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Source of document:	Department of Veterans Affairs Veterans Affairs Central Office FOIA/Privacy Act Officers 810 Vermont Avenue, NW Washington, DC 20420 Email: vacofoiaservice@va.gov

VA | U.S. Department of Veterans Affairs

Veterans Health Administration
Washington DC 20420

In Reply Refer To:

September 21, 2015

FOIA Request: **VHA-15-01307-F**

This letter is in response to your Freedom of Information Act (FOIA) request, 5 U.S.C. § 552 to the Department of Veterans Affairs, VA FOIA Service submitted on November 24, 2014. The FOIA Service determined that the records you seek may be located within the Veterans Health Administration (VHA) and as a result your request was referred to the VHA FOIA Office on December 1, 2014 and assigned FOIA tracking number 15-01307-F. Within your request you seek the two most recent reports entitled: "Activities of the Office of Research" produced under Public Law 108-170, Section 401(a)(1).

VHA Initial Agency Decision

A search for responsive records has concluded. At the time of your request the two (2) most recent reports entitled: "Activities of the Office of Research" were available for calendar years 2012 and 2013. At this time VHA is also proving the most recent report for calendar year 2014. All reports are provided in their entirety therefore no information has been redacted or otherwise withheld. This concludes VHA response to your request for information.

If you have any questions, please feel free to contact me at (717) 450-4662.

Sincerely,

Deana Marakowski

Deana Marakowski
VHA FOIA Officer

Enclosures

Department of Veterans Affairs
Veterans Health Administration

Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2012

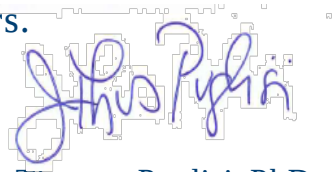
OFFICE OF RESEARCH OVERSIGHT

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

This report summarizes the activities of the Veterans Health Administration Office of Research Oversight (ORO) from January 1 through December 31, 2012, and describes all suspected lapses in protecting human subjects and others in VA research as required under title 38 United States Code (38 U.S.C.) §7307(d)(4).

The report was prepared for the Committees on Veterans' Affairs of the Senate and the House of Representatives of the United States pursuant to 38 U.S.C. §7307(f).

ORO reports directly to the Under Secretary for Health in monitoring, reviewing, and investigating compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Federalwide debarment for research impropriety, and the activities of facility-level research compliance officers.



J. Thomas Puglisi, PhD
Director and Chief Officer
Office of Research Oversight

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APPENDIX: COMPLIANCE CASE SUMMARIES

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A. INTRODUCTION

The Department of Veterans Affairs (VA), through the Veterans Health Administration (VHA) Office of Research Oversight (ORO), conducts one of the most comprehensive programs of research compliance oversight in the Federal Government.

Creation of ORO within VA was mandated under legislation signed by the President of the United States on December 6, 2003, as Public Law 108-170. Section 401 of this statute stipulates ORO's functions as follows:

> *(a) Requirement for Office.-- (1) There is in the Veterans Health Administration an Office of Research Oversight (hereinafter in this section referred to as the 'Office'). The Office shall advise the Under Secretary for Health on matters of compliance and assurance in human subjects protections, research safety, and research impropriety and misconduct. The Office shall function independently of entities within the Veterans Health Administration with responsibility for the conduct of medical research programs. (2) The Office shall -- (A) monitor, review, and investigate matters of medical research compliance and assurance in the Department with respect to human subjects protections; and (B) monitor, review, and investigate matters relating to the protection and safety of human subjects and Department employees participating in medical research in Department programs.*

This report summarizes ORO's activities for the period from January 1 through December 31, 2012. The summary includes oversight activities carried out by ORO in advising the Under Secretary for Health (USH) on matters of regulatory compliance related to the protection of human research subjects, research safety, research laboratory security, and research misconduct, as required under title 38 United States Code (38 U.S.C.) §7307.

These activities reflect ORO's responsibilities to monitor, review, and investigate matters of regulatory compliance in each of these aspects of VA research. The report addresses suspected lapses from all causes in protecting human subjects and others in VA research as required under 38 U.S.C. §7307(d)(4).

The report also includes ORO's activities in providing oversight of laboratory animal welfare, research information security and privacy, Governmentwide nonprocurement suspensions and debarments for research impropriety, facility research compliance officer (RCO) audits, and RCO education, as directed by the USH.

A total of 108 VHA facilities operated research programs in CY2012. All 108 of these facilities operated human research programs, 80 of these facilities operated laboratory research programs, and 77 of these facilities operated animal research programs.

In addition, the VHA Central Office Human Research Protection Program (HRPP) operates an Institutional Review Board (IRB) for oversight of multi-center clinical trials sponsored by VA, such as trials conducted under the VA Cooperative Studies Program (CSP).

Summaries of ORO's compliance cases have been provided in ORO's activity reports for the first, second, and third quarters of calendar year 2012 (CY2012). ORO's activities for the fourth quarter of CY2012, including case summaries, are incorporated into this report, which provides a complete listing of ORO cases for CY2012.

Because this report contains sensitive information related to open investigations, distribution of the report should be limited to those persons engaged in authorized Congressional oversight and to other required Congressional entities.

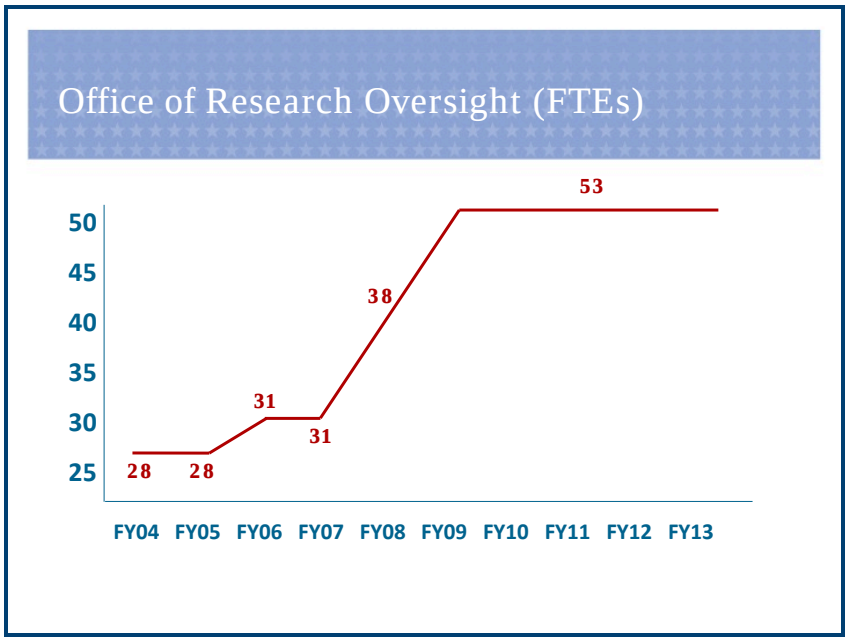
B. BACKGROUND

ORO Central Office (CO) develops and manages ORO's programs. CO professionals also provide direct oversight of VA research activities related to laboratory animal welfare, research safety, research laboratory security, research information protection and privacy, research misconduct, Governmentwide suspension and debarment for research impropriety, RCO audits, and RCO education. ORO Regional Offices (ROs) provide direct oversight of VA research activities related to the protection of human subjects and facility research program administration and oversight.

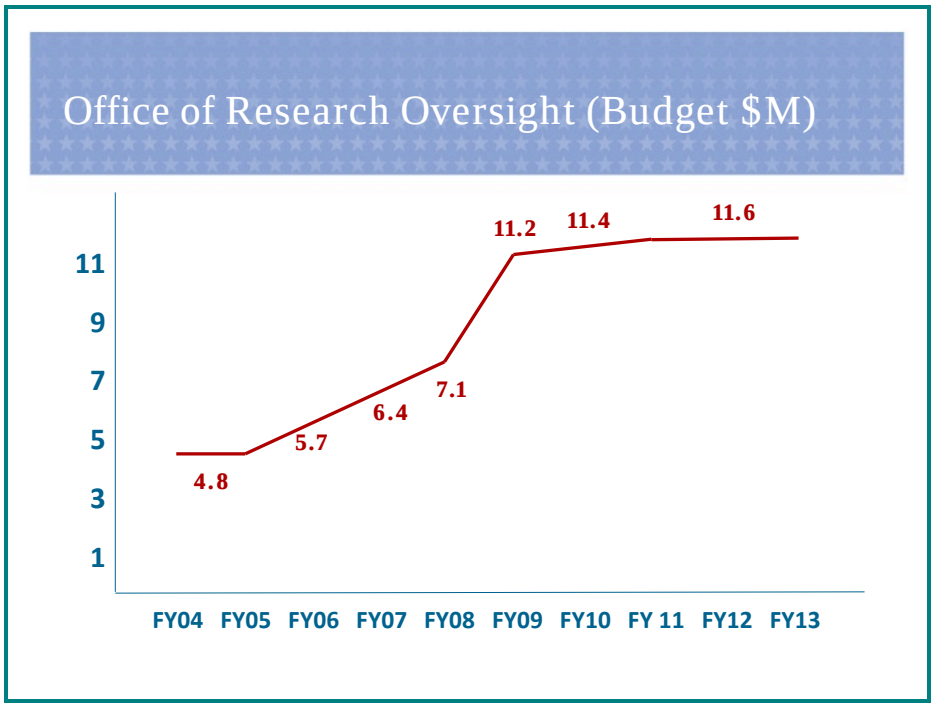
ORO's ROs are located within VA space in four geographic regions to provide prompt access and response to issues that may require onsite review and assistance. Each RO has oversight responsibility for approximately 25-30 VA research facilities:

- Midwestern RO (Edward Hines, Jr. VA Hospital, Chicago, IL)
- Northeastern RO (Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA)
- Southern RO (Veterans Integrated Service Network 7 Headquarters, Duluth, GA)
- Western RO (VA Loma Linda Health Care System, Loma Linda, CA)

A full ORO staff includes 26 individuals in ORO's CO, and 27 individuals in ORO's ROs. Figure 1 below illustrates the staffing levels for ORO since its creation in December 2003.



ORO's current fiscal year budget is approximately $11.6 million. Figure 2 below illustrates the funding provided to ORO since its creation in December 2003.



ORO fulfills its review and oversight responsibilities for regulatory compliance and assurance through three types of programs:

- Onsite program reviews and inspections
- Remote compliance reviews
- Research assurances, education, and quality assurance

ORO solicits advice and feedback from the research community through the ORO Field Advisory Committee. The ORO Chief Officer chairs the Committee and appoints members annually for 3-year staggered terms.

Committee members are encouraged to raise any and all matters of concern related to ORO's activities and to recommend strategies to enhance efficiency and effectiveness in the fulfillment of ORO's mission. The Committee convenes quarterly by video conference. Members are also invited to participate in ad hoc work groups pertinent to ORO's mission.

C. Onsite Research Compliance Reviews

ORO conducts four types of onsite compliance reviews:

- For-cause onsite reviews
- Routine (proactive) onsite reviews
- Onsite reviews of Biosafety Level 3 (BSL-3) research laboratories
- Onsite technical assistance reviews

Most onsite reviews are announced to the facility in advance, but ORO also may conduct unannounced onsite reviews as warranted. Summaries of ORO's onsite compliance reviews are provided in the Appendix to this report. Complete reports of these reviews are available upon request.

C1. For-Cause Onsite Reviews

ORO receives reports of possible noncompliance from a variety of sources, including other VA offices, other government agencies, VA employees, Veterans, family members of Veterans, and the media.

In cases where there may be serious, systemic concerns about a facility's research protection programs, ORO may conduct for-cause onsite compliance reviews to establish the nature and severity of the possible noncompliance, and to assess the effectiveness of the facility's research protection programs. These reviews involve in-depth evaluations of potentially serious noncompliance with the laws, regulations, and policies governing VA research.

