources:**

   a. **Microsoft Outlook Forms/Templates:**
   http://odoerdb2.od.nih.gov/gmac/download/outlook_forms.html -
   Intranet website housing a variety of Microsoft Outlook
   Forms/Templates including a standard Notification of Co-Funding
   Commitment Worksheet.

   b. **Co-funding Topic Page:**
   http://odoerdb2.od.nih.gov/gmac/topics/cofund_main.html -
   Intranet website providing consolidated policy documents and
   references, including historical.

4. **NIH Grants Administration Manual 4104-204, Responsibilities of NIH
   Grants Administration Staff:** Outlines the primary responsibilities of
   Grants Management Officers, Program Officials in managing NIH grant
   programs.

5. **NIH Grants Administration Manual 4204-204C, Notification of
   Funding:** States the NIH policy for awarding grants.

6. **NIH Manual Chapter 1743, Keeping and Destroying Records:** States
   the policy for maintaining grants management records in Appendix 1,
   Records Control Schedule.

D. Definitions:

1. **Administering IC:** The IC that has the primary assignment of the
   assistance award and is responsible for management of the award in
   consultation with the participating IC(s). In general, the administering IC is
   the IC referenced in the award number. The exceptions to this are OD
   Common Fund/Roadmap programs that carry an OD primary assignment
   in the award number. These programs are administered by an IC on
   behalf of OD, and are not considered co-funded as long as only OD funds
   are used. The servicing IC is considered the administering IC when

another IC desires to co-fund an award with an OD primary assignment.

2. **Assistance Awards:** For the purposes of this chapter, assistance awards include grants (including fellowships) and cooperative agreements.

3. **CAN (Common Account Number):** A seven-character number that appears on the Notice of Award (NoA), accounting documents, and obligating documents indicating the appropriation and allowance to be charged.

4. **Co-funding:** An agreement by two or more ICs to jointly participate in the support of an assistance award. For the purposes of award processing and reporting, co-funding occurs when more than one CAN is used to jointly fund a single award. It also occurs when one IC administers the grant but another NIH component totally funds the grant. In this case, only a single CAN is used; however, when actually processing the award, it is processed as a co-funded award since the CAN used is for a component outside of the administering IC.

5. **Direct CAN Citation Policy:** Established in 1999, replaced the use of the Intra-agency Agreement where the ultimate award is a grant, contract, task order, purchase order, or other document where the awarding NIH component may cite the CAN of the NIH component providing the funds. The direct CAN citation policy relates to agreements between or among NIH ICs.

6. **Future Year Commitments:** The term used to reference any anticipated total costs funding for future years when such commitments are recommended and approved. These commitments are always subject to the availability of funds and satisfactory progress of the project. For the purposes of co-funding, the obligating document should include the co-funding ICs intent to fund future years.

7. **Memorandum of Understanding (MOU):** A written agreement between/among two or more NIH ICs, between NIH and another NIH

component, or between an NIH IC and another agency. For the purposes of this Manual Chapter, an MOU is always used in conjunction with some other obligating document as described in Section B.5 above.

8. **Notice of Award (NoA):** The official, legally binding document, signed (or the electronic equivalent of signature) by the Grants Management Officer that: 1) notifies the recipient of the award of a grant; 2) contains or references all terms and conditions of the grant, and Federal funding limits and obligations; and 3) provide the documentary basis for recording the obligation of Federal funds in the NIH accounting system. When a grant is co-funded, the NOA also includes information about all co-funding components.

9. **Participating IC:** An IC that has a mutual interest with the administering IC in a program area and participates in co-funding award(s) made by the administering IC.

E. Responsibilities:

Grants Management, Program, and Budget Office staff of the administering and participating ICs share in the co-funding responsibilities. ICs should establish internal procedures for reviewing, approving, and disseminating co-funding documents.

1. **Responsibilities of Administering IC**

   The Program and/or Grants Management staff of the administering IC will consult with the participating IC's program and/or grants management staff on those matters pertinent to their responsibilities if any non-routine matters develop.

   When a Worksheet is the authorizing document, the administering IC's CGMO will receive the Worksheet from an authorized official of the participating IC(s) and review it for completeness. While the

worksheet reflects only total costs, the administering IC will apportion the total costs between direct and F&A costs using the applicable base/rate calculation. Completed Worksheets must be filed as part of the official grant file. In accordance with IC-established processes, the CGMO is also responsible for disseminating the worksheet within the IC to all appropriate personnel (Program, Grants Management, and Budget).

When a MOU is used in conjunction with an obligating document, the MOU may be stored in a central IC program file instead of each official file since the obligating document will be stored in the respective official grant files.

The administering IC is responsible for documenting all pre-award programmatic and administrative reviews, including receipt of all necessary assurances and all required coding (e.g. AIDS coding) when appropriate.

The administering IC is responsible for processing the co-funded NoA in the IMPAC II GM system ensuring that the NoA shows the proper amount of funding contributed by each participating IC and the proper CAN for each IC. When offsets are taken on an award, the administering IC is responsible for applying the offset to the administering IC's CAN unless otherwise negotiated with the participating IC. If the amount of the offset exceeds the support provided by the administering IC, the administering IC should consult with participating IC(s) regarding the allocation of the offset amount to various CANs.

The administering IC is responsible for coordinating all post-award management of the co-funded award, including reviewing/sharing progress reports, issuing awards, and resolving issues related to

stale obligations.

Note these administering IC's responsibilities apply even when the funding is provided exclusively by another NIH component.

2. **Responsibilities of Participating IC(s)**

The participating IC(s) will: 1) assure approval of the application from their IC Council prior to initiating any co-funding action; 2) initiate and complete the applicable obligating document; 3) secure all necessary IC approvals; and 4) in accordance with established IC procedures, notify all appropriate IC personnel (Program, Grants Management, Budget) of the intended co-funding commitment. It is expected that the participating IC(s) will identify the anticipated funding for all future year commitments at the time the initial obligating document is executed. Any anticipated funding that comes from appropriations which have not yet been made must be identified as being subject to the availability of funds. If future year commitments are unknown, the obligating document should include specifics about the ICs intent to fund future years. When the participating IC(s) co-funding is only for future years, it is still expected that the obligating document be provided at the time of the initial award so that the anticipated co-funding commitment can be built into the future year commitments on the NoA.

For the Worksheet, a Grants Management Specialist may be the "contact"; however, the Worksheet must be sent to the Chief GMO of the administering IC by a GMO with the authority to obligate the participating IC's funds and who has the approval from the responsible Chief GMO or budget officer for this co-funding action.

Participating ICs also have the responsibility to establish an internal process to ensure any application expected to be co-funded

receives Council review/approval from their IC Council prior to initiating the co-funding document. See section *B.3. Policy/Council Review*.

If the participating IC wishes to change its amount of anticipated contribution for a future year or CAN, that IC must notify the administering IC in writing as soon as possible. The notification will serve as file documentation; a revised obligating document is not necessary.

Note that when an IC works with eRA to execute a system sweep of a CAN change, this automatically updates co-funded records; however, system CAN sweeps by eRA do not affect records that have already been funded or where a Work-In-Progress has been created. Therefore when a participating IC changes a CAN, it will be vital for that information to be communicating to the administering IC prior to the issuance of the award.

3. **Responsibilities of the Office of Financial Management (OFM)**

   For the purposes of this manual chapter topic, the OFM responsibilities involve resolving unobligated balances on FSRs and providing administering ICs with timely Stale Obligation Reports.

F. Procedures:

1. **Obligating Documents**

   a. **Notification of Co-funding Commitment Worksheet (Worksheet)**

      The participating IC completes the Worksheet, securing all internal IC approvals. A GMO with authority to obligate funds or their designee then forwards it to the CGMO of the

administering IC, with copies to the assigned GMS & PO and IC Budget Officer of the participating ICs as appropriate. It is preferred that the participating ICs commit all future years at the time of the initial Worksheet. If future year commitments are unknown, the Worksheet should include specifics about the IC's intent to fund future years.

The administering IC should receive a completed, authorized Worksheet via e-mail, from each of the participating ICs. This notification will identify the participating IC's CAN number, and that portion of total costs for the current budget period and all future budget periods, when applicable. The Worksheet reflects total costs only. Individual budget categories need not be shown on the Worksheet prepared by the participating IC(s), nor is it necessary to show a direct and F&A breakdown. The administering IC will apportion between direct and F&A costs using the applicable rate/base calculation.

The Worksheet, once transmitted, authorizes the issuance of the award obligating the co-funding IC's funds. Since the Worksheet reflects future year commitments, it is sent once, used for the entire competitive segment and filed in the official grant file. If future year commitments are adjusted using standard NIH-wide business practices, it is not necessary for revised Worksheets to be issued. When budget constraints require an across-the-board reduction of a non-competing commitment, the reduction will generally be uniformly applied to all co-funding contributions. Exceptions to this standard practice will be negotiated between the ICs.

b. **NIH Direct CAN Citation Agreement**

When an NIH Office co-funds an IC award, the Direct Can Citation Agreement, can serve as the obligating/reimbursable document for the Office and IC in lieu of a Worksheet. The agreement is issued by the IC or Office Budget Officer and requires the signature of a high level IC official such as the IC Director from both the administering and participating ICs. The agreement can address multiple co-funding actions and include both grants and contracts. Unlike the co-funding Worksheet, the document generally reflects only the current FY funding commitment. ICs should follow the guidance provided in Manual Chapter 1165 for processing this form.

2. **Council/Board Approval**

As stated in the *B.3. Council Review*, in order for an IC to contribute any amount of co-funding, an application must be reviewed/approved by the Council of that IC, regardless if the IC is the primary or dual assignment to the application. Participating ICs should be mindful of this requirement and develop internal procedures to assure their IC is appropriately listed as dual on any application where there is a potential for co-funding. ICs must follow established IC procedures to assure Council approval is received before any co-funding action is awarded. The official grant file should be appropriately documented to reflect this approval.

When a decision to co-fund a grant is made after the competing year is funded, the participating IC must assure the grant received appropriate review by their own Council before the co-funding action can occur. This can be accomplished in two ways:

   a. The participating IC determines they were listed as dual on the applicable competing application when it went through Council

review. No further action is needed by the participating IC before the co-funding action can occur.

b. If the participating IC was not dual on the competing application when that application initially received Council review, then the participating IC will need to take the applicable competing application and summary statement to their Council as a special action. The participating IC need not be added as a dual at this stage; however, they must assure Council review is completed before the co-funding action can occur.

3. **Funding Methods**

   a. **Multiple CAN Method**

   The multiple CAN method is used when it is in the mutual interest of two or more ICs to co-fund assistance awards and all ICs contribute to funding each award. Each CAN shows on the award as documented on the obligating document provided by the participating IC(s). See *F.4 Notice of Award* for procedures on processing the actual award.

   b. **Single CAN Method**

   The single CAN method is used when it has been decided by two or more ICs that they have a mutual interest in a program area (e.g., Request for Application or Program Announcement), but only one IC contributes to funding each award. In such an arrangement, one IC may solely fund some awards while another IC funds the remaining awards. These are not considered co-funded awards; however, the ICs may still programmatically consider this a jointly-funded program. In this case, the procedures in this chapter do not apply since the award is processed as an individually-funded

award. The administering IC may choose to acknowledge the programmatic interest of the other IC(s) in an IC-specific term on the NoA.

When one IC fully funds an award but another IC administers the award, this is considered to be a co-funded award and the policy and procedures in this chapter apply. This model is primarily used when funds are provided by an OD office. When a grant is fully funded using a single CAN provided by an OD Office, including Common Fund/Roadmap programs, it is considered a co-funded award and the policy and procedures in this chapter apply.

Any time an IC is considering fully funding a grant with a primary assignment to another IC, the two ICs should consider a Change of Institute action prior to issuing the award.

4. **Notice of Awards (NoA)**

   a. **Processing**

   The administering IC will process the co-funding in the IMPAC II GM system. Selecting the grant, the specialist will go to the CAN screen and click on Add CAN, entering the co-funding IC's CAN in the blank box. After the CAN is entered, the two-letter initials of the IC assigned to the CAN should automatically appear in the box next to the CAN. The direct costs and F&A amounts for each year should then be entered.