ORO requires remedial actions to resolve any serious or continuing noncompliance that is identified. All facilities that are required to develop and execute remedial action plans are carefully monitored, and cases are held open until ORO confirms that remedial actions have been implemented satisfactorily to ensure compliance.

Number of For-Cause Onsite Reviews:

- 9 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- 1 = New Cases – April 1 through June 30
- 0 = New Cases – July 1 through September 30
- 0 = New Cases – October 1 through December 31
- 1 = New Cases in Calendar Year
- 10 = Total Cases (Continuing Plus New) in Calendar Year

ORO's for-cause onsite compliance reviews are summarized in Table 1 of the Appendix. Complete reports of these reviews are available upon request.

C2. Routine (Proactive) Onsite Reviews

Routine onsite reviews are systematic proactive inspections of regulatory compliance to assist VA facilities in fulfilling their responsibilities to conduct research with appropriate human subject protections, care and use of laboratory animals, research safety, research laboratory security, and research information protection.

The routine onsite review program involves a process of thorough onsite review, assessment, and follow-up of issues identified concerning regulatory compliance in VA research programs. Routine onsite reviews are performed on a rotating basis by teams of two to six ORO professionals.

Number of Routine (Proactive) Onsite Reviews:

- 91 = Cases Continuing from Previous Calendar Year
- 26 = New Cases – January 1 through March 31
- 24 = New Cases – April 1 through June 30
- 21 = New Cases – July 1 through September 30
- 16 = New Cases – October 1 through December 31
- 87 = New Cases in Calendar Year
- 178 = Total Cases (Continuing Plus New) in Calendar Year

ORO's routine (proactive) onsite compliance reviews are summarized in Table 2 of the Appendix. Complete reports of these reviews are available upon request.

C3. Onsite Reviews of Biosafety Level 3 (BSL-3) Research Laboratories

ORO proactively conducts onsite safety reviews and physical security inspections of VA's BSL-3 research laboratories. The inspections involve verification of compliance with VA research safety requirements and required security controls.

Number of Onsite Reviews of BSL-3 Research Laboratories:

- 6 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- 1 = New Cases – April 1 through June 30
- 0 = New Cases – July 1 through September 30
- 0 = New Cases – October 1 through December 31
- 1 = New Cases in Calendar Year
- 7 = Total Cases (Continuing Plus New) in Calendar Year

ORO's onsite reviews of BSL-3 research laboratories are summarized in Table 3 of the Appendix. Complete reports of these reviews are available upon request.

C4. Onsite Technical Assistance Reviews

ORO onsite technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Number of Onsite Technical Assistance Reviews:

- 3 = Cases Continuing from Previous Calendar Year
- 11 = New Cases – January 1 through March 31
- 6 = New Cases – April 1 through June 30
- 7 = New Cases – July 1 through September 30
- 15 = New Cases – October 1 through December 31
- 39 = New Cases in Calendar Year
- 42 = Total Cases (Continuing Plus New) in Calendar Year

ORO's onsite technical assistance reviews are summarized in Table 4 of the Appendix.

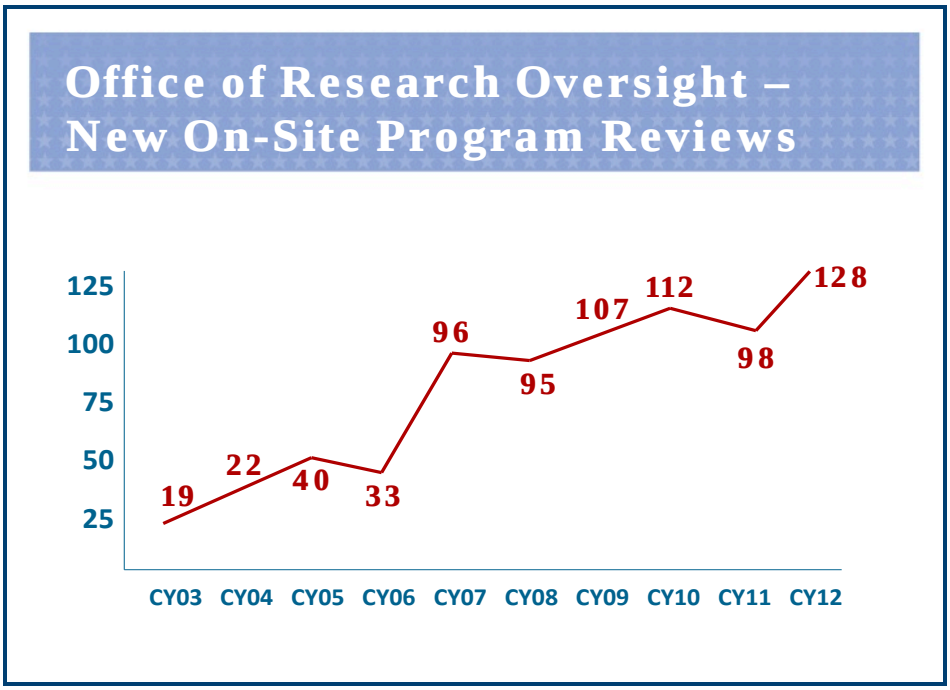
C5. Summary: Onsite Compliance Reviews

The number of onsite program reviews conducted to date is consistent with ORO's goal of conducting approximately 90-100 such reviews annually.

Summary: Number of Onsite Program Reviews and Inspections:

- 109 = Cases Continuing from Previous Calendar Year
- 37 = New Cases – January 1 through March 31
- 32 = New Cases – April 1 through June 30
- 28 = New Cases – July 1 through September 30
- 31 = New Cases – October 1 through December 31
- 128 = New Cases in Calendar Year
- 212 = Total Cases (Continuing Plus New) in Calendar Year

Figure 3 below illustrates the number of new onsite reviews conducted by ORO since its creation.



D. Remote Compliance Reviews

Certain compliance cases can be evaluated and managed remotely through written communications with facility leadership and facility compliance personnel. ORO conducts seven types of remote reviews to ensure compliance with VA research requirements:

- Reviews of externally identified noncompliance
- Reviews of facility self-identified noncompliance
- Reviews of Research Compliance Officer (RCO) audits
- Reviews of annual facility director certifications of research oversight
- Remote technical assistance reviews
- Reviews of unanticipated serious adverse events related to research
- Reviews of research misconduct and debarment proceedings

Each review includes monitoring by ORO to verify that remedial actions have been implemented as warranted.

D1. Remote Reviews of Externally Identified Noncompliance

ORO's remote compliance reviews include cases of apparent noncompliance that have been identified by sources external to the facility's HRPP. Such sources include, but are not limited to, apparent noncompliance identified by ORO, by other VA offices, by government regulatory agencies, and by industry sponsors.

Number of Reviews of Externally Identified Noncompliance:

- 22 = Cases Continuing from Previous Calendar Year
- 48 = New Cases – January 1 through March 31
- 30 = New Cases – April 1 through June 30
- 40 = New Cases – July 1 through September 30
- 52 = New Cases – October 1 through December 31
- 170 = New Cases in Calendar Year
- 192 = Total Cases (Continuing Plus New) in Calendar Year

ORO's remote reviews of externally identified noncompliance are summarized in Table 5 of the Appendix.

D2. Remote Reviews of Facility Self-Identified Noncompliance

Both ORO and the VHA Office of Research and Development (ORD) strongly encourage VA research facilities to accept responsibility and accountability for maintaining a compliant research program and fostering a culture that values adherence to the required protections for Veterans and other human research subjects, research personnel, and research animals. Building a culture of local accountability has been the focus of ORO and ORD education activities for the past several years.

VA facilities are required to report to ORO any events that might reasonably indicate serious or continuing noncompliance in research. As the focal point for fulfilling VA's research mission and a responsible steward of VA resources, each VA research facility has an obligation to serve as the primary watchdog for identifying and correcting noncompliance problems in its own research programs.

ORO works cooperatively with VA research facilities to manage their self-identified noncompliance cases by assisting them in developing appropriate remedial action plans and monitoring resolution of any deficiencies.

Number of Reviews of Facility Self-Identified Noncompliance:

- 78 = Cases Continuing from Previous Calendar Year
- 50 = New Cases – January 1 through March 31
- 54 = New Cases – April 1 through June 30
- 60 = New Cases – July 1 through September 30
- 56 = New Cases – October 1 through December 31
- 220 = New Cases in Calendar Year
- 298 = Total Cases (Continuing Plus New) in Calendar Year

ORO's remote reviews of facility self-identified noncompliance are summarized in Table 6 of the Appendix.

D3. Remote Reviews of Research Compliance Officer (RCO) Audits

Facility RCOs must conduct audits of all informed consents obtained for VA research throughout the year. Regulatory audits of all VA research must be conducted at least every 3 years. Facilities are required to report to ORO any noncompliance identified in these audits.

Number of Reviews of RCO Audits:

- 79 = Cases Continuing from Previous Calendar Year
- 41 = New Cases – January 1 through March 31
- 85 = New Cases – April 1 through June 30
- 75 = New Cases – July 1 through September 30
- 47 = New Cases – October 1 through December 31
- 248 = New Cases in Calendar Year
- 327 = Total Cases (Continuing Plus New) in Calendar Year

ORO's remote reviews of RCO audits are summarized in Table 7 of the Appendix.

D4. Reviews of Annual Facility Director Certifications of Research Oversight

ORO requires that the director of each VA research facility lead an annual program-wide self assessment of research compliance and provide ORO with an annual certification of research oversight based on this self assessment. Certifications must be completed and forwarded to ORO by July 31 each year.

The program requires that the facility director's certification include an action plan to remediate any deficiencies identified by the self assessment. ORO monitors the case until appropriate remedial actions have been implemented satisfactorily.

Number of Reviews of Annual Facility Director Certification of Research Oversight:

- 26 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- 0 = New Cases – April 1 through June 30
- 108 = New Cases – July 1 through September 30
- 0 = New Cases – October 1 through December 31
- 108 = New Cases in Calendar Year
- 134 = Total Cases (Continuing Plus New) in Calendar Year

ORO's remote reviews of annual facility director certifications of research oversight are summarized in Table 8 of the Appendix.

D5. Remote Technical Assistance Reviews

ORO remote technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Remote technical assistance reviews may be conducted

at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Number of Remote Technical Assistance Reviews:

- 12 = Cases Continuing from Previous Calendar Year
- 67 = New Cases – January 1 through March 31
- 30 = New Cases – April 1 through June 30
- 41 = New Cases – July 1 through September 30
- 71 = New Cases – October 1 through December 31
- 209 = New Cases in Calendar Year
- 221 = Total Cases (Continuing Plus New) in Calendar Year

ORO's remote technical assistance reviews are summarized in Table 9.

D6. Remote Reviews of Unanticipated Serious Adverse Events

VA requires that unanticipated serious adverse events (SAEs) in research be reported to, and rapidly reviewed by, the responsible IRB. Reporting to ORO is required for any unanticipated SAEs, including deaths, that the IRB suspects were caused by, or probably caused by, the research. ORO uses these reports to review local SAE management and assist facilities in improving their research programs.

Number of Reviews of Unanticipated SAEs Related to Research:

- 7 = Cases Continuing from Previous Calendar Year
- 6 = New Cases – January 1 through March 31
- 5 = New Cases – April 1 through June 30
- 8 = New Cases – July 1 through September 30
- 5 = New Cases – October 1 through December 31
- 24 = New Cases in Calendar Year
- 31 = Total Cases (Continuing Plus New) in Calendar Year

Summaries of ORO's remote reviews of unanticipated SAEs suspected to have been caused by research are provided in Table 10 of the Appendix.

D7. Research Misconduct and Debarment Procedural Reviews

All Federal agencies that conduct or support research have adopted the following uniform definition of research misconduct: *fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.* VA has established precise processes for responding to allegations of misconduct involving

VA research and for sanctioning with Governmentwide debarment VA investigators who commit serious improprieties in the conduct of research. The potential consequences and severity of research misconduct and Governmentwide debarment necessitate procedurally detailed mechanisms for adjudication.

Number of Reviews of Research Misconduct and Debarment Proceedings:

- 4 = Cases Continuing from Previous Calendar Year
- 2 = New Cases – January 1 through March 31
- 2 = New Cases – April 1 through June 30
- 2 = New Cases – July 1 through September 30
- 3 = New Cases – October 1 through December 31
- 9 = New Cases in Calendar Year
- 13 = Total Cases (Continuing Plus New) in Calendar Year

ORO's research misconduct and debarment reviews are summarized in Table 11 of the Appendix.

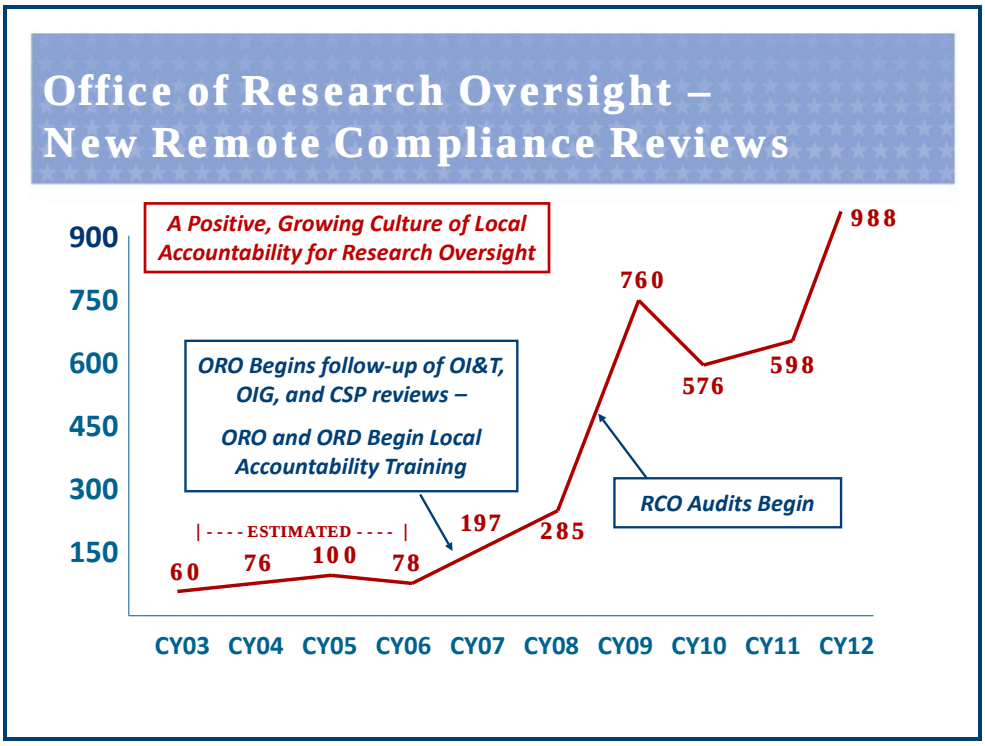
D8. Summary: Remote Compliance Reviews

Summaries of all ORO remote reviews of non-systemic noncompliance incidents, facility self-identified noncompliance, and noncompliance identified by facility RCO audits have been provided previously in ORO's Quarterly Activity Reports. Additional copies of these summaries are available upon request.

Summary: Number of Remote Compliance Reviews:

- 228 = Cases Continuing from Previous Calendar Year
- 214 = New Cases – January 1 through March 31
- 206 = New Cases – April 1 through June 30
- 334 = New Cases – July 1 through September 30
- 234 = New Cases – October 1 through December 31
- 988 = New Cases in Calendar Year
- 1216 = Total Cases (Continuing Plus New) in Calendar Year

Figure 4 below illustrates the number of remote compliance reviews conducted by ORO since its creation.


Office of Research Oversight –
New Remote Compliance Reviews
A Positive, Growing Culture of Local Accountability for Research Oversight
ORO Begins follow-up of OI&T, OIG, and CSP reviews –
ORO and ORD Begin Local Accountability Training
RCO Audits Begin
| - - - - ESTIMATED - - - - |
900
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CY12

E. Human Research Assurance Program

ORO administers the VA human research assurance program. Assurances are formal agreements required by regulation and signed by VA facility directors and network directors assuring compliance with VA and other Federal requirements, including provision of adequate training and resources, for the protection of human research subjects. The Federalwide assurance (FWA) for any VA research facility requires the approval of both ORO and the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (HHS).

ORO has the authority to restrict or suspend a VA facility's FWA for failure to meet its responsibilities for protecting human subjects.

All 108 VA research facilities and the VHA Central Office HRPP hold active, approved FWAs.

Although FWAs are typically approved for 5 years, the facility must modify its FWA whenever certain changes occur (e.g., a change in the designation of an IRB or a change in responsible facility officials). ORO's participation in the approval, renewal, or modification of FWAs during this calendar year is reflected in Table 9. ORO also tracks membership and membership changes in all IRBs used by VA research facilities to ensure regulatory compliance.

Each VA research facility that uses an IRB operated by another VA facility (54 facilities), operated by the VHA Central Office HRPP (94 facilities), or operated by the facility's academic affiliate (40 facilities) must effect a memorandum of understanding (MOU) indicating how the entities will work together to support the IRB and collaborate in the protection of human research subjects. MOUs documenting these IRB arrangements must be reviewed by ORO whenever substantive modifications occur and at the time of FWA renewal.

The MOU can also be used to document other related organizational arrangements used in human research protection programs, such as using the Research and Development Committee (R&DC) of one VA facility to oversee the research program of another VA facility. ORO regularly reviews MOUs and provides guidance to facilities on developing appropriate MOUs, as reflected in Table 9.

F. Research Compliance Officer (RCO) Education and Guidance

Every VA research facility is required to support at least one RCO to provide facility-level oversight of its research program. The lead RCO at each facility must report directly to the facility director, and each facility director has a responsibility to ensure the functional independence of the facility's RCO(s).

ORO conducts an RCO education program to strengthen oversight of research at the facility level and monitors RCO activities to ensure compliance with VA requirements.

The primary function of RCOs is to conduct mandatory informed consent and regulatory audits of VA research. Every VA research study must receive a 100% audit of informed consent documentation each year, as well as a regulatory audit approximately every 3 years. ORO provides audit tools for this purpose on its Web site and trains RCOs in their use.

RCOs also serve as local resources on research compliance requirements and as official consultants to the R&DC, IRB(s), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), and other facility research oversight committees.

During this calendar year, ORO developed a variety of informational materials and audit tools (listed in Appendix B) and conducted monthly "Live Meeting" teleconferences for RCO education. Educational materials and audit tools prepared during the reporting period are available on the ORO Web site and the ORO Research Compliance and Technical Assistance SharePoint site, which is available to all VHA employees at http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx.

Each VA research facility is required to report the results of its RCO informed consent and regulatory audits annually. RCOs conducted audits of over 99,000 informed consent documents and regulatory audits of over 4,200 human research protocols during this period (see Section IV of this report). The regulatory audits involved review of case records for over 26,200 human research participants.

ORO regularly develops updated policy, guidance materials, and oversight tools to assist the VA research community in implementing optimal protections for human research subjects, laboratory animals, and research investigators. These materials are provided on the ORO public Web site at http://www.va.gov/oro/ and the ORO SharePoint site for VA employees at http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx. ORO also maintains several large ListServs for rapid distribution of guidance materials and important announcements.

Topics addressed during CY2012 included common findings of noncompliance in human research, research information protection and privacy, and animal care and use programs; research safety and security training requirements; research versus non-research operational activities; audit tools and guidelines; research information security and privacy checklist; and frequently asked questions on HRPP roles and responsibilities, advertising and subject recruitment, informed consent, Health Assurance Portability and Accountability Act (HIPAA) authorizations, IRB membership, and training.

ORO holds nationwide research compliance "Live Meeting" teleconferences at 2-month intervals and contributes extensively to educational activities sponsored by ORD and national professional associations such as Public Responsibility in Medicine and Research (PRIM&R) and the American Association for Laboratory Animal Science (AALAS).

ORO has been instrumental in convening and continues to participate vigorously in collaborative workgroups with the VHA ORD, the VHA Privacy Office, the VA Office of General Counsel, the VA Office of Information and Technology (OI&T), and the Association of American Medical Colleges (AAMC) to address common areas of concern, including data ownership and data security issues in research with VA's university affiliates.

ORO also participates actively in several interagency workgroups, including the HHS Secretary's Advisory Committee on Human Research Protections (SACRHP), the Federal Research Integrity Workgroup and the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight.

G. QUALITY ASSURANCE

Over the past several years, ORO has developed a set of indicators for assessing the quality of VA research protection programs. These quality indicators have been incorporated into RCO informed consent and regulatory audits and the annual facility director certifications of research oversight.

Quality indicators for human research include documentation of informed consent, Health Insurance Portability and Accountability Act (HIPAA) authorization for use and disclosure of protected health information, IRB approval, protocol documentation, and investigator qualifications and training.

Quality indicators for animal research include Institutional Animal Care and Use Committee (IACUC) approval and investigator qualifications and training. Quality indicators for research safety include Subcommittee on Research Safety (SRS) approval.

ORO compiles the data for these indicators to identify areas for system-wide quality improvement and provides these data to each VA research facility and Veterans Integrated Service Network (VISN) for quality improvement purposes at the facility and VISN level.

The 2012 quality assurance data cover the period between June 1, 2011 and May 31, 2012. Data were collected from all 107 VA research facilities active as of July 1, 2012.

1. Human Research Quality Indicators

The table below illustrates selected quality indicators for documentation of informed consent and HIPAA authorization since ORO began collecting these data. These data reflect a 100% audit of all informed consent documents and HIPAA authorizations obtained in VA research during the reporting period.

Human Research Quality Indicators	2009	2010	2011	2012
Informed Consent Documents (ICDs)				
ICDs Reviewed	**92,208**	**89,216**	**100,832**	**99,013**
ICDs Missing or Lacking Subject Signature/Date	167 (0.2%)	197 (0.2%)	284 (0.3)%	201 (0.2%)
ICD with Other Deficiencies	2141 (2.3%)	2143 (2.4%)	1478 (1.5%)	1086 (1.8%)
HIPAA Authorizations				
Authorizations Reviewed	**92,208**	**89,216**	**95,916**	**96,290**
Authorizations Missing or Lacking Subject Signature/Date	1243 (1.3%)	480 (0.5%)	1,383* (1.4%)	827 (0.9%)

* Coincides with new VA requirement for separation of ICD from HIPAA authorization.

ORO's review found that the majority VA research facilities reported no informed consent or HIPAA authorization deficiencies. ORO has required remedial actions by those facilities at which deficiencies were identified.

The table below illustrates selected quality indicators for IRB approval, protocol documentation, and investigator qualifications and training since ORO began collecting these data. These data were derived from protocols receiving RCO regulatory audits during the reporting period. Because VA research protocols receive an RCO regulatory audit on a triennial basis, these data reflect approximately one third of the human research protocols that were active during the reporting period. Each regulatory audit includes a 3-year look-back period for the protocol under review. Thus, as improved processes are implemented, reports of regulatory audits may continue to reflect issues that occurred up to 3 years previously. For this reason, improvements as reflected in regulatory audits may lag actual improvements in current protocol implementation.