   When offsets are taken on an award, the default approach is to apply the offset to the administering ICs CAN unless

otherwise negotiated with the participating IC. If the amount of the offset exceeds the support provided by the administering IC, the administering IC should consult with participating IC(s) regarding the allocation of the offset amount to various CANs.

A GMO of the administering IC will sign, release and issue the NoA to the grantee. The participating IC does not automatically receive notification that the award has been issued; however, they can obtain a copy of the NoA in the electronic Grant Folder through appropriate IMPAC II modules.

b. **Co-funding Information and Terms**

There are several places on the NoA, where co-funding information is found:

1) **Section I** - Award Data/Fiscal Information section: A chart appears in this section detailing each participating IC's initials, the CAN to which these funds are charged, and total costs for each fiscal year. This section of the NoA includes a reminder that all future year commitments are subject to availability of funds and satisfactory progress of the project.

2) **Section III** - Terms and Conditions: The following term became a standard term and condition added automatically to every co-funded NoA:
"This award is funded by the following list of institutes. Any paper published under the auspices of this award must cite the funding support of all institutes. [*A chart is inserted that includes the names of each contributing IC*]"

3) **Section IV** – IC Special Terms and Conditions: A specific footnote may be added that identifies the total cost contribution from the participating IC(s) as well as any restriction regarding the use of the participating IC's funds, if applicable. (See Appendix 2 for sample footnotes).

5. **Acknowledgements**

Acknowledgement of individual IC participation in a co-funding arrangement is automatically shown in: 1) NoA Section I - Award Data; 2) NoA Section III - Terms and Conditions; and, 3) NIH annual publications and monthly news releases reflecting the amount of funding by each IC. If additional acknowledgement outside of these automatic standards is desired, the participating and administering ICs should mutually agree to the wording of any IC-specific terms and conditions.

6. **Final Unobligated Balances and Stale Obligations**

The OFM will return any final unobligated balance to the administering IC. In circumstances where the unobligated balance exceeds the amount contributed by the administering IC in the final budget period, OFM will apportion the remainder to the participating IC(s) in proportion to its funding during the final year of support.

Stale Obligation reports will be provided to ICs by OFM on a quarterly basis. Any resolution of issues related to stale obligations of co-funded awards will be managed by the administering IC.

7. **Final Reports**

The administering IC holds the responsibility for reviewing/approving all applicable final reports. Notification when

final reports are available in the electronic grant folder will be provided by the administering ICs to the participating IC(s) upon request. Any documents uploaded using eAdditions are only viewable by the administering IC; therefore, the administering IC may need to establish special procedures for sharing documents.

G. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743,"Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Section 4000 Grants and Awards (all that apply). Refer to the NIH Manual Chapter for specific instructions.

NIH e-mail messages, including attachments that are created on NIH computer systems or transmitted over NIH networks that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison for additional information.

All e-mail messages are considered Government property and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Back-up files are subject to the same requests as the original messages.

H. Internal Controls:

The purpose of this manual issuance is to state the policy and procedures

for processing awards when two or more NIH institutes and centers (ICs), have agreed to co-fund.

1. **The Office Responsible for Reviewing Internal Controls Relative to this Chapter:** The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

2. **Frequency of Review:** The frequency of review will be based on the outcome of a risk assessment that will determine how often an internal control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

3. **Method of Review:** OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

4. **Review Reports are sent to:** The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

Appendix 1: Sample Notification of Co-funding Commitment Worksheet:

Note this sample is provided for informational purposes only. Specialists completing this notification must download the appropriate e-mail template from the Grants Management Infonet at:

http://odoerdb2.od.nih.gov/gmac/download/outlook_forms.html

NOTIFICATION OF CO-FUNDING COMMITMENT

This e-mail worksheet provides notification of a co-funding for the current budget period for the referenced award. This worksheet also contains an anticipated co-funding amount, for future budget periods for the referenced award when applicable. The amounts are to remain the same (subject to the availability of funds) unless there is agreement between the administering IC and the participating IC to change the costs. Changes in funding levels or common accounting numbers (CANs) should be negotiated between the administering and participating ICs more than one month prior to the scheduled start date of the award. The Grants Management contact is the individual preparing this electronic mail message and a person with Grants Management Officer authority is forwarding this worksheet to the Chief GMO of the administering IC.

While this worksheet reflects only Total Costs, it is understood that the administering IC will apportion this total between Direct and F&A costs using the applicable base/rate calculation.

The administering IC will maintain this e-mail communication for documentary purposes and will file it in the official grant file.

[*Enter IC*] will co-fund the following grant(s): _____

Application #: _____

Principal Investigator: _____

CAN: _____

GMS Comments: _____

Fiscal Year	Grant Year			Total Costs
				$0.00
1	1			$0.00
2	2			$0.00
3	3			$0.00
4	4			$0.00
Totals				**$0.00**

Grants Management Specialist: _____

Program Staff Contact: _____

Cc: Participating IC Budget Officer, Participating IC PO

Appendix 2: Co-funding Terms and Conditions:

A. **Automatic NoA Term**

In section III--Terms and Conditions of all NIH award templates, the following term is automatically included on every co-funded NoA:

"This award is funded by the following list of institutes. Any paper published under the auspices of this award must cite the funding support of all institutes.
[A chart is inserted that includes the names of each contributing IC]
"

B. **Optional IC-Generated Terms**

ICs have the option of also including a more detailed term in Section IV--
IC Special Terms and Conditions. This may identify the total cost
contribution from the participating IC(s) as well as any restriction
regarding the use of the participating IC's funds, if applicable.

Sample 1:

This award includes co-funding from the _____ ($ _____
direct costs, $ _____ F&A costs) in order to [*fill in appropriate
information*.] These funds are restricted for use in this project only.

Sample 2:

This award includes co-funding from the:

_____

IC: _____

PI: _____

DC / F&A: $ _____ / $ _____

These funds are restricted for use in this subproject only. They may
be rebudgeted within the subproject but may not be rebudgeted
from this subproject to another one.

NIH POLICY MANUAL

55201 - Change of Grantee Institution

Issuing Office: OPERA/OER 435-0949

Release Date: 12/15/00

1. **Explanation of Material Transmitted:** This chapter is being revised to reflect the policy and procedural changes that are to be used by NIH awarding units to effect a change of grantee institution. Specifically, this update includes reference to modular applications.

2. **Filing Instructions:**

   Remove: NIH Manual 5201 dated 08/15/99 in its entirety
   Insert: NIH Manual 5201 dated 12/15/99

3. **Distribution:** Text is available on-line. See the last bullet on this page for on-line information.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support, OMA, OA, on 496-2832.

- on-line information, enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This issuance states the NIH policy and procedures to be used by NIH awarding units to effect a change of grantee institution. The two basic principles upon which this policy is based are: (1) funds relinquished by one grantee may be re-awarded to a new grantee even if the appropriation from which they originated has expired; and (2) in certain circumstances, an award may be made to a replacement or new grantee without recompetition.

B. Applicability:

This policy applies to all NIH discretionary projects and cooperative agreements, hereinafter, referred to as grants. A training grant (Institutional National Research Service Award), a research resource, program project, center grant, or construction grant may be transferred only under unusual circumstances and generally be approved only when all of the permanent benefits attributable to the original grant can be transferred. This policy is not applicable to certain awards to individuals or to transfers of grants to or between foreign institutions.

C. References:

1. Code of Federal Regulations, Title 42 - Public Health, Part 52

2. Code of Federal Regulations, Title 45 - Public Welfare, Part 74.30 through 74.37, Property Standards

3. PHS Grants Administration Manual Part 131, Change of Grantee Institution

4. PHS Grants Administration Manual Part 129, Grant Suspension and Termination

5. NIH Grants Manual Chapter 4104, NIH Research Grants to Foreign Institutions and International Organizations

6. NIH Grants Manual Chapter [5205](#), Successor in Interest and Name Change Agreements

7. [Modular Grant Application Guidelines](#)

D. Definitions

1. Change of Grantee Institution - A process whereby the legal and administrative responsibility for administering a grant-supported project or activity is transferred from one eligible, qualified grantee to another prior to the ending date of the approved competitive segment.

2. **Successor in Interest** - A process whereby the rights and obligations to an NIH grant or grants are acquired incidental to the transfer of all of the assets of the grantee or all of that part of the assets involved in the performance of the grant. Such a transfer may result from legislative or other legal actions such as a merger, divestiture, or other corporate change. This chapter does not address the specifics or procedures associated with processing this type of action.

3. **Name Change** - An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of the parties involved (such an action is not considered to be a Change of Grantee Institution). This chapter does not address the specifics or procedures associated with processing this type of action.

4. Relinquishment - A process whereby a grantee institution willingly waives all interests and rights to a grant supported project or activity.

5. Termination - Permanent withdrawal of a grantee's authority to obligate grant funds, including the voluntary relinquishment of that authority by the grantee.

E. Policy:

1. **Disposition of a Funded Grant:**

a. General principles and conditions:

The NIH awarding unit may approve the use of current or prior year funds originally obligated, but unexpended to effect a transfer of a funded project provided:

- the necessary documentation is submitted and approved;

- there remains a need for the project;

- the research objectives have not significantly changed from those previously approved;

- the facilities and resources at the new institution will allow for successful completion of the project; and

- the change of grantee action meets all other applicable requirements of this policy.

If a proposed change of grantee action does not clearly meet the programmatic and administrative requirements, the NIH awarding unit may require that the application receive a competitive review in accordance with the usual peer review procedures. For example, this would be necessary if a change in scope is requested. If a competitive review results in award, the support should be funded using current fiscal year monies.

The appropriate NIH awarding unit must be notified by the principal investigator and the business official of the grantee institution when the principal investigator/program director of an NIH-supported research project expects to resign from a grant and/or the grantee institution. This notification should occur prior to the actual date of resignation and preferably several months in advance. The awarding unit may approve

either of the options detailed below for continued support of a grant. Funding will be terminated if neither option is proposed or approved and closeout procedures should be followed.

A project [except for Career Development Awards (K)] may be retained at the original grantee institution under the direction of another principal investigator;

OR

The remainder of a competitive segment may be supported at a new institution on behalf of the same principal investigator transferring between two domestic institutions or from a foreign institution to a domestic institution without competitive review.

When a change of grantee is contemplated, the NIH awarding unit should advise the original institution to maintain a reasonable spending pattern so that continued support at a proposed new institution will not be adversely affected. Furthermore, the original grantee should be advised that relinquishment of a project does not guarantee Institute or Center (IC) approval of a transfer application for the continued funding of a project.

b. Length of Award:

A transfer of a budget/project period may be made for a length of time generally not to exceed the total length of time remaining in the competitive segment. There are occasions, however, when it is appropriate to provide a length of time in excess of that originally remaining. For example, a principal investigator may request a no-cost extension of the grant year being transferred in order to accomplish the originally approved goals. This type of request will be acted upon on a case-by-case basis by the particular IC and the official file will be documented accordingly. Care should be exercised to avoid multi-year

funding.

c. Funding Level:

The direct cost level for a transfer occurring within an awarded budget period will be based on the direct costs remaining from the original grantee as reflected on the relinquishing documentation. For both modular and non-modular awards, the direct cost level for a transfer occurring on an anniversary date will be based on the previously committed level for that year. The applicable F&A rate will be applied to the direct cost level. On a case-by-case basis, an IC may approve administrative increases to the previously recommended levels.

d. Termination:

When a grant is terminated either by mutual consent or unilaterally by the grantee, the awarding unit should request a written statement from the original grantee relinquishing its interests and rights to the grant.