Human Research Quality Indicators	2010	2011	2012
Human Research Protocols – Initial IRB Reviews			
Protocols Audited	**2,102**	**3,558**	**4,229**
Protocols Conducted or Initiated Without IRB Approval	3 (0.14%)	4 (0.11%)	5 (0.11%)
Protocols Suspended by IRB	*	47 (1.3%)	63 (1.48%)
Human Research Protocols – Continuing Reviews			
Protocol Requiring Continuing IRB Review	**1,606**	**2,942**	**3411**
Protocols Conducted Without Continuing IRB Review	2 (0.12%)	6 (0.2%)	4 (0.12%)
Human Research Protocol Documentation			
Protocol Case Histories Reviewed	**11,387**	**23,657**	**26,291**
Procedures Initiated Prior to Subject Consent	249 (2.2%)	39 (0.2%)	91 (0.4%)
Inclusion Criteria Documentation Lacking	*	226 (0.9%)	657 (2.5%)
Exclusion Criteria Documentation Lacking	*	167 (0.7%)	189 (0.7%)
Human Research Investigator Qualifications			
Personnel in Human Research Protocols Audited	*	**12,328**	**16,598**
Personnel Lacking Research Scope of Practice	*	294 (2.4%)	92 (0.55%)
Personnel Working Outside Research Scope of Practice	*	9 (0.1%)	7 (0.04%)
Personnel Lacking Initial VHA-Required Training	*	92 (0.8%)	73 (0.44)

* Not obtained.

These data indicate a relatively low incidence of noncompliance related to basic human research protections in VA research. It is ORO's goal over a period of years to develop more refined quality indicators that reflect more complex aspects of human research protection.

2. Animal Research and Research Safety Quality Indicators

ORO has also developed quality indicators for animal care and use programs and research safety programs. The tables below illustrate selected quality indicators for these programs collected for the 2012 reporting period.

Animal Research Quality Indicators	2010	2011	2012
Animal Research Protocols – Initial IACUC Reviews			
Protocols Audited	**585**	**1347**	**1286**
Protocols Conducted or Initiated Without Initial Approval	*	2 (0.2%)	2 (0.2%)
Animal Research Protocols Suspended by IACUC	*	12 (0.9%)	14 (1.09%)
Animal Research Protocols – Annual IACUC Reviews			
Protocols Requiring Annual IACUC Review	*	*	**1159**
Protocols Conducted Without Annual IACUC Approval	*	*	25 (2.16%)
Animal Research Investigator Qualifications			
Personnel in Animal Research Protocols Audited	*	4926	4604
Personnel Lacking Research Scope of Practice	*	170 (3.5%)	276 (6.0%)
Personnel Working Outside Research Scope of Practice	*	1 (0.02%)	1 (0.02%)
Personnel Lacking Initial VHA-Required Training	*	93 (1.9%)	26 (0.56%)

* Not obtained.

Research Safety Quality Indicators	2011	2012
Protocols Requiring Initial SRS Reviews		
Protocols Audited	**2264**	**2722**
Protocols Conducted or Initiated Without SRS Approval	79 (3.48%)	28 (1.02%)
Protocols Suspended by SRS	7 (0.30%)	6 (0.22%)

These data indicate a relatively low incidence of noncompliance in VA related to basic animal research oversight and basic research safety protections. It is ORO's goal over a period of years to develop more refined quality indicators that reflect more complex aspects of VA's animal care and use programs and research safety programs.

VA is among the first entities to develop systematic quality indicators for research protections. VA is making public its data for these quality indicators in an effort to stimulate the development of comparable quality measures for university and private sector research protection programs.

H. Outreach

ORO conducts a variety of outreach activities to familiarize the VA community, VA research affiliates, Veterans, and the public with VA's programs to protect human research subjects; promote appropriate care and use of laboratory animals; ensure research safety, research laboratory security, and research information protection; and promote the responsible conduct of research.

ORO outreach to Veterans includes participation in Veterans Service Organization (VSO) national meetings and the annual meeting of the Association of Military Surgeons of the United States (AMSUS) - The Society of the Federal Health Agencies. ORO also maintains a Web site to assist Veterans in deciding whether or not to participate in research and a telephone Hotline through which Veterans and other participants in VA research can anonymously express concerns or file complaints about specific VA research studies.

I. FUTURE CHALLENGES

Lessons learned from ORO's compliance cases from 2003 to the present indicate that strong leadership and oversight at the facility level are essential to establishing and maintaining an effective research compliance program. The facility Director, Chief of Staff, Associate Chief of Staff for Research (ACOS/R), Administrative Officer for Research (AO/R), and facility research committees must all exercise their leadership and oversight roles to ensure consistent adherence to VA research requirements.

The current and future challenge for VA is to clarify, and where necessary redefine, these roles to adapt to changing research and health care environments. Other challenges include (a) fine tuning the RCO audit program to maximize the most critical research protections; (b) adapting an aging infrastructure to meet current research safety and security requirements; (c) implementing reliable standards for data ownership, data security, privacy, and confidentiality relative to collaborative research with VA's university affiliates; and (d) adapting quickly and effectively to meet VA's Transformational Initiatives for creating a 21st Century people-centric, results-driven, and forward-looking VA.

ORO has identified the following four strategic objectives for CY2013:

1. Ensure the effectiveness of VA research compliance programs by (a) revising VHA Handbooks to produce clear, consistent, and complete policies; (b) providing improved facility self-assessment tools; (c) developing and tracking specific research compliance performance metrics; (d) implementing standards for distinguishing research activities from non-research program operations activities; and (e) developing mechanisms for oversight of research conducted by VHA Program Office personnel.

2. Regularize ORO onsite reviews to provide proactive oversight of all VA research by developing and implementing a 3-5 year review cycle to include all facility research compliance programs.

3. Implement an expanded education program for all VA RCOs by integrating the work of the research compliance education program with the work of ORO Regional Office and Central Office teams to provide national and regional RCO training within a structured curriculum that includes use of specific audit tools and strategies and continued professional development.

4. Enhance research protections by aligning ORO's activities with those of relevant internal and external offices and agencies, including (a) the VA OI&T, the VA Office of Inspector General, the VHA ORD and the VHA Privacy Office; (b) the

Department of Defense; (c) the Office of Science and Technology Policy (OSTP) and Department of Health and Human Services (HHS) initiative to revise the Federal Policy (Common Rule) for the protection of human research subjects; the HHS Office of Research Integrity (ORI), Office of Human Research Protections (OHRP), and Office of Laboratory Welfare; and (d) the VA-designated human research and animal research accrediting organizations.

Department of Veterans Affairs
Veterans Health Administration

Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2012

Appendix: Compliance Case Summaries

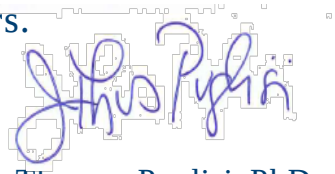
OFFICE OF RESEARCH OVERSIGHT

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

This report summarizes the activities of the Veterans Health Administration Office of Research Oversight (ORO) from January 1 through December 31, 2012, and describes all suspected lapses in protecting human subjects and others in VA research as required under title 38 United States Code (38 U.S.C.) §7307(d)(4).

The report was prepared for the Committees on Veterans' Affairs of the Senate and the House of Representatives of the United States pursuant to 38 U.S.C. §7307(f).

ORO reports directly to the Under Secretary for Health in monitoring, reviewing, and investigating compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Federalwide debarment for research impropriety, and the activities of facility-level research compliance officers.



J. Thomas Puglisi, PhD
Director and Chief Officer
Office of Research Oversight

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TABLE 1. FOR-CAUSE ON-SITE REVIEWS

ORO for-cause onsite reviews involve in-depth evaluations of suspected serious systemic non-compliance with VA or other federal research requirements. ORO review teams typically spend 4 to 5 days at the facility examining records and interviewing key personnel involved in the issues under review. Remediation involves development by the facility of an action plan acceptable to ORO, and oversight of corrective actions by ORO until remediation is complete. NOTE: Cases under the jurisdiction of additional offices (for example, OIG or FDA) or involving physical infrastructure improvements may remain open for extended periods.

SUMMARY

- 9 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- 1 = New Cases – April 1 through June 30
- 0 = New Cases – July 1 through September 30
- 0 = New Cases – October 1 through December 31
- 1 = New Cases in Calendar Year
- 10 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 1. FOR-CAUSE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	Issue of Noncompliance	Remedial Actions
1	05	VA Maryland HCS	P	01/29/2010	ORO on-site review of R&DC program beginning December January 19, 2010. Facility reported improper entry into ePromise of non-VA, affiliate research valued at $15 million.	Remedial actions: Correct previously identified regulatory concerns; R&DC annual program reviews; Annual MOU reviews; COI management; Membership and quorum; Inventory of investigational and research-related drugs; accurate entry of protocols into ePromise. CASE CLOSED
2	08	VA Caribbean HCS	H	02/16/2010	ORO for-cause onsite review beginning on February 16, 2010. Off-site VA research did not receive substantive VA IRB review and oversight.	Remedial actions: Complete IRB, PO, ISO review/re-review of off-site studies, including ICD; ensure inclusion of VA responsibility for injury; MCD permission for recruitment of non-Veterans; CRADO waiver for child research; renewed consent from off-site. All protocols to be re-reviewed. CASE CLOSED
3	16	Jackson	H	05/07/2010	Follow-up review of HRPP (incomplete protocol inventory and lapsed study approvals).	Remedial actions: SOP lacked recurring procedures: initial review; risk-benefit assessment, risk level, quorum, recusals, teleconferencing, HIPAA waiver, cont. review, exempt& expedited criteria; protocol tracking; SOPs; RCO change reports, reports to ISO/PO, IRB Ed; 4.27.12 SOP completed case close

TABLE 1. FOR-CAUSE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	Issue of Noncompliance	Remedial Actions
4	16	Jackson	S	05/07/2010	ORO for-cause on-site review of RSPP beginning May 7, 2010 in follow-up of February 5, 2010 R&DC on-site review. Noted that significant progress had been in all areas. Self-assessments conducted; research-wide database management of all research activities; qualified Biosafety Officer, SOP revisions	Remedial actions: Protocol management database established; self-assessments completed; research staff trained; qualified biosafety officer appointed; rDNA expert appointed; SOPs revised; lab inspections; weekly lab access reviews; SRS SOPs; safety concerns. CASE CLOSED
5	01	Bedford	A	06/22/2010	Follow-up review of ACUP (complete installation of substantial HVAC upgrade).	Remedial actions: Comprehensive VMU HVAC upgrade; replace primary VMU HVAC; individual backup heating/cooling units and sensors in all animal; 24-hour environmental monitoring and emergency response plan; HVAC commissioning; final QA checks CASE CLOSED
6	16	Houston	A	01/03/2011	ORO For-Cause review of ACUP beginning January 3, 2011. Four non-human primate deaths reported. ORO Southern Regional Office (SRO) reviewed redacted IACUC minutes and found other non-human primate injuries and rabbit deaths. Other deficiencies related to OSHP were also noted by the SRO.	Remedial Actions: Noncompliance was not identified during the visit; further techical assistance requested for the animal procedures under investigation; an advisor with an improved technique has been identified to assist the VAMC. CASE CLOSED.
7	08	VA Caribbean HCS	H	02/28/2011	ORO follow-up review of HRPP (inadequate IRB review and oversight of off-site research) beginning on February 28, 2011.	Remedial actions: Substantive review of all research; revise IRB and HRPP SOPs; admin resources needed; accurate meeting minutes; ISO and PO review, IRB quorum no joint meetings, etc. Adequate resources hired, CASE CLOSED
8	08	VA Caribbean HCS	R	02/28/2011	Follow-up review of R&DC (inadequate administrative support and R&DC oversight).	Remedial Actions: The MCD must ensure adequate administrative support; the R&DC cannot use designated review procedures; research team members must have current scopes of practice or functional statements; and the R&DC must receive and approve minutes from every subcommittee. CASE CLOSED
9	21	VA Northern California HCS	P	04/26/2011	ORO for-cause onsite review of multiple areas (confusion regarding VA versus affiliate research and jurisdiction of affiliate IRB for oversight of VA research) beginning April 26, 2011.	Remedial actions: Use only IRBs designated on FWA; suspend research lacking R&DC & VA IRB approval; use policy definition of VA research; establish institutional culture of regulatory and policy compliance; acquire & maintain required records; adhere to VHA investigational drug policy. CASE CLOSED.
10	01	VA Boston Healthcare System	P	05/01/2012	Allegation of possible research misconduct and/or noncompliance against the LSI. ORO for-cause onsite review beginning May 1, 2012.	Remedial actions: Implement monitoring plans; ensure compliance of pharmacy practice; determine any disciplinary action needed.