An IC may terminate a grant unilaterally (after obtaining approval from the NIH Director) during the course of a budget period for failure of a grantee to comply with terms and conditions of the grant. In this case, the NIH awarding unit would not consider a replacement principal investigator. If the grantee will not provide a written statement relinquishing interests and rights to the original grant, no action may be taken by the NIH affecting the original grant until the original grantee institution has exhausted or forfeited its appeals rights. However, a limited replacement grant may be awarded to a replacement institution using funds out of the current year appropriation, while the original grantee is appealing the grant termination action. A limited replacement grant may be appropriate if disruption of project activities would either seriously jeopardize the success of the project; or endanger the physical or mental health of the persons served by the project. The replacement grant may be made for a single budget

period of no more than 18 months duration (this would not require approval for multi-year funding), after which time the replacement institution must compete for support.

2. **Disposition of an Unfunded Grant Application:**

When a principal investigator leaves an institution and a pending application has been recommended for further consideration but has not been awarded, the original applicant institution may request that the project be supported at that institution on behalf of another principal investigator. Alternatively, the original applicant may relinquish the application and a request may be made to support the project at a new institution under the direction of the originally proposed principal investigator. If neither option is pursued, the application is administratively inactivated.

3. Facilities and Administrative (F&A) Costs:

The negotiated F&A rate in effect at the new institution should be used to calculate the F&A for all remaining budget periods of a transfer grant. See section G.5 for specific procedures.

4. Changes Involving a Foreign Institution:

In accordance with NIH policy, administrative approval may not be given for a change involving a transfer to or between foreign institutions. An investigator transferring to or between foreign institutions is required to submit a competing application from the new institution. This application will be reviewed as a new application and must compete for available funds. A grant made to a foreign institution may be administratively transferred to a domestic institution. However, this will result in the need to include F&A costs, which were not originally part of the award to a foreign entity.

5. Transfer of a Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer (STTR) Grant:

In accordance with NIH policy, administrative approval may not be given for proposed transfers from an SBIR/STTR grantee to a non-SBIR/STTR eligible organization. This prohibition may not be waived. SBIR/STTR grants may, however, be administratively transferred between two SBIR/STTR eligible organizations.

6. Changes Involving an Academic Research Enhancement Award (AREA) Grant:

In accordance with NIH policy, AREA grants may only be transferred to other AREA eligible institutions.

7. Other Changes in Location or Institutional Sponsorship:

a. Relocation in the same university system:

If a research project is transferred from one "campus" to another within the same university system and there is a change in administrative responsibility and a corresponding change in the Entity Identification Number (EIN), the move should be considered a Change of Institution and be subject to the procedures stated in this document.

b. Grantee reorganization:

If the grantee institution undergoes a reorganization (e.g., a name change or successor in interest), the awarding unit should be notified and advice sought concerning the effect on active or pending grants at that institution. If the reorganization or administrative change does not affect actual administrative responsibility, geographic location, facilities, resources, or objectives of the project, it will NOT be considered a change in institution and no formal application for a change of project support will be required.

8. Transfer/Disposition of Equipment, Supplies and Data:

a. Equipment:

As reflected in 45 CFR Part 74.2, the definition for equipment means tangible nonexpendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. A list of equipment reflected in the Relinquishing Statement, as being transferred to the new grantee, should include equipment purchased on the project and still in use, using the equipment dollar threshold as set by this definition.

Unless there are overriding terms of award, title to equipment acquired by a recipient with NIH funds shall vest in the recipient, subject to the conditions under 45 CFR 74.34.

b. Supplies:

Title to supplies shall vest in the recipient upon acquisition. Generally, the transfer of supplies is negotiated between the principal investigator and the original grantee. IC involvement is rare. Disposition instructions are detailed in 45 CFR Part 74.

c. Data/Inventions:

Grantees will retain custody of and primary rights to the data, including software, developed under an award, subject to current Government policies regarding rights of access as contained in 45 CFR Part 74.53. If an inventor moves to a new organization, the rights to existing patents usually remain with the former organization, although the inventor remains entitled to a share of the royalties. For specific details, see the NIH Grants Policy Statement, and 45 CFR Part 74.

F. Required Documentation *:

SITUATION	ORIGINAL INSTITUTION	NEW INSTITUTION
1. **Replacement of Principal Investigator** PI moves and original institution requests approval to retain an awarded or unfunded grant under the direction of a new principal investigator.	• Submission of a countersigned letter (authorized by the business official and new proposed principal investigator). The letter must include a biographical sketch of the new principal investigator and other revised application pages as determined by the awarding unit.	• N/A
2. Transfer of		

an Unfunded Project PI moves and there is an NIH approved application that has not been funded. PI requests approval to support the project at a new institution.	• Submission of an Official Statement Relinquishing Interest and Rights to a PHS Grant ([PHS Form 3734](#)) or a formal countersigned letter in lieu of this form relinquishing rights to the grant application.	• Submission of an original and two copies of transfer application pages ([PHS Form 398](#)) with CHANGE OF INSTITUTION typed across the top of the face page. The application must include but is not limited to: - a face page; - budget pages (current and future years); - an updated biographical sketch; - a statement indicating whether the overall research plans/aims have

		changed from the original submission (including the date of the original submission). If the research plans/aims have changed, updated information must be provided. If there are no changes, additional information is not necessary. - an updated other support page(s), if necessary; - a resources page; - a checklist page; and - an approved IRB/IACUC, assurance, if applicable.

SITUATION	ORIGINAL INSTITUTION	NEW INSTITUTION
3. Transfer of Active Grants - **Anniversary Date Transfer** PI requests that the next full year of funding be supported at a new institution. - **Partial Year Transfer** PI requests transfer of a project to a new institution during the course of a budget period.	• Submission of a Relinquishing Statement ([PHS Form 3734](#)) or formal countersigned letter in lieu of this form. For a **PARTIAL YEAR TRANSFER**, the documentation must include an estimate of the unexpended balance (direct costs and	• Submission of an original and two copies of transfer application pages (PHS Form 398) with CHANGE OF GRANTEE INSTITUTION typed across the top of the face page. The application must include but is not limited to: For a non-modular application, the

	F&A) from current year funding (carry-over funds from a previous budget period should not be included) that is expected to remain at the termination date. • If equipment was purchased under the grant and is to be transferred, the relinquishing documentation must include a list. • Submission within 90 days of the termination date:	following is required: - a face page ; - budget pages (current and future years); - an updated biographical sketch ; - an updated other support page(s), if necessary; - a resources page; - a checklist page; For a modular application, the following is required: - a face page; - narrative budget information, including annual total direct costs and F&A costs; - biographical sketches for key

	- a Final Invention Statement and Certification ([PHS Form 568](#)), and	personnel;
		- other support pages;
	- a final Financial Status Report ([Standard Form 269](#)).	- resource page;
		- checklist page;
	For an eligible grant, the Financial Status Report (FSR) may reflect automatic carry-over to the new institution. Prior approval of the awarding unit must be obtained for use of an unobligated balance that is not reported as automatic carry-over.	- if future budget periods remain, include information regarding the number of modules and the basis for computing F&A costs;
		- for an **ANNIVERSARY DATE TRANSFER**, a progress report for the current year, including a statement regarding the goals for the upcoming year;
		- for a **PARTIAL YEAR TRANSFER**, an updated current progress report if determined to be

		needed by the IC. If required, this should include a statement regarding the goals for the upcoming year;
		- a statement indicating whether the overall research plans/aims have changed since funding of the most recent competing application (including the date on that application submission). If the research plans/aims have changed, updated information must be provided. If there are no changes, additional information is not necessary;
		- an approved IRB/IACUC assurance, if

		applicable.
		If the move includes the transfer of equipment purchased with grant funds, the application must include a detailed list. This list, as part of the transfer application, is an acceptance of title by the new institution. [This is the same list contained in the Relinquishing Statement.]

SITUATION	ORIGINAL INSTITUTION	REPLACEMENT INSTITUTION
4. Mutual Termination or Termination of Project by the Grantee	• Submission of a Relinquishing Statement (PHS Form 3734) or a letter	· N/A

	confirming the termination date for the project. • Submission within 90 days of the termination date: - a Final Invention Statement (PHS Form 568); - a final Financial Status Report (Standard Form 269), and - a final Progress Report	
5. Unilateral Termination by the NIH The original grantee does not		· Submission of an original and two copies of completed replacement application pages

relinquish the project and a temporary replacement is awarded, see E.1.b.		(PHS Form 398) with REPLACEMENT GRANTEE INSTITUTION typed across the top of the face page. · The replacement application must include but is not limited to: - a face page reflecting a requested single budget period of up to 18 months (this would not require approval for multi-year funding); - a budget page based on figures provided by the IC; (only annual direct costs, F&A costs and budget narrative if

		modular);
		- budget figures for the remainder of the project period (if modular, given only as narrative, reflecting direct and F&A costs)
		- biographical sketches for key personnel;
		- an updated current progress report if determined to be needed by the IC;
		- a discussion and detailed information regarding the specific goals for the proposed upcoming period of support in relation to the research

		plans/aims originally approved;
		- other support page(s),
		- a resources page,
		- a checklist page; and
		- an approved IRB/IACUC, assurance, if applicable.

*All documentation should be submitted directly to the Grants Management Specialist.

G. Procedures:

1. Designation and assignment of a transfer application:

a. For a transfer occurring prior to a Type 1 award, the application will receive a new Type 1 grant number. A competing continuation application (Type 2 or Type 9) transferring at the time of funding maintains the originally assigned designation. In addition, the root grant number and year remain the same.

A non-competing continuation transfer occurring during a budget period or on an anniversary date will reflect a Type 7 designation and the root grant number will remain the same. Retention of the same grant number ensures reporting continuity. For a partial year Type 7, the grant year

advances by one and the alpha suffix of the document number advances to the next letter. The transfer of a grant on an anniversary date will reflect the grant year originally recommended and the alpha suffix of the document number will advance to the next letter. The following example illustrates these points.

Grant Number	Document Number	Entity Number
1 R01 CA12345-01	R1CA12345A	1938006492A1
7 R01 CA12345-02	R1CA12345B	1486135902A1
5 R01 CA12345-03	R1CA12345B	1486135902A1

b. The awarding unit will forward a revised face page, budget page(s) and relinquishing documentation to the Division of Extramural Information Systems, Office of Policy for Extramural Research Administration, for all non-competitive transfers. These pages will also be submitted to this unit for a pending Type 2 or Type 9 application when the transfer occurs subsequent to Initial Review Group (IRG) review. They will update the IMPAC System to reflect a new institution.

For a transfer of a pending Type 1 application, the awarding unit will forward a revised face page, budget page(s) and relinquishing documentation to the Division of Receipt and Referral, Center for Scientific Review (CSR). This unit will update the IMPAC System to reflect both a new institution and a new application grant number.

2. Fiscal Year Appropriations:

A transfer at the time of a competing award (Type 1, 2 or 9) or on an anniversary date (Type 7) will use current fiscal year appropriations. A partial year Type 7 will cite the same fiscal year funding as the award to the original grantee.

3. Partial Year Transfer:

a. For a partial year Type 7, a Notice of Grant Award will be issued to the new institution using the estimated unobligated direct cost balance as reported on the Relinquishing Statement. F&A costs will be awarded at the current negotiated rate. The original grantee will receive a revised decreased Notice of Grant Award based on the estimated grant expenditures through the relinquishment date. The revised award to the original grantee will also reflect revised budget/project period end dates and the deletion of any future year support.

b. When a partial year Type 7 is awarded using funds appropriated from a previous fiscal year, the revised Notice of Grant Award for deobligation of funds to the original institution should be released simultaneously with the Notice of Grant Award for obligation of funds to the new grantee.

c. A term and condition of the Type 7 Notice of Grant Award should be: IF THE UNEXPENDED BALANCE FROM THE PRIOR INSTITUTION HAS BEEN OVERESTIMATED, IT MAY BE NECESSARY TO REDUCE THE AMOUNT OF THIS AWARD.

4. Anniversary Date Transfer:

For an anniversary date Type 7, a Notice of Grant Award will be issued to the new institution reflecting the direct cost level previously committed. If the original application was submitted in the modular format, the Type 7 will be modular as well.   F&A costs will be awarded at the actual negotiated rate in effect. The original grantee will receive a revised Notice of Grant Award reflecting the revised budget/project period end dates and the deletion of any future support.