TABLE 2. ROUTINE (PROACTIVE) ON-SITE REVIEWS

ORO routine onsite inspections provide a prospective, systematic approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite reviews involve a two stage process of assessment and remediation. The assessment stage includes a review of compliance with current federal laws, regulations, and VA policies governing research. Remediation involves development by the facility of an action plan acceptable to ORO, and oversight of corrective actions by ORO until remediation is complete.

SUMMARY

- 91 = Cases Continuing from Previous Calendar Year
- 26 = New Cases – January 1 through March 31
- 24 = New Cases – April 1 through June 30
- 21 = New Cases – July 1 through September 30
- 16 = New Cases – October 1 through December 31
- 87 = New Cases in Calendar Year
- 178 = Total Cases (Continuing Plus New) in Calendar Year

Case	VISN	Facility	Focus	Date of Review	TABLE 2. ROUTINE (PROACTIVE) ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
1	20	Portland VAMC	I	01/07/2008	Remedial actions: OI&T ITOC review noted concern that the facility requires VA CIO waiver for use of university servers to store VA data. ORO referred apparent ISO approval of deficient procedures to OI&T Central Office and OGC for follow-up. CASE CLOSED
2	01	VA Boston Healthcare System	S	04/17/2008	Remedial actions: wire mesh screening for research buildings; training program; replace emergency eye wash stations with stainless steel (flush weekly in interim). CASE CLOSED.
3	09	VA Tennessee Valley HCS	I	04/21/2009	Remedial actions: Remediate off-site storage of VA sensitive information; update equipment inventories; revise sample HIPAA authorization document. CASE CLOSED
4	09	VA Tennessee Valley HCS	S	04/21/2009	Remedial actions: SRS education on NIH guidelines for rDNA research; IBC approval of rDNA research; designation of research safety coordinator; weekly review of lab access records. CASE CLOSED.
5	15	St Louis	A	06/15/2009	Remedial actions: halt unapproved research; expand SOPs; protocol/space review; track investigator training; committee chairs and members; correct identified deficiencies; emergency plan and drills; risk and hazard vulnerability assessments; lab access monitoring; staffing. CASE CLOSED
6	15	St Louis	S	06/15/2009	Remedial actions: halt unapproved research; expand SOPs; lab chemical inventories and safety plans; track training; committee chairs and members; correct deficiencies; emergency plan/drills; risk and hazard vulnerability assessments; lab access monitoring; staffing; replace ACOS/R.CASE CLOSED
7	08	Bay Pines	A	07/07/2009	Remedial actions: safety review of animal research; facility inspection risk reviews; OSHP animal research personnel at risk; SOPs; documentation of semi-annual program reviews; IACUC meeting minutes; information security; registered IBC for rDNA research; IACUC member appointments. CASE CLOSED

Case	VISN	Facility	Focus	Date of Review	TABLE 2. ROUTINE (PROACTIVE) ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
8	05 SR	DC VAMC	A	08/31/2009	Remedial actions: Ensure required IACUC quorum/recusals; timely IACUC/SRS annual reviews; SRS review prior to study initiation; USDA pain/distress documentation/justification; annual overheat test; 5% IACUC protocol audit; presentation of semi-annual program evaluations to MCD. CASE CLOSED
9	05 SR	DC VAMC	S	08/31/2009	Remedial actions: Annual program evaluations; chemical hygiene program; current chemical inventories; current fume hood/safety cabinet certifications; incident response plans; annual drills; SRS SOPs; SRS continuing review protocols; unapproved rDNA research; Child research CRADO waiver. CASE CLOSED
10	02	VA Western New York HCS	A	09/28/2009	Remedial actions: rDNA review; semi-annual program reviews and inspections; annual overheat tests; animal monitoring; SOPs; pest control program; safety showers and eyewashes; signage, PPE. CASE CLOSED.
11	18	New Mexico VA HCS	S	10/19/2009	Remedial actions: Initial and continuing SRS review; emergency preparedness and response plans; annual drills; lab staff training; bloodborne pathogen exposure control plan; annual multidisciplinary vulnerability assessment; chemical hygiene plan; registered IBC for rDNA research. CASE CLOSED.
12	12 NE	Hines	A	10/26/2009	Remedial actions: Annual overheat tests; SOPs for documented IACUC-SRS communication; Occupational Health Safety Plan (OHSP) for all-risk ACUP personnel, engineering, housekeeping personnel. CASE CLOSED
13	07	Charleston	I	11/16/2009	Remedial actions: Modify SOPs per VA requirements; unattended work stations requirements; employee separation procedures; encryption and protected environment for all computers with VASI; IT equipment inventory controls; ISO and PO protocol reviews; finalize MOU/Interconnection Agreement CASE CLOSED
14	16	Houston	I	01/19/2010	CASE CLOSED Remedial actions: MOU/SIA approval by ESCCB; VA and non-VA equipment tracking and accountability; compliant document shredders; revise HIPAA Authorization template.
15	16	Houston	P	01/19/2010	Remedial actions: Affilite MOU; CRADO waiver for pediatric research; unredacted IRB meeting minutes; IRB membership roster; IRB SOPs; contingent approval process; effective R&DC compliance oversight; CRADO waivers for non-VA tissue banks; VA required tissue banking consent information. CASE CLOSED.
16	01	VA Connecticut HCS	S	04/26/2010	Remedial Actions: Annual program review; emergency preparedness and incident response plans; annual safety drills; multidisciplinary vulnerability assessment; chemical inventory; annual chemical hygiene plan review; review of protocol hazardous chemical inventories; off-site access logs. CASE CLOSED
17	16	Houston	S	05/24/2010	Remedial actions: Annual program reviews; hazardous chemical reviews; IBC documentation; SRS SOPs; emergency plan; research-specific safety and security plan; annual safety drills; chemical inventory reviews; oversight of offsite research; occupational safety and health. CASE CLOSED
18	22	VA Greater Los Angeles HS	A	06/07/2010	Remedial Actions: VMU HVAC monitoring, testing, temperature, pressure regulation, routine maintenance; security of outside canine exercise area; VMU supervision; pest control; cage standards; veterinary access to animals and records; canine husbandry; protocol adherence; SOPs; offsite oversight.
19	21	San Francisco VAMC	I	06/28/2010	Remedial actions: Compliance with VASI protection and VA data storage requirements; application of HIPAA privacy rule; ISO/PO protocol reviews; SIA with affiliate; secure storage of paper documents; complete IT property inventories; repository requirements; record retention; training. CASE CLOSED
20	17	VA Central Texas HCS	A	06/28/2010	Remedial Actions: MOUs; semi-annual IACUC program reviews; IACUC to consistently adhere to VHA-specific policies; scopes of practice; OSHP requirements. CASE CLOSED

Case	VISN	Facility	Focus	Date of Review	TABLE 2. ROUTINE (PROACTIVE) ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
21	17	VA Central Texas HCS	S	06/28/2010	Remedial Actions: IBC MOU; annual program review; multidisciplinary vulnerability assessments; safety, security, emergency preparedness plan; safety drills; research-specific security plan; lab inspections; hazardous chemical inventories; research-specific safety training; lab access reviews; SOPs.
22	17	VA North Texas HCS	A	09/07/2010	Remedial actions: Administrative review procedures; review of protocol modifications; safety reviews; noncompliance reporting; OSHP for all animal research personnel. CASE CLOSED
23	11	Detroit	A	09/21/2010	Remedial actions: System to monitor research actions; SRS reviews of ACORPS; Written approval to start research; Resolution of audit findings; Minimum audits completed. Annual overheat test; MCD briefed on semi-annual reviews; RSSP MOUs; Comprehensive OHSP; VMU eyewash/shower. CASE CLOSED
24	21	San Francisco VAMC	A	10/18/2010	Remedial actions: RCO audits; annual safety testing; SOPs; MOU; safety and biosecurity procedures; semiannual program evaluations; continuing reviews; monitor breeding colonies; emergency safety showers, veterinary care plan. CASE CLOSED
25	22	VA Southern Nevada HS	H	11/17/2010	Remedial actions: Appoint VA representatives to IRB; ensure completion of appointment letters; VA representative present at IRB; MOU for SRS with coordinating VA; draft SOP for HRPP; PI training scheduled. CASE CLOSED.
26	12	Milwaukee	S	11/29/2010	Remedial Actions: R&DC annual oversight of SRS & RSSP; R&DC monitor access to VA labs; SRS risk assessments, safety reviews animal protocols; non-exempt rDNA research. CASE CLOSED.
27	20	VA Puget Sound HCS	A	12/07/2010	Remedial actions: SRS review of animal studies; IACUC review of modifications; continuing review; occupational health and safety risk assessments; HVAC settings; SOPs. CASE CLOSED
28	19	VA Eastern Colorado HCS	I	01/10/2011	Remedial actions: Move VASI off OE, place all IT on the appropriate EIL, ensure all human subject protocols have an ISO and PO review. Case Closed
29	19	VA Eastern Colorado HCS	S	01/10/2011	Remedial Actions: Evaluate annual performance of SRS/RSSP; establish procedures for reporting noncompliance; document lab access records; monitor annual physical security surveys; conduct annual vulnerability assessment; conduct semiannual review of hazardous chemicals inventory. CASE CLOSED.
30	02	Albany	A	02/15/2011	Remedial Actions: Establish procedures to ensure electronic voting not used to approve research; ensure procedures for use of designated member review are consistent w/ PHS Policy; ensure quorum of voting members and annual overheat test is conducted annually; expand OHSP; revise SOPs. CASE CLOSED
31	02	Albany	S	02/15/2011	Remedial actions: Establish procedures to report noncompliance; establish procedures to review the research security plan; ensure multidisciplinary vulnerability assessment of research; establish procedures to review chemical hygiene; research personnel complete mandatory training. CASE CLOSED
32	08	VA Caribbean HCS	I	02/28/2011	Remedial actions: Logical Access controls; VASI on OE; VASI unsecured; HIPAA Auth Template; Unapproved waivers of HA,ISO/PO Review; unauthorized network connection. CASE CLOSED
33	23	Iowa City	H	04/04/2011	Remedial actions: Update SOPs, MOU, IRB roster; require justifications for inclusions of non-veterans; require waiver of informed consent for recruitment; update ICD template; expand investigational drug study reviews; implement LOU's as needed. CASE CLOSED.
34	20	Boise VAMC	A	04/11/2011	Remedial Actions: Establish procedures to review effectiveness of the ACUP annually; ensure appropriate oversight of animal research activities conducted off-site; establish SOPs for using Designated Member Review; ensure annual overheat test is conducted and reported to IACUC.
35	20	Boise VAMC	S	04/11/2011	Remedial Actions: Ensure risk assessment results of proposals are adequately documented; adhere to MOU with collaborating VA for the establishment of shared rDNA subcommittee; ensure annual assessment security plans; R&DC annual review of SRS and RSSP; correct lab inspection findings.

Case	VISN	Facility	Focus	Date of Review	TABLE 2. ROUTINE (PROACTIVE) ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
36	03	VA New Jersey HCS	H	04/11/2011	Remedial Actions: Conduct substantive risk/benefit levels review; Assure signed audio consent form in participant's file; IRB ensure protocol changes approved before implementations; IRB ensure IC and protocol consistency; HIPAA has required language. All remedial actions completed.
37	03	VA New Jersey HCS	R	04/11/2011	Actions taken: All remedial actions completed.Org chart revised, SRS properly constituted, procedures for proper approval of continuing review in place, SOPS re-written, annual QA reviews conducted.
38	19	VA Salt Lake City HCS	H	04/11/2011	Remedial actions: Develop SOPs to ensure VA research is distinguished from affiliate research and that IRB action regarding VA research is separate and distinguishable from the affiliate research and R&DC only approves VA research; R&DC must ensure all research is reviewed as required. CASE CLOSED.
39	16	Central Arkansas VHS	S	04/25/2011	Remedial Actions: Appropriately constitute IBC; SRS must annually review safety, security, and emergency response plans; SRS must review inventories of hazardous chemicals every six months; SRS ensure deficiencies noted during lab inspections are addressed; lab findings must be addressed.
40	04	Philadelphia	I	04/25/2011	Remedial Actions: VASI stored on OE, PHI disclosed to non-VHA entities that are not listed on the HIPAA Authorization; use of personal USB drive; SOPs; IT equipment not on appropriate EIL; permissive access to electronic data. Case Closed
41	01	VA Boston Healthcare System	A	05/09/2011	Remedial Actions: Maintain safety program consistent with VA policies and NIH guidelines; ensure protocol review process is consistent with SOPs; document official actions correctly in minutes; ensure staff completes credentialing; address VMU deficiencies.
42	01	Bedford	H	05/10/2011	Remedial actions: IRB must ensure that protocols are not inappropriately exempted from IRB review, IRB must ensure within 120 days that protocols either include prospective informed consent or that waivers of informed consent are justified and documented; CASE CLOSED.
43	01	Bedford	R	05/10/2011	Remedial Actions: RDC must ensure all protocols are appropriately reviewed and approved; RDC must maintain oversight of and ensure subcommittees operate in compliance with VHA requirements; and MCD must ensure provision of adequate resources. All actions completed. Case closed.
44	21	VA Palo Alto HCS	H	06/13/2011	Remedial Actions: Revisions of applications and policies to ensure distinction of VA from non-VA research and to ensure that research is not initiated in advance of required CRADO waivers.
45	21	VA Palo Alto HCS	R	06/13/2011	Remedial Actions: R&DC SOPs for initial and continuing reviews not assigned to a subcommittee; improve tracking of initial and continuing reviews; ensure appropriate approvals; ACOS/R must conduct annual QA reviews; retain records per Records Control Schedule. CASE CLOSED.
46	23	Sioux Falls	H	06/21/2011	Remedial actions: SOP approval; compliant IRB minutes for COI/ recusals/vote counts; document primary member for whom alternates are substituting; ensure changes in IRB roster are submitted to ORO CO. CASE CLOSED
47	23	Sioux Falls	R	06/21/2011	Remedial actions: Updated IRB SOPs missing RDC approval; annual review of subcommittees completed without vote by members; review of Dec/Jan RDC minutes for annual review. CASE CLOSED
48	01	VA Connecticut HCS	H	06/27/2011	Remedial Actions: Document ISO/PO review; IRB minutes; Research not to be initiated before R&DC approval; revise HIPAA Authorization template; complete thorough IRB reviews; obtain CRADO approval for international research; Investigational Devise procedures. CASE CLOSED
49	01	VA Connecticut HCS	R	06/27/2011	Remedial Actions: Revise R&DC Org Chart; properly constitute SRS; R&DC Annual reviews of Subcommittees and Research Programs; annual review of publications; lapse in training CASE CLOSED

Case	VISN	Facility	Focus	Date of Review	TABLE 2. ROUTINE (PROACTIVE) ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
50	05	VA Maryland HCS	I	06/27/2011	Remedial actions: VA CIO waiver for VASI on OE; remediate unauthorized device on LAN; secure paper VASI; revise HIPAA authorization template; list 7332 info on HIPAA; get proper person rep to sign HIPAA; get & document HIPAA waivers; revise SOPs re ISO/PO roles/review; training CASE CLOSED
51	02	Syracuse	A	06/28/2011	Remedial Actions: Facility must describe the nature and reasons for the departures from the Guide and PHS Policy; IACUC minutes must identify the Chair and Veterinarian by name; the OSHP must include all at-risk personnel; refrigerator signage; emergency eye wash; emergency shower. CASE CLOSED
52	02	Syracuse	S	06/28/2011	Remedial Actions: Establish written procedures to report noncompliance & unexpected events; must make local RSSP policies consistent & represent actual practices; label lab chemicals as per SOP; emergency eyewash station must meet safety standards; chemical fume hood inspection annually. CASE CLOSED
53	08	Tampa	H	07/12/2011	Remedial Actions: ISO review exempt research; report serious unanticipated problems and SAEs; data destruction; exempt research appropriately; provide required IRB approval documents to pharmacy; IRB suspend protocol if approval lapses. CASE CLOSED.
54	08	Tampa	R	07/12/2011	Remedial Actions: Create process for continuing review and oversight for which R&DC is responsible; provide R&DC and ACOS/R approval notifications; satisfy annual review requirements; record votes on actions in meeting minutes. CASE CLOSED.
55	19	VA Eastern Colorado HCS	H	07/18/2011	Remedial Actions: Identify VA/affiliate research, approve VA research; MDC appointments of VA IRB members; VA IRB member present for VA research review; Provide IRB minutes in 3 weeks; Complete pharmacy records; IRB to determine serious/continuing noncompliance. Case closed.
56	19	VA Eastern Colorado HCS	R	07/18/2011	Remedial Actions: R&DC must ensure all protocols are appropriately reviewed and approved prior to initiation; completion of all required QA reviews and assessments; develop and implement SOPs; ensure completion of mandated training; and ensure compliant R&DC and subcommittee membership appointments
57	10	Dayton	H	07/25/2011	Remedial Actions: Update IRB membership roster/appointment letters; revise IRB MOU; suspend study until CR review completed; revise HIPAA template; IRB determine disposition of data; update Investigational Pharmacy binders; ISO and PO reviews to IRB; ensure ICDs consistent with protocol. CASE CLOSED
58	10	Dayton	R	07/25/2011	Remedial Actions: Org Chart and roster updated; R&DC minutes reviewed; brief proper voting procedures; R&DC minutes will be available; R&DC minutes accurately recorded; institute research safety review process; conduct annual assessments of subcommittees and publications; Scopes reviewed. CASE CLOSE
59	23	VA Black Hills HCS	H	07/25/2011	Remedial actions: Complete VHA Pharmacy Form (#10-9012) accurately; SOPs; accurate IRB minutes; IRB appointment letters; accurate ICD language. Remedial action completed. CASE CLOSED.
60	23	VA Black Hills HCS	R	07/25/2011	Remedial Actions: RDC needs to meet monthly; RDC membership composition; RDC minutes correction; appointment letters; additions needed to RDC SOP. Remedial Actions complete. CASE CLOSED.
61	01	Providence	I	08/01/2011	Remedial Actions: VASI not to be stored on non-VA OE; do not store VASI on unencrypted removable media; do not use unencrypted removable storage devices; revise HIPAA template/authorization language; document HIPAA waivers properly.
62	16	Central Arkansas VHS	R	08/09/2011	Remedial Actions: Annual subcommittee evaluations; quality assurance reviews; Member recusal during votes on own studies; accurately count/record attendance and votes; IRB not R&DC determines human subjects research; Appointment letters specify term dates; revise SOPs. CASE CLOSED.
63	20	VA Puget Sound HCS	H	08/15/2011	Remedial actions: Meeting minutes; timely PO reports to IRB; expedited review findings to IRB; HIPAA authorization content; SOPs; IRB review of noncompliance. All corrective actions completed.

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64	20	VA Puget Sound HCS	R	08/15/2011	Remedial actions: Annual program quality reviews; procedures for recording accurate committee votes; SOPs. CASE CLOSED.
65	12	Chicago HCS	I	08/29/2011	Remedial actions: VASI not to be stored on OE; secure paper with PHI; encrypted PHI on CDs; SOPs; obtain HIPAA Auth when required; complete PO reviews prior to research commencement; ensure training completed as required; PI not to depart VA with research records. CASE CLOSED
66	00	VA Central Office	H	08/30/2011	Remedial actions: HRPP organizational chart; incident reporting; SOP revision; consent template revision; and required annual program review.
67	15	Columbia	H	09/13/2011	Remedial actions: Add HIPAA record retention statement; revise IRB/ICD checklist content; Update IRB roster and member appointments; update IRB members appt; PO review each protocol; ensure informed consent waiver for recruitment; IRB roster to id alt members substitute; update SOPs. CASE CLOSED.
68	15	Columbia	R	09/13/2011	Remedial actions: Limit R&DC approvals to VA research; establish current MOU with affiliate IRB; conduct annual program reviews; ensure signed approval notifications to ACOS; upgrade PO reviews; ensure review of manuscripts; compliant SRS activities: RDC Chair term appt. CASE CLOSED.
69	11	Ann Arbor HCS	I	09/19/2011	Remedial Actions: Encrypt VASI outside VA protected environment; restrict access to VASI; use VA thumb drives only; secure VASI in locked cabinets; put IT equipment on proper EIL; fix HIPAA template; identify all users of PHI in HIPAA; ISO/PO summary reports prior to IRB. CASE CLOSED
70	09	Huntington	A	09/19/2011	Remedial Actions: Ensure overheat test is conducted annually; ensure test results are reviewed by the IACUC; address 6 facility issues (unsecured CO2 tank, recapped needles, etc) in timely manner. CASE CLOSED.
71	17	VA Central Texas HCS	H	09/20/2011	Remedial Actions: Increase HRPP administrative resources; improve IRB protocol review and documentation; ensure drug storage compliance; revise SOPs.
72	17	VA Central Texas HCS	R	09/20/2011	Remedial Actions: Establish MOU for use of affiliate IACUC; review (and, as appropriate) increase administrative support; review and consolidate, revise, and/or expand SOPs; conduct annual program reviews. Corrective actions completed, case closed.
73	04	Coatesville	H	09/26/2011	Required Actions: Protocols and ICDs must contain compliant records retention language; IRB meeting minutes must document attendance and vote counts; investigator files must not be used as the IRB administrative files. All actionable items completed. Case Closed
74	04	Coatesville	R	09/26/2011	Remedial Actions: R&D Org Chart corrected; accurate R&DC and IRB rosters; ensure compliant SRS; education complete; completed PO and ISO reviews; signed COI forms obtained. CASE CLOSED
75	04	VA Pittsburgh HCS	H	10/17/2011	Required Actions: IRB must ensure: members recuse themselves when COI exists; new protocols have HIPAA and ICD as separate documents and active protocols meet this requirement at the CR; minutes accurately document attendance and vote. CASE CLOSED
76	04	VA Pittsburgh HCS	R	10/17/2011	Required Actions: R&D Org Chart and roster must be corrected; R&DC Annual reviews of subcommittees and Research Programs, and ACOS/R&D annual quality assurance review of publications must be done; R&DC must ensure quorum when conducting business; ensure shredder bin security. CASE CLOSED
77	17	VA South Texas HCS	H	10/17/2011	Remedial actions: Revisions of SOPs (one SOP revision remaining); revision of IRB application forms to distinguish VA research from affiliate research completed; clarification of IRB alternate member designation clarified. All corrective actions completed.
78	17	VA South Texas HCS	I	10/17/2011	Remedial Actions: Obtain waiver for VASI residing on OE, account for non-VA equipment used for VA research. Case Closed