5. Facilities and Administrative Costs:

As stated in Section E. 3., the negotiated F&A rate in effect at the new institution should be used to calculate the F&A for all remaining budget periods of a transfer grant. If a partial year transfer is to be funded using prior year funds and the F&A rate in effect at the new institution is higher than that originally provided, the applicable Institute/Center budget office staff must be contacted to verify availability of funds. If a transfer will require the use of current year funds and an IC does not have sufficient monies to accommodate an increase for F&A, the allocation between direct and F&A cost categories may need to be adjusted to reflect the actual F&A rate. A decision to reallocate direct costs into F&A costs should include an analysis of the impact on the research project. For recommended future years, total cost commitments should be adjusted to reflect the new F&A rate.

6. Unobligated Balances:

The unobligated balance reflected on the final FSR from the original grantee will be transferred to the account of the new institution by the Office of Financial Management, NIH. These funds are not automatically available as an additional authorization to the new grantee unless the final FSR reflects automatic carry-over, if allowable. The new grantee is notified by OFM in writing, with a copy to the awarding unit, concerning the availability of the unobligated balance. If automatic carry-over is not allowable or has not been reflected on the final FSR, prior approval from the awarding unit is necessary to effect a carry-over of the unobligated balance. In this case, a revised Notice of Grant Award will be issued to reflect the action.

H. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743,

"Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule," Section 4000 which covers NIH Grants and Awards and Section 1100 – G which covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail messages: NIH e-mail messages (messages including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. **These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.**

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staffs conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Accountability and Management Controls:

The purpose of this manual issuance is to state NIH policy and procedures to be used by awarding units to effect a change in grantee institution.

1. The Office Responsible for Reviewing Management Controls Relative to this Chapter: The Division of Grants Policy (DGP) Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), is accountable for the method used to ensure that management administration are implemented.

2. Frequency of Review: Ongoing reviews will occur as scheduled or on an ad hoc basis.

3. **Method of Review**: Working with the NIH Grants Management Advisory Committee (GMAC), DGP/OPERA is developing an NIH internal grants management compliance model (GMCM). The model will address: 1. The importance and expectations resulting from the formalization of roles and responsibilities in the grant award process, 2. The necessity of developing and maintaining an expert grants management staff trained and certified in a formal certification process, 3. The currency of NIH grants policies and procedures, and 4. The development of a management culture with a zero tolerance for noncompliance with established requirements.

The GMCM will contain a review component to ensure that management controls in grants management are in place. Reviews of NIH awarding components will utilize a review protocol designed for this purpose and will occur as scheduled or on an ad hoc basis as a result of specific policy, operational or I/C issues. The purpose of the reviews will be to determine, among other things, the level of compliance with established policies and procedures and to ascertain how well they are achieving their desired effects. OPERA will issue reports of findings and recommendations resulting from the reviews to I/Cs for appropriate action. Day-to-day oversight issues will be brought by NIH grants management staff to the attention of DGP/OPERA and the GMAC for discussion and resolution.

The Director, OPERA, is routinely apprised of any difficulties in the I/C

implementation of policy and, may recommend additional policy guidance or training for grants management staff.

4. **Review Reports are Sent to**: The DDER and the Director, OPERA, OER.

Through this manual issuance the OPERA/OER is accountable for the methods used to ensure that management controls are implemented and working. The current methods used to maintain oversight and a system of internal controls ensuring effective implementation and compliance with this policy will be monitored on a continuing basis by the OPERA/OER and the Grants Management Advisory Committee.

NIH POLICY MANUAL

55205 - Successor-in-Interest and Name Change Agreements

Issuing Office: OER/OPERA 301 435-0949

Release Date: 09/15/00

1. **Explanation of Material Transmitted:** This chapter states the NIH's policy with regard to the following actions: (1) formal recognition of a new grantee organization as the **successor-in-interest** to the assets included in grant-supported activities, and (2) formal recognition of a **name change** that does not affect the rights and obligations of the original grantee. This issuance differs from the previous chapter in that the procedures have been refined, and the three-party document known as the "Successor-In-Interest Agreement" (PHS Grants Administration Manual, Appendix 133-A) is no longer required. Further, legal action recognized by the NIH as a "merger" has been addressed, including the applicability of these procedures thereto.

2. **Filing Instructions:**

   Remove: NIH Manual Chapter 5205 dated 11/13/87

   Insert: NIH Manual Chapter 5205 dated 09/15/00

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System, contact the Division of Management Support, OMA, OA, on 496-2832.

- On-line information, go to: http://oma.od.nih.gov/manualchapters/

A. Purpose:

This issuance states the NIH's role in the following actions: (1) formal recognition of a new grantee organization as **the successor-in-interest** (SII) to assets included in NIH grant-supported activities, (2) formal recognition of a name change that does not affect the rights and obligations of the grantee, and (3) mergers, i.e., those legal actions that result in the unification of two or more legal entities. When such actions involve the transfer of assets, the procedures for the recognition of successor-in-interest will generally apply. When such actions do not involve the transfer of assets, procedures for the recognition of name change will generally apply.

B. Background:

Formerly, when an SII or name change affected grants from more than one Institute or Center (IC), the responsibility for processing such actions resided with Division of Grants and Contracts, in the Office of the Assistant Secretary for Health (OASH), Public Health Service (PHS). With the elimination of the Division of Grants and Contracts, OASH, PHS, SII and name change actions became the responsibility of the individual PHS agencies. Thus, it is necessary to establish formal NIH policy and procedures for the processing of these actions.

C. Policy:

This policy is applicable to NIH-issued grants only. Grantee organizations having grant-related interests with other federal agencies are responsible for notifying those agencies of any change of grantee organization status.

D. References

1. PHS Grants Administration Manual Part 131, Change of Grantee Institution

2. NIH Manual Chapter [5201](#), Change of Grantee Institution

3. NIH Grants Policy Statement,
http://grants.nih.gov/grants/policy/policy.htm

E. Definitions:

1. **Successor-In-Interest** - A process whereby the rights to and obligations under an NIH grant or grants are acquired incidental to the transfer of all the assets of the grantee, or the transfer of that part of the assets involved in the performance of the grants.

2. **Name Change** - An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee.

3. **Merger** - A legal action resulting in the unification of two or more legal entities. When such actions involve the transfer of assets, the procedures for the recognition of successor-in-interest will generally apply. When such actions do not involve the transfer of assets, procedures for the recognition of name change will generally apply.

F. Policy:

1. The current recipient of NIH grant support is responsible for promptly notifying the awarding IC, in writing, of pending SII and name change actions.

2. When an SII or name change affects more than one IC, responsibility for processing applicable changes for all affected grants and preparing a formal letter of acknowledgment resides with either the IC with the most grant support awarded, or the IC with the most pressing need. The "lead IC" will be determined by negotiation between the Grants Management Officer (GMO) of the IC first contacted by the grantee, and the GMO of any other affected IC.

Note: Neither a name change nor a successor-in-interest is considered a **Change of Grantee Institution**. (Please see NIH Manual Chapter 5201.)

G. Procedures for Successor-in-Interest Actions:

1. The GMO of the lead IC will appoint an individual to serve as the designated NIH contact for the SII action. The contact will be responsible for the collection and dissemination of all material. The contact will also be responsible for entering and tracking information in the Successor-In-Interest and Name Change Database, (located at http://odoerdb2.od.nih.gov/cfdocs/gmac_sii/sii_main.cfm) as well as for inputting the final approval date. The final approval date signifies the documents have been reviewed and approved and that awards may be issued.

2. In order to be recognized as the successor-in-interest, the "new" organization must meet the grant program's eligibility requirements. The responsibility for evaluating eligibility generally rests with the lead IC. However, an IC may re-evaluate eligibility if a particular program issue requires a different approach. For example, if the successor is in conflict with the stipulations of a program announcement as a result of an SII, an IC may choose to "grandfather" or waive the conflicting requirements of the program.

In accordance with NIH policy, administrative approval may not be given for proposed transfers from an SBIR/STTR grantee to a non-SBIR/STTR eligible organization. This prohibition may not be waived. SBIR/STTR grants may, however, be administratively transferred between two SBIR/STTR eligible organizations.

3. The grantee should be advised to submit the following documents directly to the designated NIH contact as soon as possible so that actions can be processed prospectively:

a. A letter signed by appropriate institutional officials of both the current

grantee (transferor) and the successor (transferee) that includes the following:

1) Discussion of the pending SII and a request that the NIH modify its records to reflect the transferee as the grantee of record.

2) Confirmation that the transfer of assets was properly effected in accordance with applicable law.

3) Identification of the effective date of the transfer. (Note: There may only be one effective date.)

4) Information regarding the transferee's entity (EIN) number.

- Will the old EIN continue to be used? If so, for what purpose?

5) For the transferee, provide the following:

- Verification of compliance with applicable requirements (e.g., research misconduct as indicated in the Form PHS 398, Application for a Public Health Service Grant).

6) A list of all affected NIH grant(s) (active and pending) that includes the following information:

- complete grant number (e.g., 5 R01 GM 12345-04),

- name of principal investigator (PI),

- budget and project periods, and

- budgetary information on all affected grants that reflects the total direct costs (as originally recommended) plus applicable facilities and administrative (F&A) costs for each budget period remaining in the grant(s). If the SII is to occur during a budget year (i.e., not on an anniversary date), the transferor must also provide estimated levels of current year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on an Official Statement Relinquishing

Interests and Rights in a Public Health Service Research Grant (PHS 3734), or "relinquishing statement," for each affected grant, or itemized by grant number as an attachment to the letter.

b. Completed face pages (form PHS 398) for all affected grants showing the transferee as the applicant organization. Each face page must be signed by both the PI and the responsible business official at the transferee organization.

c. A copy of the negotiated F&A rate agreement for the transferee.

- If applicable, explain how funding is expected to be affected due to any changes in the F&A rate.

- If applicable, identify any shift from direct costs into F&A.

4. The successor should be advised to contact the Office for Human Research Protections (OHRP) regarding human subjects and vertebrate animal assurances. OHRP will determine if the grants involved may be covered under existing assurances, or if new assurances will need to be negotiated.

5. Upon receipt and acceptance of all required documentation, the GMO of the lead IC will send a letter of acknowledgment to the grantee institution (see Appendix for sample letter). A copy of each new face page will be forwarded to the Division of Extramural Information Systems, OPERA, OER, OD.

6. The GMO of the lead IC will analyze the implications of the change in F&A rate from the original rate to the rate proposed for the new entity, and discuss such implications in a memo to all involved parties. This memo, a copy of the letter of acknowledgment, and all pertinent documents will be forwarded to the appropriate GMO(s); Division of Extramural Information Systems, OPERA, OD; Office of Financial Management, OD, Office of Research Integrity, DHHS; Office for Human Research Protections; and the Division of Financial Advisory Services, Office of Acquisition

Management and Policy, OD.

7. A revised Notice of Grant Award (NGA) (Form PHS 5152) will be issued for each affected grant as a type 6 action on either the effective date of the transfer or the anniversary date of the grant, as negotiated with the grantee. The terms and conditions should refer to the aforementioned letter of acknowledgment.

A partial year action will cite the same fiscal year as the award to the transferor. For a partial year action, a Notice of Grant Award will be issued to the transferee using the estimated unobligated direct cost balance as reported on the relinquishing statement or letter from the transferor. The F&A cost rate of the successor institution will be used to calculate the award. If a partial year transfer is to be funded using prior year funds and the F&A rate in effect at the new institution is higher than that originally provided, the Office of Financial Management, NIH, must be contacted to verify availability of funds. The transferor will receive a revised decreased Notice of Grant Award based on the estimated grant expenditures through the relinquishment date. The revised award to the transferor will also reflect revised budget/project period end dates and the deletion of any future year support.

When a partial year action is awarded using funds appropriated from a previous fiscal year, the revised Notice of Grant Award for deobligation of funds to the transferor should be released simultaneously with the Notice of Grant Award for obligation of funds to the transferee.

8. The F&A cost rate of the successor institution will be used to calculate the award. If the transfer occurs during a budget period and the F&A cost rate at the new institution is higher, funds may be added to accommodate the increase in total costs. If additional funds are not available to accommodate the increase, the grantee may adjust the allocation between direct and F&A costs so that F&A costs are reimbursed at the new rate. Future year total cost commitments will be adjusted to reflect the new

institution's F&A cost rate.

There are some successor-in-interest actions where the transferee is a new entity, and thus does not have a negotiated F&A cost rate at the time the successor action is completed. In those cases, it may be appropriate to negotiate the use of the F&A cost rate used to calculate the original competing award to the transferor institution as a "provisional" rate until the transferee establishes an F&A cost rate. Such negotiations would include the designated NIH contact, transferee organization, the Division of Financial Advisory Services, and staff responsible for negotiating the rate agreement. The F&A rate proposal for the new entity shall be submitted no later than three months after the effective date of the first award to the successor.

H. Procedures for Name Change Actions:

1. The GMO of the lead IC will appoint an individual to serve as the designated NIH contact for the name change action. The contact will be responsible for the collection and dissemination of all material. The contact will also be responsible for entering and tracking information in the Successor-In-Interest and Name Change Database, (located at http://odoerdb2.od.nih.gov/cfdocs/gmac_sii/sii_main.cfm) as well as for inputting the final approval date. The final approval date signifies the documents have been reviewed and approved, and that awards may be issued. The GMO will also contact the Site Manager of the Grants Management Infonet (website - http://odoerdb2.od.nih.gov/gmac/home.html) to list the pending action in the database of SII/name change actions currently in process. Providing this information via the database will avoid duplication of effort when more than one IC is affected.

2. The grantee should be advised to submit the following documents directly to the designated NIH contact as soon as possible so that actions can be processed prospectively:

a. A letter signed by an appropriate institutional official notifying the NIH of the name change and requesting that its records be modified to reflect the name change. The letter should include the following:

1) Confirmation that the name change was properly effected in accordance with applicable law.

2) Identification of the effective date of name change. (Note: there may only be one effective date.)

3) Information regarding entity (EIN) numbers.

- Will the organization be changing its EIN?

- Will the old EIN continue to be used? If so, for what purpose?

4) A list of all affected NIH grants (active and pending) that includes the following information:

- complete grant number (e.g., 5 R01 GM 12345-04),

- name of principal investigator (PI), budget and project periods

3. The grantee should be advised to contact the Office for Human Research Protection, HHS, regarding human subjects and the Office of Laboratory Animal Welfare, OER, for vertebrate animal assurances. These two offices will determine if the grants involved may be covered under existing assurances, or if new assurances will need to be negotiated.

4. Upon receipt and acceptance of the above documents, the GMO of the lead IC will send a letter of acknowledgment to the grantee institution (see Appendix for Sample Letter). The designated NIH contact will forward a copy of the letter and all pertinent documents to the appropriate GMO(s); the Division of Extramural Information Systems, OPERA, OD; the Office of Research Integrity, DHHS; the Office of Human Research Protection, DHHS; the Office of Laboratory Animal Welfare, OD; and the Office of

Financial Management, OD.

5. It is not necessary to revise the active NGA to reflect the "new" name, but the letter of acknowledgment should be placed in the official grant file.

The NGA for the next budget period, if any, will reflect the new name of the grantee organization, and the new EIN, if applicable. The terms and conditions should refer to the aforementioned letter of acknowledgment.

I. Records Retention and Disposal:

Documentation of SII and name change actions will be placed in the official file(s) of each affected grant. Records retention and disposal requirements for the official grant file can be found in the NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, item 4000-B-1. Also, refer to 4000-A and 4000-D-3 of NIH Manual 1743 for additional information.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up

files are subject to the same requests as the original messages.

J. Management Controls:

The purpose of this manual issuance is to state the basic requirements for the formal recognition of a new grantee organization as the successor-in-interest to assets included in NIH grant-supported activities, and formal recognition of a name change that does not affect the rights and obligations of the grantee.

1. **The Office Responsible for Reviewing Management Controls Relative to this Chapter**: The Division of Grants Policy (DGP), Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), is accountable for the method used to ensure that management controls in grants administration are implemented.

2. **Frequency of Review**: Ongoing reviews will occur as scheduled or on an ad hoc basis.

3. **Method of Review**: Working with the NIH Grants Management Advisory Committee (GMAC), DGP/OPERA is developing an NIH internal grants management compliance model (GMCM). The model will address: 1) the importance and expectations resulting from the formalization of roles and responsibilities in the grant award process; 2) the necessity of developing and maintaining an expert grants management staff trained and certified in a formal certification process; 3) the currency of NIH grants policies and procedures; and 4) the development of a management culture with zero tolerance for noncompliance with established requirements.

The GMCM will contain a review component to ensure that management controls in grants management are in place. Reviews of NIH awarding components will utilize a review protocol designed for this purpose and will occur as scheduled or on an ad hoc basis as a result of specific policy, operational or I/C issues. The purpose of the reviews will be to determine, among other things, the level of compliance with established policies and

procedures and to ascertain how well they are achieving their desired effects. OPERA will issue reports of findings and recommendations resulting from the reviews to I/Cs for appropriate action. Common issues will be brought to the GMAC for resolution and corrective action. Day-to-day oversight issues will be brought by NIH grants management staff to the attention of DGP/OPERA and the GMAC for discussion and resolution.

The Director, OPERA, is routinely apprised of any difficulties in the IC implementation of policy and, depending upon the nature and extent of problems, may recommend additional policy guidance or training for grants management staff.

4. **Review Reports are Sent to**: The DDER and the Director, OPERA, OER.

Appendix - Sample Letter

Date

[Name]
[Address]

Our Reference: [Grant #]

Dear [Authorized Institutional Official]:

This letter is in reference to the documentation submitted by [   ] relating to the [Name of Institution]'s recent successor-in-interest agreement. This letter serves to acknowledge the Institute's/Center's receipt and acceptance of these documents.

We have forwarded a copy of these documents to the National Institutes of Health's (NIH's) Office of Policy for Extramural Research Administration to reflect these changes in the NIH IMPAC System and have notified appropriate NIH awarding components.

The current Notices of Grant Award will not be revised to reflect the successor-in-interest for your organization. Subsequent Notices of Grant Award, if any, will reflect the change.

If you have any questions or need further information, please contact me at telephone number (301) xxx-xxxx, fax number (301) xxx-xxxx, or the following email address: [   ].

Sincerely,

[Name of GMO]
Grants Management Officer

cc: [Names]

NIH POLICY MANUAL

55805 CLOSEOUT OF NIH GRANTS
ISSUING OFFICE: OPERA/OER 435-0949
RELEASE DATE: 02/16/00

1. **Explanation of Material Transmitted:** This chapter is being revised to update the basic requirements for the administrative closeout of assistance awards following expiration of support from the National Institutes of Health.

2. **Filing Instructions:**

   Remove: NIH Manual 5805 dated 02/14/86 in its entirety

   Insert: NIH Manual 5805 dated 02/16/00

3. **Distribution:** NIH Manual Mailing Keys F-401 and F-406 (transmittal sheet only): Chapter text is available on-line. See the last bullet on this page for on-line information.

Please Note: For information on:

♦ **content of this chapter,** contact the issuing office listed above.

♦ **NIH Manual Mailing Keys** or for a **paper copy** of this chapter, contact the **Division of Support Services, ORS,** on **496-4808.**

♦ **NIH Manual System,** contact the **Division of Management Support, OMA, OA,** on **496-2832.**

♦ **on-line information use:** http://www3.od.nih.gov/oma/manualchapters

CLOSEOUT OF NIH GRANTS

A. Purpose: This issuance states the basic requirements for the administrative closeout of assistance awards following expiration of support from the National Institutes of Health (NIH).

B. Applicability: This policy applies to NIH assistance awards. See Section F. Special Procedures, for closeout of fellowships and institutional training grants.

C. References:

1. 45 CFR 74.53-Retention and Access Requirements for Records

2. 45 CFR 74.71-Closeout Procedures

3. 45 CFR 92.50-Closeout Procedures

4. PHS Grants Administration Manual Part 127, Grant Closeout

5. NIH Manual Chapter 1742, Transfer, Withdrawal and Destruction of Records at the Washington National Records Center

6. NIH Manual Chapter 1743, Keeping and Destroying Records

7. NIH Manual Chapter 4810, National Research Service Awards

8. NIH Manual Chapter 5806, Overdue Reports - Discretionary Grants

9. NIH Manual Chapter 1130, Delegations of Authority, **Program: Grants & Awards #8,** Deviations from HHS Grant Regulations and Policies

D. Policy: NIH recipients shall submit, within 90 calendar days after the date of completion of the award, all financial, performance, and other reports as required by the terms and conditions of the award. Grant closeout procedures shall ensure that the interests of the Government have been adequately protected, all significant actions have been documented, and all necessary scientific and administrative reports have been received.

Closeout may affect the time period for retention of records by the grantee since submission of the final financial status report establishes the 3-year record retention period. See 45 CFR Part 74.53 Retention and access requirements for records.

The specific reports required by the NIH are:

1. **The Final Financial Status Report (FSR) - (Standard Form 269**)

CLOSEOUT OF NIH GRANTS

Grantees are instructed to submit a hardcopy or an electronic final FSR directly to the Office of Financial Management (OFM), NIH. This report must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. Once approved, OFM will forward a hard copy of the final FSR to the appropriate Institute or Center (IC). The approved report can also be accessed electronically.

2. **The Final Invention Statement & Certification (HHS Form 568)**

This statement must list all inventions conceived or reduced to practice during the course of work under the project from the original effective date of support through the date of expiration or termination, whether or not previously reported.   If an invention is reported, the IC must forward a copy of Form 568 to the Division of Extramural Inventions and Technology Resources, OPERA, OER, NIH.   (Note: Even if no inventions have been made, Form 568 must be submitted.)

For certain mechanisms (C06, R13, R25, S15, Ts, and Fs), the Final Invention Statement is not currently required.   In general, training and educational mechanisms do not require invention reporting.

3. **The Final Progress Report**

This report should be prepared in accordance with instructions provided by the awarding component. At a minimum, it should include a statement of progress made toward the achievement of originally stated aims, a list of results (positive or negative) considered significant, and a list of publications resulting from the project, with plans, if any, for further publication. A copy of reprints or publications not previously submitted should accompany the progress report.

If a competitive renewal (Type 2) has been submitted, whether funded or not, the progress report contained in that application may serve in lieu of a separate final progress report. In addition, at the discretion of the awarding unit, a reprint or preprint may be used for this purpose.

4. **Other**

For any for-profit grantee including Small Business Innovative Research and Small Business Technology Research grants that received an award with a start date prior to August 25, 1994, title to equipment purchased with grant funds vests with the Federal government. These recipients must complete a final inventory of equipment on Form HHS-565, "Report of Accountable Personal Property." At the time this form is completed, the awardee may request transfer of the title.   For awards issued on or after

CLOSEOUT OF NIH GRANTS

August 25, 1994, the equipment vests with the grantee and thus, the above procedure is no longer required.

If the inventory (HHS-565) is returned indicating that equipment was purchased, the original form and the disposition instructions from the Chief Grants Management Officer (GMO), must be forwarded to the Research Contracts Property Administrator, Property Management Division (PMD), Office of Logistics Management (OLM), Bldg. 13, Room 2E65D. Once PMD processes the inventory of equipment, it will be returned to the awarding unit indicating "complete." The PMD is responsible for notifying the grantee in writing of the disposition.

If the inventory is returned indicating no equipment was purchased, no further action is required.