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79	17	VA South Texas HCS	R	10/17/2011	Remedial actions: Update SOPs; R&DC to establish program objectives; R&DC review of IRB exempt protocols; Update MOU; and R&DC approval of final subcommittee minutes. Case closed.
80	23	Minneapolis	A	10/18/2011	Remedial actions: Ensure that an overheat test is conducted annually. CASE CLOSED
81	23	Minneapolis	S	10/18/2011	Remedial actions: Destroy exempt quantities of select toxins; conduct annual vulnerability assessment; review research access records & safety manual annually, conduct annual drills; review access status of personnel authorized to do research; revise policies for reporting noncompliance. CASE CLOSED
82	16	Houston	H	10/24/2011	Remedial Actions: Research pharmacy records; Report suspension or termination to MCD within 5days; sufficient detail in IRB minutes; substantial changes back to full IRB; ISO in IRB reviews; R&DC to evaluate and monitor alternate subs process; evaluate CIRB; match SOPs & VA policy; all signatures on scopes of practice.
83	09	VA Tennessee Valley HCS	H	11/01/2011	Remedial actions: Ensure Pharmacy has oversight of all investigational drugs; IRB meeting minutes must include actions and vote taken on actions. Remedial actions complete. CASE CLOSED.
84	09	VA Tennessee Valley HCS	R	11/01/2011	Remedial actions: update SOP for record retention language; ACOS/RDC perform adequate QA of publications and institute policy and procedure for submission. CASE CLOSED.
85	20	Portland VAMC	A	11/14/2011	Remedial actions: Conduct the annual overheat test per VHA Use of Animals in Research Handbook (1200.07). CASE CLOSED
86	20	Portland VAMC	S	11/14/2011	Remedial actions: IBC review and approval of non exempt rDNA research; R&DC conduct annual review of IBC; conduct vulnerability assessment of research areas; properly store and label chemical hazards; proper signage posted on research lab entrances; resolve lab findings cited. CASE CLOSED
87	05	VA Maryland HCS	H	11/28/2011	Remedial actions: Maintain accurate protocol list; Research must have R&DC approval; R&DC must conduct initial & continuing reviews of IRB exempt protocols; PI must provide IRB approval to pharmacy; and IRB-approved ICDs must contain required information. CASE CLOSED.
88	16	Gulf Coast HCS	I	12/12/2011	Remedial actions: Transition to updated HIPAA Authorization template; SOPs; ensure data is appropriately categorized in protocols; harmonization of ICF, HIPAA Authorization, and protocol; Data Repository SOPs CASE CLOSED
89	04	Wilkes-Barre	H	12/12/2011	Remedial Actions: Draft minutes within 3 weeks; document IRB members who attend via videoconference; maintain research records separately from administrative records, record meeting attendance correctly. CASE CLOSED.
90	07	Atlanta	A	12/13/2011	Remedial actions: IACUC to ensure overheat test is conducted as described in VHA Handbook 1200.07 CASE CLOSED
91	07	Atlanta	S	12/13/2011	Remedial Actions: IBC review of non exempt rDNA research; conduct and report safety, security, and emergency drills properly; full committee review of research involving new hazards; proper storage and labeling of chemical hazards; post proper signage on lab entrances; correct lab findings cited.
92	08	Miami	A	01/10/2012	Remedial Actions: Conduct annual overheat test; properly review and approve offsite research; develop SOP for reporting research noncompliance; properly review protocols for alternatives; review VMU SOPs annually.
93	08	Miami	S	01/10/2012	Remedial Actions: Conduct annual security plan drill; review all rDNA research; conduct annual vulnerability assessment; develop safety and security plan policies; make eyewash stations compliant; establish MOU with affiliate; evaluate status of WOC researchers.

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94	04	Clarksburg	H	01/23/2012	Remedial Actions: Revise expedited review procedures; Revise exempt study determinations; Revise study recruitment procedures; revise HIPAA Authorization template; Revise record retention language; PO/ISO protocol review procedures; Complete training; Revise COI policy/procedure. CASE CLOSED
95	04	Clarksburg	R	1/23/2012	Remedial Actions: RCO role clarification; Revise procedures for committee voting, documentation and membership; Revise committee approval procedures and notifications to PI; ISO and PO review procedures revised; Satisfy requirements for Annual Reviews and quality assurance reviews. Case Closed.
96	16	Shreveport	I	01/23/2012	Remedial actions: Restrict access to folders; secure PHI; account for non-VA IT; decide if data under invalid authorization may be used; document review process used to grant HIPAA waivers; obtain waivers for subject recruitment; ISO/PO assessments for exempt studies; information security training. CASE CLOSED
97	15	VA Kansas City Medical Center	H	01/23/2012	Remedial Actions: Exempt protocols must meet criteria; PO review to be provided prior to IRB review; PI to maintain master list of subjects; IRB reviewer to sign PI notice; IRB minutes to document COI; IRB to review cost statement in ICD; SAE SOP to be updated. Remedial actions complete, CASE CLOSED.
98	15	VA Kansas City Medical Center	R	01/23/2012	Remedial Actions: Facility to address deficiencies in R&DC/ACOS/R annual QA reviews; R&DC and IRB member appointments; R&DC minutes. All actions complete. Case closed.
99	07	Columbia	H	01/24/2012	Remedial actions: Maintain drug logs; Investigational drugs must be stored separately; Pharmacy must maintain required documents; IRB must utilize expedited review appropriately; SOPs must be consistent with VHA policy; and HIPAA Authorizations must contain required statements. CASE CLOSED.
100	07	Columbia	R	01/24/2012	Remedial Actions: R&DC must cease expedited reviews and electronic voting; PIs must have official VA appointment; Must not approve research prior to subcommittees' full approval; Must conduct annual reviews; and Update SOPs. CASE CLOSED
101	07	Atlanta	I	02/13/2012	Remedial Actions: Firewall management for the system interconnection; Improve process for justification of waivers of HIPAA Authorization; Improve compliance with research records retention requirements
102	07	Birmingham	A	02/14/2012	Remedial Actions: ACOS/R must consistently issue letters to PI's to initiate research; secure laboratory areas; establish MOU for affiliate IBC oversight; revise protocol recordkeeping practices to comply with VHA policy
103	06	Durham	H	02/21/2012	Remedial Actions: Committee approvals to Research Pharmacy; Study drugs properly labeled; Study drugs dispensed directly to subjects; investigational drugs stored separately from clinical stock.
104	01	VA Boston Healthcare System	H	02/21/2012	Remedial Actions: HIPAA template revised; IRB Chair offered VA part-time appointment; delegation of authority issued to allow research drug storage outside of pharmacy; IRB SOP revised; obtain consent for audio recordings.
105	01	VA Boston Healthcare System	R	02/21/2012	Remedial Actions: Revised Organizational Chart, revised committee rosters, issued appointment letters and updated R&DC SOPs.
106	06	Durham	R	02/22/2012	Remedial Actions: Describe recurring processes in SOP; R&DC must not conduct expedited review; Ensure current training for all research staff & committee members; R&DC members must not be appointed for terms > 3 years. CASE CLOSED.
107	09	Louisville	H	02/27/2012	Remedial Actions: Revision of ICD and HIPAA Authorizations templates; modification of previously approved ICDs and HIPAA Authorizations; revision of SOPs and practices regarding review, reporting, and determinations of reports of apparent serious/continuing noncompliance. CASE CLOSED.

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108	09	Louisville	R	02/27/2012	Remedial Actions: Update RDC SOPs to comply with current VHA policies; perform QA of publications; review CIRB on annual basis; accurate RDC roster information; Election of Chair and Vice Chair
109	18	New Mexico VA HCS	H	02/27/2012	Remedial Actions: Distinguish VA from non VA research (using VA definition of research); monitor approval periods and ensure cessation of research upon expiration; discontinue use of expedited review for greater than minimal risk/substantive changes.
110	18	New Mexico VA HCS	R	02/27/2012	Remedial Actions: R&DC and ACOS/R to conduct annual QA reviews and review of subcommittees and research program; R&DC not to use expedited review procedure; update R&DC roster; revise SOPs. All required actions completed, case closed.
111	09	Huntington	I	03/19/2012	Remedial actions: Revise HIPAA Authorization template; documentation of waivers of HIPAA Authorization; SOPs; disposal of PHI in secure containers; ISO/PO review for one protocol; affiliate IT equipment on appropriate EIL. CASE CLOSED
112	19	VA Salt Lake City HCS	H	03/26/2012	Remedial actions: Distinction of VA from non-VA human subject research; determinations of minimal risk; use of expedited review procedures; documentation for HIPAA decisions; consistency of SOPs with VHA policy; receipt, storage and dispensing of investigational drugs.
113	19	VA Salt Lake City HCS	R	03/26/2012	Remedial Actions: The RDC to establish SOPs; Develop program objectives; Conduct annual reviews of subcommittees and research programs; Individuals participating in VA research to be officially appointed; and Scopes to Practice to be established. CASE CLOSED.
114	06	Salem	H	03/27/2012	Remedial Actions: Committee approval docs to Research Pharmacy; Direct dispense of study drugs to subjects; all study drugs properly labeled; Reportable events are submitted and reviewed within guidelines; all personnel have scopes of practice; Greater detail of IRB minutes. CASE CLOSED.
115	06	Salem	R	03/27/2012	Remedial Actions: R&DC not use expedited review; R&DC approval to initiate research must not occur prior to final subcommittee approval; IRB and SRS must notify R&DC of project approvals via a written communication; R&DC review manuscripts before publication. CASE CLOSED.
116	08	VA North Florida/ South Georgia HCS	A	03/27/2012	Remedial Actions: Formalize a written policy for DMR subsequent to FCR protocol review; update PHS Assurance; document oversight of animal research at affiliate institution; provide emergency shower and eyewash stations in cagewash area; remediate specific VMU inspection findings.
117	08	VA North Florida/ South Georgia HCS	S	03/27/2012	Remedial Actions: Review and document access records; Document review of multi-disciplinary vulnerability assessment; Ensure annual drills are conducted; Install emergency shower & eyewash stations; Document review of semi-annual chemical inventories; remediate specific laboratory findings.
118	11	Detroit	H	04/02/2012	Remedial actions: Update SOPs; IRB report to MCD UAP, SAE, noncompliance in 5 days; amend template ICD to VHA policies, ensure ICD consistent with protocol; ISO/PO summary reports to IRB; RCO reports to IRB; identify alternates on IRB; minutes in 3 weeks; IRB member missing training. CASE CLOSED.
119	11	Detroit	R	04/02/2012	Remedial Actions: SOPs and RDC minutes to be updated to comply with VHA policies; RDC to review meeting and quorum requirements; RDC to fully satisfy requirements of annual Quality Assurance reviews; RDC rosters to be updated to reflect current membership. CASE CLOSED.
120	18	Phoenix VA HCS	I	04/03/2012	Remedial Actions: Limit access to folders account for non-VA IT; revise noncompliant HIPAA Authorization; remediate unauthorized disclosure; separate ICF and HIPAA; revise Privacy Policy; stop requests for SSN by phone; ensure timely ISO review; revise records retention language. CASE CLOSED
121	12 NE	James A. Lovell Federal Health Care Center	H	04/16/2012	Remedial Actions: Update SOP procedures to include FWA, MOU and IRB registrations; investigational drug logs not overseen by licensed physician; expired IRB appointment letters. CASE CLOSED