E. Procedures:

1. The following procedures are recommended as the standard for NIH. However, each awarding unit **may implement** them in accordance with its own IC practices/procedures.

a. The awarding unit should advise the grantee of the closeout requirements by a term and condition on the Notice of Grant Award for the final year of each competitive segment. This term should list the required documents and the possible sanctions for noncompliance. For example, failure to submit the required reports, when due, may result in the imposition of a special award provision or the withholding of other eligible projects or activities involving the grantee organization.

b. Upon receipt of the reports, IC staff will prepare a checklist documenting that all closeout requirements have been met. (See **Appendix 1**) The completed checklist should reflect program staff's acceptance of the Final Progress Report.

c. Prior to closing a grant file, grants management staff will ensure that all pertinent documents required throughout the life of a project are contained in the official grant file.

2. Time frames for obtaining delinquent reports:

a. **90 calendar days following termination**:

Grants management staff will send a letter to the business/institutional official with a copy to the principal investigator (PI). This letter should list the documents needed and should include language regarding the sanctions for noncompliance. The grantee should be given 30 calendar days to respond. (See **Appendix 2**)

b. **120 calendar days following termination**:

CLOSEOUT OF NIH GRANTS

If there is no response to the original request, grants management staff will send a letter to the dean/head of the grantee institution, with copies to the principal investigator and the business official. The letter should be co-signed by both grants management and program staff. It should include the possible sanctions for noncompliance and should give the grantee 30 calendar days to respond. (See **Appendix 3**)

c. **150 calendar days following termination**:

As stated in the NIH Grants Policy Statement (Part II, Closeout), " *failure to submit timely final reports may affect future funding to the organization or awards with the same principal investigator."* If after 150 calendar days all documents have not been received, one of the following sanctions may be imposed:

(1) **If the PI has other pending awards (competing or noncompeting) in the same IC**, funding should be held until the delinquent reports are received. A letter should be sent to the dean/head of the grantee institution with copies to the principal investigator and business official advising them of this sanction. The letter should be co-signed by the Chief Grants Management Officer and the Director of the IC.

(2) **If the PI or organization has other pending grants (competing or noncompeting) with a different IC**, the Chief GMO may contact the other IC to request withholding of future support.

(3) **If it is determined that delinquent submission of reports is a pattern for a particular grantee organization**, this should be reported to the Office of Policy for Extramural Research Administration (OPERA). OPERA and the Grants Management Advisory Committee (GMAC) will make a determination concerning the appropriate corrective action(s) and/or sanction(s); e.g., exclusion from Expanded Authorities.

F. Special Procedures:

1. **Closeout of Fellowships** - A Termination Notice (PHS 416-7) is required upon completion of a National Research Service Award (NRSA). Neither a final Financial Status Report **(SF 269)** nor a Final Invention Statement & Certification **(HHS 568)** is required. However, fellowships awarded under the NRSA must fulfill all payback requirements prior to IC staff officially closing the file. The NIH Policy Manual 4810 should be consulted for specific details on payback.

2. **Closeout of Institutional Training Grants** – The closeout of NRSA institutional training grants should follow a similar procedure to that of research grants, i.e., a Final Progress Report and final Financial Status Report are required within 90 days of the termination. However, a Final Invention Statement & Certification is not required.

CLOSEOUT OF NIH GRANTS

Although the official file may be closed, an individual's payback file (including the Statement of Appointment form(s) and the Termination Notice) cannot be closed until all payback requirements are fulfilled. This applies to all postdoctoral trainees. In addition, this applies to predoctoral trainees who incurred payback obligations prior to June 10, 1993.

G. Deviation/Waiver:

In unusual circumstances, after all reasonable efforts to secure the required documentation have been exhausted, the Chief GMO has the authority to waive the requirements for specific closeout documents. See OER, Policy Announcement 1997-02-(01/30/97), "Single-Case Deviation from PHS/NIH Grants Policy."
http://odoerdb2.od.nih.gov/oer/policies/oer_announce_1997_02.htm

Examples where a waiver might be considered are provided below.

1. Final Invention Statement

The grantee has consistently reported "no inventions" in all applications and staff has confirmed that no inventions have been reported to the Division of Extramural Inventions and Technology Resources, OPERA, OER, NIH.

2. Final FSR

All authorized funds are shown as disbursed and charged in the Payment Management System (PMS). Staff should contact OFM so that a closing transaction '059' can be entered into PMS. Once the '059' has been entered, the file should be annotated by printing a copy of the PMS report showing the record as financially closed.

Staff in OFM should be consulted before taking the above action.

H. Records Retention And Disposal:

All records (**e-mail** and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule." Item 4000 covers NIH Grants and Awards and item 1100-G covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific disposition instructions.

<u>**NIH e-mail messages**</u> (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. **These records**

CLOSEOUT OF NIH GRANTS

must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.
All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls: The purpose of this manual issuance is to state the basic requirements for the administrative closeout of assistance awards following the expiration of support from the NIH.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter: The Division of Grants Policy (DGP), Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

2. Frequency of Review: Ongoing reviews will occur as scheduled or on an ad hoc basis.

3. Method of Review: **Other Review**. DGP, working with the NIH Grants Management Advisory Committee (GMAC), is developing a NIH internal grants management compliance model (GMCM). Part of the GMCM will contain a file review component to ensure that I/C grant files are properly maintained and processed. Reports of findings and recommendations resulting from GMCM reviews or other similar types of reviews will be issued to I/Cs for appropriate action. Common issues will be brought to the GMAC for resolution and corrective action. Depending upon the nature and the extent of problems found, if any, the Director OPERA may recommend additional policy guidance or training for grants management staff.

4. Review Reports are sent to: The DDER, DDM and the Director, OPERA.

CLOSEOUT OF NIH GRANTS

Appendix 1

DATE: _____

GRANT NUMBER:_____

GRANT PERIOD DATES: _____

INVESTIGATOR: _____

INSTITUTION: _____

PROGRAM DIRECTOR: _____

GRANTS SPECIALIST: _____

I.   Notification to Grantee of Required Closeout Reports

☐   Closeout Terms & Conditions reflected on _____ Year Award ISSUED ON _____

☐   90 Day Letter to Business/Institutional Official (cc to PI) DATE SENT: _____

☐   120 Day Letter to Dean/Head of Grantee Institution DATE SENT: _____

==

II.   Final Progress Report

☐   Final Progress Report Accepted:
      Program Director: ACCEPTANCE/DATE _____

☐   Progress Report in Type 2 Accepted:
      Program Director: ACCEPTANCE/DATE _____

☐   Reprints in Lieu of Progress Report Accepted:
      Program Director: ACCEPTANCE/DATE _____

III.   Date Final Financial Status Report Received _____

IV.   Date Final Invention Statement Received _____

V.   Deviation/Waiver (Documentation Required – See Section G of Manual Issuance)
      CHIEF GMO: APPROVAL/DATE _____

CLOSEOUT OF NIH GRANTS

Appendix 2

SAMPLE

DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200

http://www.nih.gov/nigms/

March 1, 1998

Jennifer Kalish
Director, Sponsored Research Projects
University of Texas Southwestern Medical Center
Department of Physiology
5323 Harry Hines Boulevard
Dallas, Texas 75235-9040

Re: 5 R01 GM12998-08

Dear Ms. Kalish:

The above referenced grant ended on November 30, 1997. To administratively close this project, our policy requires the submission of three final reports within 90 calendar days after termination. As stated in the Terms and Conditions of your award, "Failure to submit these required reports when due may result in the imposition of special award provisions or the withholding of support for other eligible projects or activities involving your institution or the individual responsible for the delinquency." The following report (s) checked below, are now overdue:

☐ Final Progress Report (Preparation guidelines enclosed, if applicable.)
      (Note: a publication resulting from the research will suffice.)
☐ Final Invention Statement & Certification (HHS 568) (Form enclosed, if applicable)
☐ Final Financial Status Report (submit electronically, if applicable)

It is imperative that these reports be submitted immediately to me at the address indicated below. Thank you for your assistance. Should you have any questions, please contact me.

Sincerely yours,

Grants Management Specialist
Building 45, Room 2AS 55K
45 Center Drive, MSC 6200
Bethesda, MD 20892-6200

Enclosure(s)
cc:
Dr. Principal Investigator

CLOSEOUT OF NIH GRANTS

Appendix 3

SAMPLE

DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

_____

National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200

http://www.nih.gov/nigms/

April 1, 1998

John Smith, Ph.D.
Dean
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, Texas 75235-9040

Re: 5 R01 GM12998-08

Dear Dr. Smith:
This is in follow-up to our letter dated March 1, 1998 to Ms. Jennifer Kalish regarding the closeout
documents for the above referenced grant. In accepting the grant, your institution agreed to comply with
our policies, including the requirement for submitting final reports in a timely manner. Despite our efforts,
the following report (s), checked below, are now 30 days past due .

   ☐   Final Progress Report (Preparation guidelines enclosed, if applicable.)
            (Note: a publication resulting from the research will suffice.)
   ☐   Final Invention Statement & Certification (HHS 568) (Form enclosed, if applicable)
   ☐   Final Financial Status Report (submit electronically, if applicable)

We are concerned that your institution has been unable to comply with the Terms and Conditions of the
award. It is imperative that the required reports be submitted immediately at the address below. Failure to
do so could jeopardize future funding.

Please contact either one of us if you should have questions.

Sincerely yours,   Sincerely yours,

Program Director   Grants Management Specialist
Building 45, Room 2AN.25A   Building 45, Room 2AS 55K
45 Center Drive, MSC 6200   45 Center Drive, MSC 6200
Bethesda, MD 20892-6200   Bethesda, MD 20892-6200

Enclosure(s)
cc:
Dr. Principal Investigator
Business Official

NIH POLICY MANUAL

55806 - Overdue Reports — Discretionary Grants

Issuing Office: OER 301-496-5967

Release Date: 11/30/84

A. Purpose:

This issuance states the guidelines for administrative action to be taken in assuring that grantees submit to NIH such reports as may be required as a condition of a grant award.

B. Background:

A recurring problem in the administration of many NIH grant programs is the delinquency on the part of some grantees in submitting reports required as a condition of the grant award. These reports are divided into two general categories, identified as progress reports and management reports. Progress (performance) reports describe technical scientific accomplishments toward meeting project objectives. Management reports cover financial, administrative, or other non-technical (non-scientific) aspects of the grant-supported project.

C. Applicability:

This issuance applies to all assistance programs (grants and cooperative agreements) in which the amount of the award and the decision to make the award are within the discretion of the NIH awarding unit.

D. References:

1. PHS Grants Administration Manual Chapter 1-42, Overdue Reports-

Discretionary Grants.

2. NIH Manual Issuance 5805, Closeout of NIH Grants.

3. NIH Manual Issuance 5807, Submission and Acceptance of Revised Reports of Expenditures.

4. CNIH Manual Issuance 5808, Establishment and Documentation of Files and Other Records, Including Monitoring Actions, for NIH Grant Programs.

E. Policy:

Each discretionary grant award is made subject to the condition that the grantee shall prepare certain technical progress reports and management reports and shall submit them on a predetermined basis to the appropriate unit at NIH. Awarding units shall take appropriate administrative action to assure the submission by grantees of required reports.

F. Guidelines for Administrative Action:

The particular administrative action taken by the awarding unit will depend on the response, if any, receive from the grantee to written requests for overdue required reports. The following procedures shall be followed by awarding units encountering a delinquent reporting situation:

1. *Delinquent Technical Progress Reports* When a grantee continues to be delinquent in submitting a required progress report or final report on the scientific and technical aspects of the grant (i.e., 30 days beyond the due date), the Grants Management Officer (GMO) of the awarding unit is responsible for the following actions:

a. The GMO shall send a letter to the program director, principal investigator, or other person directly responsible for the report, notifying that person of the delinquency and requesting the report. The letter shall

state that, if the report cannot be submitted promptly, the responsible individual should explain the reason and should state the date by which the awarding unit will receive the report.

b. If neither the report nor an acceptable explanation for not submitting it is received within 30 days of the date of the first letter, the GMO shall promptly send a second letter. This letter shall be sent to the official of the grantee institution who is responsible for the administration of the grant notifying that official of the delinquency and of the prior attempt to obtain the required report. This letter may advise the grantee that failure to submit the report within 30 days could result in the awarding unit withholding any additional grants in which the principal investigator, or person responsible for the delinquent report, is involved until the overdue report is received.

c. If neither the report nor an acceptable explanation for further delay is received within 30 days of the date of the second letter, the head of the grantee institution should be informed by letter from an awarding unit official at the Associate Director or Executive Officer level of the previous attempts to secure the required report. This letter may also state definitively that the awarding unit will not award any additional grants in which the program director, principal investigator, or person responsible for the delinquent report, is involved until the overdue report is received.

d. If there is no acceptable response within 30 days of the above letter (it now being at least 120 days beyond the due date), the matter should be submitted to the Deputy Director for Extramural Research and Training (DDERT) with full documentation. (In case of a final progress report, at least seven months have elapsed since the project ended.) The DDERT will determine alternative procedures which may be applied in order to try to obtain the missing report.

2. *Delinquent Management Reports* A delinquent management report is defined as: A management report which has not been received within seven months following expiration of the grant budget period it is to cover or, specifically with respect to a Financial Status Report (FSR), an FSR which has appeared on the Division of Financial Management (DFM) monthly delinquent report list for three months. (Under the DFM reporting schedule, FSRs that have appeared on the delinquent list three times are then roughly 4 months overdue or, in other words, approximately seven months have elapsed since the grant budget period ended.) When, under the above definition, a grantee is delinquent in submitting a required management report, the GMO of the awarding unit is responsible for the following actions:

a. The GMO shall send a letter to the grantee official responsible for the administration of the grant notifying that official of the delinquency and requesting submission of the report within 30 days of the date of the letter.

b. If there is no reply within the 30 day period, the head of the grantee institution should be informed by letter from an awarding unit official at the Associate Director or Executive Officer level of the previous attempts (including the DFM delinquent reports lists, if appropriate) to secure the required report. An acknowledgment of this letter within 2 weeks should be requested.

c. Continued delinquency will result in the following actions: (1) for active grants, no continuation award may be made if required reports have not been received. (2) for both active and expired grants, if required reports have not been received prior to the normal anniversary date of the next grant (i.e., within a 12-month period), the case should be submitted to the DDERT with full documentation. The DDERT will determine alternative procedures which may be applied to try to obtain the missing reports.

d. If a grantee institution is consistently delinquent on a general basis in the submission of required management reports, the situation will be called to the attention of the Division of Management Survey and Review, OA, NIH, for appropriate corrective action.

3. *No Report Received - Waiver Procedure* In unusual cases, the GMO of the awarding unit may waive the requirement for a progress or management report or extend the date for submission when the grantee can satisfactorily demonstrate that it cannot furnish the report in a timely manner for reasons legitimately beyond its control or the purposes for which the report is to be used will be accomplished through other means. Grant files must be adequately documented to support the awarding unit's action.

G. Effective Date:

This policy is effective on date of release.

H. Additional Information:

For further information on this manual chapter, contact the Grants Policy Office, OERT, 496-5967.

I. Additional Copies:

Copies of this manual chapter can be obtained by sending Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DTS, Building 31, Room B3BE07.

NIH POLICY MANUAL

55807 - Submission and Receipt of Financial Status Reports

Issuing Office: OPERA/OER 435-0949

Release Date: 05/22/00

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1. **Explanation of Material Transmitted:** This revised chapter updates the policies for submission and receipt of Financial Status Reports (FSRs) including revised and/or delinquent submissions.

2. **Filing Instructions:**

   Remove: NIH Manual 5807 dated 08/14/89 in its entirety
   Insert: NIH Manual 5807 dated 05/22/00

PLEASE NOTE: To sign up for email notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This issuance states the policy to be used for acceptance of Financial Status Reports (FSRs) including revised and/or delinquent submissions. It also establishes the assignment of responsibility for monitoring and oversight of grantees that submit an excessive number of revised and/or delinquent FSRs.

B. Applicability:

This policy applies to all NIH assistance awards that require submission of

FSRs.

C. References:

1. NIH Manual 1742, " Transfer, Withdrawal and Destruction of Records at the Washington National Records Center"

2. NIH Manual 1743, "Keeping and Destroying Records"

3. NIH Manual 5005, "Grant Award Adjustments Related to Estimated and Actual Unobligated Grant Balances"

4. NIH Manual 5806, "Overdue Reports - Discretionary Grants"

5. NIH Manual 5808, "Establishment and Documentation of Files and Other Records, Including Monitoring Actions, for NIH Grant Program"

6. 45 CFR Part 74, Section 74.21, "Standards for Financial Management Systems"

7. 45 CFR Part 74, Section 74.52, "Financial Reporting"

8. 45 CFR Part 92, Section 92.20, "Standards for Financial Management Systems"

9. 45 CFR Part 92, Section 92.41, "Financial Reporting"

10. NIH Grants Policy Statement (NIH Publication No. 99-8, October 1998)

11. Section 1405(a) of Public Law No. 101-510 amended 31 USC §§ 1551-1557, "Expired Appropriations and Closing of Accounts"

D. Background:

Grantees are required to document and report project expenditures. Reporting is accomplished using the FSR (Standard Form SF-269

"Financial Status Report" (long form) or SF-269A "Financial Status Report" (short form). The former format is required when a grantee is reporting the use of program income. FSRs must be submitted in hard copy or by electronic submission no later than 90 days after the close of the applicable budget/project period. Revised FSRs may be submitted within the parameters described below (see F. Procedures, 4., 5., and 6.). Since most grantees, on at least an occasional basis, submit extremely late and/or revised FSRs, it is important to establish a policy that addresses this issue. This policy will assist the awarding units and the Government Accounting Section (GAS), Office of Financial Management (OFM), NIH, in determining the reasonableness and allowability of late and /or revised FSRs.

E. Policy:

1. NIH grants management staff will bring oversight issues concerning FSRs to the attention of the Division of Grants Policy/Office of Policy for Extramural Research Administration (OPERA) and the Grants Management Advisory Committee (GMAC) for discussion and resolution.

2. The NIH expects a grantee organization to maintain accurate and timely accounting records with the proper classification of expenditures. A grantee must make every effort to check and correct its records so that accurately filed FSRs are submitted.

It is expected that at least 90% of all FSRs will be received on time. Although FSRs are due no later than 90 days after the close of the applicable budget or project period, OFM will use a NIH performance standard of 120 days for monitoring the submission, receipt and acceptance of FSRs.

If a grantee submits an excessive number (10% or more) of delinquent and/or revised FSRs in one calendar year, it may be an indication of an

inadequate internal financial control system, and thus, there may be the need for closer monitoring by NIH. These grantees need to be identified so that corrective actions may be imposed should circumstances warrant such actions. Although 10% is the level established for designation of delinquency, it is anticipated that sanctions will not routinely be applied to all grantees that fall within these parameters. For example, a grantee with two awards and one late FSR (50% delinquency rate) would not necessarily warrant a corrective action plan. However, the identification of these grantees will allow NIH to review the particular circumstances involved and make a decision as to whether or not additional action is required.

Delinquency may result in award delays or enforcement actions such as withholding of support, special award terms and conditions, removal from the Expanded Authorities, or conversion to a reimbursement pay method. Expanded Authorities (i.e. Extension of a Project Period Without Additional Funds, Carryover of Unobligated Balances and the Use of Program Income) resulted when NIH waived the requirement for its approval of specified actions under certain awards and provided the authorities to grantee to take such actions without NIH prior approval.

F. Procedures:

1. The GAS, OFM, NIH, is responsible for the receipt, processing, and auditing of FSRs.

2. FSRs will be submitted to OFM no later than 90 days after the close of the project period for grants awarded under the Streamlined Non-Competing Award Process (SNAP) and no later than 90 days after the close of each budget period for awards not funded under SNAP.

The SNAP process modified the financial reporting requirements for all mechanisms routinely covered under the Expanded Authorities, except for

Program Project Grants (P01s) and Outstanding Investigator Grants (R35s). Under SNAP, an FSR is only required at the end of the competitive segment rather than annually. This became effective for all competing and non-competing grants with July 1, 1995 and later start dates. Awards may be specifically included or excluded from SNAP by a term and condition on the Notice of Grant Award.

If a grantee submits an FSR that is not required, OFM will forward the FSR to the Grants Management Officer (GMO) who will return it to the grantee with an explanation (see Appendix 1 for a sample letter).

3. Using the NIH performance standard of 120 days, the OFM will monitor the submission of delinquent/revised FSRs and will advise OPERA of those grantees who submit an excessive number (10% or more) of delinquent/revised FSRs. OPERA will disseminate the information to the GMO(s) and will coordinate, as necessary, appropriate corrective action(s). The GMOs will implement the corrective action(s).

4. If a grantee discovers that a previously submitted and accepted FSR is incorrect because of an excessive claim or overcharge (i.e., the amount of the unobligated balance will need to be increased), a revision must be submitted to the NIH as soon as the overcharge is discovered. There is no time restriction for this type of revision.

The OFM will review and audit the report and advise the grantee as to the necessary action. If the project period involved was closed in a prior fiscal year, the grantee will be advised to submit a check for the overcharge. If the project period is still active, the grantee organization's account will be adjusted through the DHHS Payment Management System.

5. The OFM will accept a revised FSR with **additional** claims by a grantee if the revision is received no later than one year from the due date of the original report (15 months following the end date of the budget/project

period) and the grantee provides an acceptable explanation for the revision. The explanation should indicate why the revision is necessary and describe what action is being taken by the grantee to preclude similar situations. If the initial/previous FSR had an unobligated balance which was used as an offset to a subsequent year's award, the GMO may issue a revised Notice of Grant Award to decrease the amount if the explanation and remedial action noted in the grantee's letter are satisfactory.

6. If a grantee submits a revised FSR with **additional** claims more than 15 months following the end of the budget/project period, the OFM will require written documentation from the GMO of **approval** or **disapproval**. The OFM will forward the revised FSR and an action memo to the awarding unit. The GMO must substantiate a decision in writing within 30 days by documenting OFM's action memo. The GMO will return the FSR and the action memo to the OFM in order that the grantee may be notified by them of approval or disapproval. The awarding unit will maintain a copy of the documented action memo in the official grant file. If approved, OFM will forward the accepted FSR to the awarding unit.

Approval of additional claims is subject to the following minimum criteria:

a. the grantee must indicate why the revision is necessary and explain and implement internal controls that will preclude similar occurrences;

b. the charge must represent otherwise allowable costs under the provisions of the grant;

c. there must be an unobligated balance for the budget period sufficient to cover the claim; and

d. the funds must still be available for use. On November 5, 1990, Public Law 101-510 was enacted to limit the availability and use of prior year funds to the current fiscal year and five subsequent years. To ensure that

the grantee will not charge costs to a grant award for which funds are no longer available, grants may not be extended for more than four years beyond the fiscal year used to fund the final budget period. For instance, if a final year was initially awarded in FY94 (budget period = 7/1/94 - 6/30/95), the account would be required to be closed in FY99. Therefore it must not be extended beyond FY99.

While this is technically the law, from an operational point of view, even this could be problematic because of delays inherent in the financial reporting requirement system. Therefore, to accommodate the additional time needed to fulfill the financial reporting, it is recommended that no award be extended for more than three years beyond the fiscal year used to fund the final budget period.

As in F. 5, if an unobligated balance was used as an offset to a subsequent year's award, the GMO may issue a revised Notice of Grant Award if the explanation and remedial action plan are satisfactory.

G. Records Retention and Disposal:

All records (**e-mail** and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule," Item 4000 which covers NIH Grants and Awards and item 1100-G which covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail messages: NIH e-mail messages (messages including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this

purpose. Contact your I/C Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

H. Management Controls:

The purpose of this manual issuance is to state NIH policies and procedures for accepting FSRs.

1. **Offices Responsible for Reviewing Management Controls Relative to this Chapter**: The Division of Grants Policy (DGP), Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER) and the Office of Financial Management (OFM) OD.

2. **Frequency of Review**: Ongoing reviews will occur as scheduled or on an ad hoc basis.

3. **Method of Review**: **Other Review**. DGP, working with the NIH Grants Management Advisory Committee (GMAC) which has a permanent member from OFM, is developing a NIH internal grants management compliance model (GMCM). Part of the GMCM will contain a file review component to ensure that the contents of I/C grant files, including FSRs, are properly processed and maintained. Reports of findings and

recommendations resulting from these reviews or other similar reviews will be issued to I/Cs for appropriate action and common issues will be brought to the GMAC for resolution and corrective action.

Moreover, as mentioned in **F. Procedures** in this chapter, OFM will monitor the submission of delinquent/revised FSRs and advise OPERA about grantees that submit an excessive number of delinquent/revised FSRs. OPERA will forward the information to the appropriate GMO(s), and coordinate, as necessary, corrective action. I/C GMOs will implement the corrective action(s).

Depending upon the nature and extent of problems found if any, the Director OPERA may recommend additional policy guidance or training for grants management staff.

4. **Review Reports are sent to**: The DDER, DDM and the Director, OPERA, OER.

[Appendix 1 - Sample Letter](#)

NIH POLICY MANUAL

55808 - ESTABLISHMENT AND DOCUMENTATION OF FILES AND OTHER RECORDS, INCLUDING MONITORING ACTIONS, FOR NIH GRANT PROGRAMS
Issuing Office: OER 496-5967
Release Date: 10/1/84

A. Purpose:

In order to maintain complete, orderly, and chronological records of grant programs and individual grants, including a history of the peer review and various administrative actions associated with a given grant, this chapter sets forth the minimum requirements for the establishment and documentation of files and other records, including monitoring action, for NIH grant programs.

B. Applicability:

This chapter is applicable to all NIH grant programs.

C. References:

1. NIH Manual Chapter 4700, Notice of Grant Award

2. NIH Manual Chapter 5805, Closeout of NIH Grants

3. NIH Manual Chapter 5806, Delinquent Reports - Discretionary Grants

4. NIH Manual Chapter 5807, Submission and Acceptance of Revised Reports of Expenditures

D. Policy:

The Grants Management Officer (GMO) of each awarding unit is responsible for assuring that complete and up-to-date program information files and official grant files for individual projects are established and maintained. These files shall be under the direct control and responsibility of the Grants Management Officer. Monitoring duties shall be the responsibility of at least one grants management and one program official for each grant.

E. Implementation:

   1. Program Information Files

      a. Grants Management Officers shall establish and maintain an official program information file in their own offices or some other publicized central location in the Bureau, Institute, or Division (BID). A separate

file folder shall be established for each program and/or mechanism of support in the BID. (Use the DRG Activity Codes to determine program involved.)

b. When the BID initiates a new program a folder should be established containing announcements, guidelines, and any other information peculiarly pertinent, such as earmarked funds, special receipt dates, arrangements for review, etc.

c. Each folder should have the documents or information listed below in d. insofar as they exist or are applicable. Where a single document (e.g., Code of Federal Regulations, Title 42, Part 52) is applicable to more than one program of the BID, a single copy can be maintained with reference in the individual file as to its applicability.

d. Items in program information files should include, as applicable:

(1) Program title

(2) DRG activity code

(3) Catalogue of Federal Domestic Assistance number

(4) Citation of legislative authorization (USC)

(5) Citation of applicable Federal Regulations

(6) Announcements (copy) (e.g., Federal Register, NIH Guide for Grants and Contracts, BID announcement)

(7) Citation of all applicable guidelines and/or policy statements (e.g., the PHS Grants Policy Statement and/or other guidelines - include one copy of the latter)

(8) Authorized deviations from (7)

(9) Description of any special review procedures not addressed in (6)

(10) Copy of any correspondence or other document from Congress, Office of General Counsel, etc., concerning the program, but not specifically about an individual grant

(11) Copy of any pertinent GAO, Audit, and Congressional Committee reports not specifically about an individual grant e. Program information files shall be reviewed at regular intervals to assure that they are complete and current.

2. Official Grant File System

A separate file folder must be established and maintained centrally within the

BID for each grant project and shall contain all significant documents which pertain to the individual grant-supported project. Pertinent material should be filed in a timely manner and maintained chronologically through final closeout.

   a. As applicable, an individual file folder shall include the following:

      (1) Application for each budget period - as well as any subsequent revisions or additions

      (2) Summary Statement for each competitive review

      (3) Grants Management/ICMS Worksheet (Form NIH 705) for each award (completed and signed original)

      (4) Cost-sharing Agreement (only for project-by-project method)

      (5) Human Subject Certifications

      (6) Notice of Grant Award

      (7) Financial Status Reports (expenditures reports)

      (8) Progress Reports (annual and final)

      (9) Invention Statements

      (10) Special documents (e.g., A&R plans and specifications, third party agreements, relinquishment statements, pertinent audit material, appeal material)

      (11) Staff on-site visit reports

      (12) Correspondence and memoranda

      (13) Closeout documentation In addition, for manpower/training grants and awards:

         (1) Activation Notices ("F" programs only)

         (2) Statement of Trainee Appointment (Form PHS-2271)

         (3) Signed Payback Agreements

         (4) Termination Notices

         (5) Annual Payback Activities Certification Forms

   b. Preceding the preparation of each Notice of Grant Award, the file will be reviewed to insure that all required documents are in hand, and the file initialed by the reviewer and dated to signify completeness.

c. No Notice of Grant Award may be issued until all required documents are on file. For active grants, no noncompeting continuation nor competing renewal award may be made unless required Financial Status Reports have been received.

d. For closeout of grants, the procedures outlined in NIH Manual Chapter 5805 shall be followed.

3. Institutional Information Sources

The NIH has a number of sources of detailed information concerning institutions and organizations participating in the NIH's extramural programs. This information is available to BID staff and should be utilized when needed. The information and location are:

a. Indirect Cost Rate File

An up-to-date collection of institutional indirect cost rate agreements. This file provides institution's name, entity identification number, city and state, type rate, effective period, indirect cost rate (%), locations (on-campus, off-campus, other sites), base description, treatment of fringe benefits, fringe benefit rates, and special remarks pertaining to treatment of costs within institutional accounting systems. This file is distributed to BIDs on a monthly basis. Further information regarding this file may be obtained from the Accounting and Indirect Cost Section (AICS), Federal Assistance Accounting Branch (FAAB), Division of Financial Management (DFM).

b. Patient Care Cost Rate Files

An up-to-date collection of institutional Research Patient Care Rates. This file provides institution's name and address, type rate, effective period, inpatient routine care rates (percentages), inpatient ancillary service rates (percentages) such as operating room, anesthesiology, laboratory, drugs, physical therapy, oxygen therapy, etc., and any optional remarks deemed necessary by the regional negotiators. Information is available upon request to the AICS, FAAB, DFM.

c. Institutional Catalogue Library and Institutions Research

A complete up-to-date collection of grantee institutional catalogues and ancillary information is maintained in the Reports, Analysis, and Presentation Section, Statistics and Analysis Branch, DRG, Room 1A18, Westwood Building.

d. Institution Profile File (IPF)

A sub-file in the NIH IMPAC data system. The IPF is the computer-based central registry of selected data on all applicant institutions dating

from 1945. It provides name, state, city, area, Congressional District, PHS region, type of organization, ownership or control, human subjects assurance code, etc. Information is available upon request from: See c. above.

e. Successor in Interest and Name Change Agreements

Centralized information is available from the Grants Policy Office, Office of Extramural Research and Training (OERT), NIH.

f. New Applicant Organizations

In those cases where a new or potential grantee institution is identified, awarding unit staff should notify the Grants Policy Office, OERT, which will act as the single NIH focal point for distribution of general information to the applicant institution. Basic information concerning the institutional administrative and fiscal management responsibilities associated with NIH grant-supported programs will be conveyed principally through a memorandum (See Illustration 2) which cites some of the more important grants management policy issuances, HHS offices having responsibility for certain administrative functions, and sources of continuing information. The Grants Policy Office, OERT, will assist in obtaining answers to any questions from the awarding units concerning management capabilities, organizational arrangements, etc., of new or unknown applicant organizations.

4. Monitoring Duties

Such duties are to be assigned to and performed by at least one grants management and one program official for each funded grant. This shared responsibility is in keeping with NIH's "team" approach to grant administration and the dual signature feature of NIH's award notices. If BID staff other than those whose signatures appear on award notices have primary responsibility for business management and program management aspects respectively, then their names and telephone numbers should be provided to each grantee at time of award (specified on the Notice of Grant Award or included on a supplemental notice) or separately conveyed by letter or other notice. For each duty listed below, the designated official shall have primary responsibility for performing the minimum monitoring actions listed:

a. Ensuring timely receipt of all required reports - Grants Management Office.

b. Review Financial Status Reports (expenditures reports) - Grants Section, FAAB, DFM, and BID Grants Management Office. All Financial Status Reports will be initially received and centrally processed by DFM, to ensure that reports are complete and accurate. On a monthly basis DFM notifies grantees of delinquent Financial Status Reports. DFM and the GMOs will coordinate the action(s) necessary to

resolve all matters of questionable or inappropriate expenditures or obligations. As part of the preaward review of non-competing continuation or competing renewal applications, the GMO must obtain all delinquent reports or notify the grantee that further awards will not be made until the delinquent reports are received.

c. Review of Progress Reports (annual and final) - Program Official. These reports shall include at a minimum (a) actual accomplishments toward meeting project goals, (b) reasons for not meeting desired goals, (c) plans for activities during the coming year.

d. With respect to items (1) through (6) below, the review of business management concerns shall be the responsibility of grants management officials and the review of programmatic concerns shall be the responsibility of program officials:

(1) Audit reports which are pertinent to a specific active grant or a grant not yet closed out

(2) Site visit reports (If neither a designated grants management official nor a designated program official was able to participate in the visit, such an official must base his or her review upon the report written by the responsible person who participated in the visit or upon an interview with such a person.)

(3) Progress report portions of continuation and competing renewal applications

(4) Correspondence from grantees or third parties in which information on grant performance is requested and provided

(5) Memoranda of significant telephone conversations requiring specific monitoring actions

(6) Closeout documents (See NIH Chapter 5805.)

e. Other responsibilities for considerations such as human subject involvement, use of animals, inventions, cost-sharing, patient care costs, alterations and renovations, etc., will be individually assigned or shared by grants management and program officials depending on the specific circumstances.

The aforementioned monitoring duties are required actions to be performed continuously and may not be omitted. For example, if a report is required from a grantee, its receipt must be checked and upon receipt it must be reviewed. The action shall be performed as soon as possible after the due date, date of receipt, or other occasion. It should be noted that in many cases the same item will require separate monitoring reviews by two persons, a grants management official and a

program official.

f. The Fiscal and Monitoring Statement to be used by NIH to document the fact that all fiscal, administrative, and other preaward actions have been completed (or if not completed, conditioned as a term of award) is Form NIH 705, "Grants Management/ICMS Worksheet" (See Illustration 1). This form also is to be used to document postaward actions such as receipt and review of Financial Status Reports, progress reports, invention statements, etc., from prior periods. The use of this form is mandatory except for individual fellowship and career awards. If deemed necessary, awarding units may at their discretion, use additional worksheets or other monitoring records to supplement Form NIH 705; however, the use of this standard form by all NIH awarding units is required as a minimum.

The original copy of Form NIH 705, completed and signed by either the Grants Management Officer or his or her designated staff member, must be maintained in the official file folder as evidence that all required fiscal, administrative, and monitoring actions have been satisfied. A Notice of Grant Award may not be processed unless a copy of this form accompanies the other necessary authorizing documentation to the Division of Financial Management.

F. Effective Date:

This policy is effective on date of release.

G. Additional Information:

For further information on this chapter, contact the Grants Policy Office, Office of Extramural Research and Training, 496-5967.

H. Additional Copies:

For copies of this manual chapter send a Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07.

Refer to Hardcopy Illustration 1

Refer to Hardcopy Illustration 2