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122	12 NE	James A. Lovell Federal Health Care Center	R	04/16/2012	Remedial Actions: Form appropriate Research Safety Subcommittee; document committee discussions; update process for finalizing committee minutes; update MOU and SOPs; monitor training; appoint committee members; and document ISO protocol reviews. CASE CLOSED
123	16	New Orleans	H	04/17/2012	Remedial Actions: Obtain LOU for affiliate research pharmacy; VA PIs must provide documents to research Pharmacy; Revise ICD text to conform with VA Policy; Review non-Vet recruitment; ISO PO must review IRB studies; ensure all IRB approval criteria are met; apply exemption criteria. CASE CLOSED.
124	16	New Orleans	R	04/17/2012	Remedial Actions: Require the IACUC & SRS to provide written and signed notification of project approvals; not use expedited review; fully satisfy annual review of subcommittee; maintain R&DC SOPs; meet VHA membership requirements.
125	22	VA Long Beach HS	H	05/07/2012	Remedial Actions: Facilitate ISO/PO reviews; No cold calling of prospective subjects; Ensure consistent use of injury language in ICDs; Reconcile pharmacy & Research Office records; Update SOPs. Form for offsite research approved/implemented; IND spreadsheet developed; SOP revised. Case Closed.
126	22	VA Long Beach HS	R	05/07/2012	Required Actions: Develop program objectives; Complete and document annual program and subcommittee reviews; Appoint eligible members to R&DC; Discontinue use of expedited approval procedures; Ensure protocol relevance to VA mission; and Establish Scopes of Practice for all staff. CASE CLOSED.
127	03	VA New Jersey HCS	I	05/14/2012	Remedial Actions: VASI on unencrypted CDs; VASI on non-VA audio recorder; affiliate IT equipment on appropriate EIL; incomplete documentation of waivers of HIPAA Authorization; SOPs; inaccurate deidentification of data; incomplete documentation of ISO and PO reviews; training lapses
128	12	Milwaukee	H	05/15/2012	Remedial Actions: Provide WOC appointment for non-affiliate IRB members; comply with SAE reporting timelines; provide documentation of justification for use of non-veterans. CASE CLOSED
129	12	Milwaukee	R	05/15/2012	Remedial Actions: ACOS/R to perform annual QA of publications/CRADAs; RDC to perform annual evaluation of subcommittees including CIRB and send summary to MCD; RDC to approve final subcommittee minutes; RDC minutes to comply with attendance requirements. Remedial actions complete. CASE CLOSED.
130	21	VA Northern California HCS	H	06/04/2012	Required Actions: Use VA ICDs with all required elements, medical record flagging, justification for inclusion of non-Veterans, and PO/ISO review; reevaluate study risk; ensure research stops when studies expire, require training and VA appointments; maintain an IND study list; comply with R
131	21	VA Northern California HCS	R	06/04/2012	Remedial Actions: Approve all research engaged by the facility; QA review of CRADAs; RDC must re-review MOUs; ensure all staff have appropriate VA appointments, scopes of practice, credentialing and training; maintain program records; and conduct and report the outcome of required audits.
132	04	Philadelphia	H	06/11/2012	Remedial Actions: Revise HIPAA templates; Recuse Vice-Chair IRB 1 from vote on COE studies; Re-review all international research studies; Request ORD Off-Site Tissue Bank Waiver. CASE CLOSED.
133	04	Philadelphia	R	06/11/2012	Remedial Actions: Revise organization chart; Complete Annual Reviews of Subcommittees; Re-review exempt protocols; ACOS notifications to PI; Appointment letters for Committee members; IACUC Self-assessments review with MCD; Appoint Chemical Hygiene Officer to RSS; Annual review of pubs.; SOP compliance. CASE CLOSED
134	06	Asheville	H	06/19/2012	Remedial Actions: None as no regulatory or policy concern identified. Final report sent. CASE CLOSED
135	06	Asheville	R	06/19/2012	Remedial Actions: Provide an accurate vote count in RDC meetings; follow their R&DC SOP. CASE CLOSED.

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136	16	Fayetteville	H	06/19/2012	Remedial Actions: 1. Revise IRB MOU to reflect current VISN Director and IOs at both facilities and to comply with current VHA research policy. CASE CLOSED.
137	16	Fayetteville	R	06/19/2012	Remedial Actions: Conduct annual evaluation of the IRB; Revise R&DC SOP to describe all recurring processes.
138	01	Togus	I	06/19/2012	Remedial Actions: Unsecured PHI in a defective collection container; incomplete waivers of HIPAA Authorization; SOPs; inaccurate de-identification of data; Awareness of Records Control Schedule CASE CLOSED
139	23	VA Nebraska/West Iowa HCS	S	06/19/2012	Required Actions: Establish research-specific plans; review research safety plans annually; conduct annual drills to test effectiveness research-specific plans; document semiannual chemical inventory review; ensure affiliate oversight; establish SOP for reporting; establish BSL-3 lab safety plan.
140	23	Minneapolis	H	06/25/2012	Remedial Actions: IRB Chairs to review and sign approval notices; ICD templates to have all VHA requirements; Pharmacy SOP needs additions; PIs to submit documents to Research Pharmacy; RCO can't be designated as voting/non-voting IRB member; IRB chairs to be appointed in 1 year terms. CASE CLOSED.
141	23	Minneapolis	R	6/25/2012	Remedial actions: RDC continuing review of protocols; RDC vote on final RDC minutes; RDC/ACOS review of manuscripts and publications. CASE CLOSED.
142	20	Portland VAMC	H	07/16/2012	Remedial Actions: Discontinue noncompliant administrative approval; communicate expedited review category in letters to PIs; specify, in appointment memoranda, status of alternate IRB members; ensure presence of a VA representative during affiliate IRB review of VA research. CASE CLOSED.
143	20	Portland VAMC	R	07/16/2012	Remedial Actions: Use definition of VA research; satisfy annual QA requirements; review of CRADAs, MOUs, and subcommittees; all personnel have appointments; oversee protocols not meeting criteria for assignment to any subcommittee; and SOPS for recurring processes. Actions completed case closed.
144	02	Bath	H	07/23/2012	Remedial Actions: Update membership on IRB to meet VHA Handbook 1200.05 requirements. CASE CLOSED
145	02	Bath	R	07/23/2012	Remedial Actions: Update Organization Chart; conduct all required annual reviews in full; conduct quality assurance reviews of publications; maintain administrative files for all human subject research protocols; records R&DC meeting vote counts accurately
146	02	Canandaigua	H	07/23/2012	Remedial Actions: Revise HIPAA Authorization template to include required language; Re-review study performed at a detox facility using non VA ICD and HIPAA authorization; educate investigators on need of CRADO waiver to conduct children research; document PO and ISO reviews of all active protocols
147	02	Canandaigua	R	07/23/2012	Remedial Actions: Update Organizational Chart; Update and revise MOU between Syracuse VAMC and Canandaigua VAMC; R&DC must conduct annual review of all its subcommittees; ACOS/R&D must conduct an annual quality assurance review of publications; Meeting minutes must accurately reflect vote summaries
148	15	VA Kansas City Medical Center	I	07/23/2012	Remedial Actions: Limit folder access; inventory IT; revise HIPAA and make consistent w/ICD; HIPAA waiver for subject recruitment; correct de-identification code; ISO review in SOP; PO review exempt studies; PO report to IRB; PO review backlog; incident reporting SOP; record retention SOP correction
149	07	Augusta	H	07/24/2012	Remedial Actions: Research must notify PI when approval expires; ICD must contain all required elements; POC must sign and date ICD; PIs maintain master list; IRB minutes document determinations; No data collection after Authorization revoked; Research can't manage RCO

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150	07	Augusta	R	07/24/2012	Remedial Actions: Chair can't be a WOC; ACOS can't chair subcommittee; No expedited review; ACOS must provide written notification to PIs; R&DC complete annual reviews of subcommittees; No electronic voting; Subcommittees complete required activities; satisfy requirements of annual quality reviews.
151	23	St Cloud	H	7/24/2012	Remedial actions: Update SOPs to include need for IRB Chair/designated reviewer approval of exempt research. Amend Scopes of Practice forms to include approval by Research Coordinator(AO). CASE CLOSED.
152	23	St Cloud	R	7/24/2012	Remedial Actions: None required; no regulatory or policy concerns identified. CASE CLOSED.
153	06	Hampton	I	08/13/2012	Remedial Actions: Ensure HIPAA authorizations or documented waivers for all research use of PHI
154	23	Sioux Falls	A	08/21/2012	Remedial Actions: Ensure IACUC documentation and assessment of annual overheat test; remove extension cord; removed locking mechanism on emergency exit; replace threshold on exterior emergency exit door.
155	23	Sioux Falls	S	08/21/2012	Remedial Actions: Conduct annual drills to assess research-specific security plan; SRS review of drill results conducted to assess effectiveness of research-specific plans; SRS review of multi-disciplinary vulnerability assessments; SRS documentation of subcommittee and programmatic activities.
156	15	VA Eastern Kansas (Leavenworth) HCS	H	08/28/2012	Remedial Actions: All Investigator's Research Records must include all required documentation; Research Pharmacy records must contain all required documentation for all investigational drug protocols; PI must implement the protocol within the parameters of the IRB approval. CASE CLOSED.
157	15	VA Eastern Kansas HCS (Leavenworth)	R	08/28/2012	Remedial Actions: Update local RDC and VA CIRB SOPs. CASE CLOSED.
158	20	Boise VAMC	H	09/10/2012	Remedial Actions: Revise and update HRPP SOPs; ensure required representation to IRB of record; require use of photographs or video/voice recordings consent form; PO conduct required reviews.
159	20	Boise VAMC	R	09/10/2012	Required Actions: Conduct annual review of subcommittees, programs, of IRB exempt research; establish and implement SOPs for all recurring and required processes; review and approve subcommittee minutes; remove ineligible voting members from the R&DC; and ensure individuals have VA appointments.
160	08	Bay Pines	R	9/17/2012	Remedial Actions: Revise R&D organizational chart; R&DC not to use expedited review procedures; and complete annual program reviews. CASE CLOSED.
161	08	Bay Pines	H	9/17/2012	Remedial actions: IRB SOP revision; ICD template revision, correctly use and document of expedite review procedures; obtaining authorization for recruitment; and correctly record recusals in minutes. CASE CLOSED.
162	02	Syracuse	I	09/24/2012	Remedial Actions: Unsecured shred bins with exposed VASI; unsecured PHI in an interview room; EILs; unencrypted VASI on CDs; HIPAA Authorization template missing required element; incomplete waiver of HIPAA Authorization; ISO review; SOPs; undocumented research data repository
163	03	VA New York Harbor HCS	H	10/01/2012	Remedial Actions: Review and revise HRPP SOP to be consistent with VA policies; revisit IRB approval expired protocols to ensure research activities not conducted during lapse period; make draft minutes available for review within 3 weeks of the meeting; committee members complete required training.
164	03	VA New York Harbor HCS	R	10/01/2012	Remedial Actions: Document R&DC activities in minutes; ensure approvals are granted only after all committees have approved project; ensure committee Chairs are appointed for appropriate term; conduct continuing reviews on all exempt protocols; ACOS/R&D letter to PI state research can be initiated.

Case	VISN	Facility	Focus	Date of Review	TABLE 2. ROUTINE (PROACTIVE) ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
165	11	Indianapolis	H	10/02/2012	Remedial Actions: Appoint VA representatives to all IRBs of record; IRB roster to identify members and each alternates; HIPAA waivers to be requested and approved prior to CPRS data mining; grant Category #4 exemptions properly; ensure compliant forms, templates, and records destruction language.
166	11	Indianapolis	R	10/02/2012	Remedial Actions: RDC must conduct continuing reviews of IRB exempt protocols; RDC must separate VA from non-VA research; RCO may not be a member of the SRS and IACUC; there must be an accurate protocol list; must update ORO of all IRB changes within 30 days.
167	22	VA Loma Linda HS	I	10/15/2012	Remedial Actions: waiver of HIPAA authorizations for recruitment from VA records; document al HIPAA authorization waivers; encrypt all laptops.
168	12	Madison	A	10/23/2012	Remedial Actions: Ensure properly constituted IACUC; establish an MOU with affiliate; establish local SOP on reporting; report and document annual overheat test; report in the semiannual program review departures from guidelines; adhere to the triennial de novo reviews of protocols
169	12	Madison	S	10/23/2012	Remedial Actions: Establish an MOU with affiliate; ensure that access records are reviewed weekly; ensure that the status of personnel with access to labs are reviewed semi-annually; ensure semi-annual inventory of hazardous chemicals; establish SOP on reporting
170	07	Atlanta	H	11/05/2012	Remedial Actions: IRB review criteria for expediting CR studies; ensure risk determination documented; IRB SOP update and revisions; apply for CRADO waiver; revise ICD template language.
171	07	Atlanta	R	11/05/2012	Remedial Actions: Revise system and review exempt protocols; ensure PO and ISO reviews submitted to committees; revise SOPs; complete annual reviews of subcommittees and quality reviews; re-assess RCO functions.
172	17	VA Central Texas HCS	I	11/05/2012	Terms for VA information on external systems; list affiliate IT equipment; correct HIPAA template, authorizations, SOPs (HIPAA waivers, 1058.01 reporting; study approval), waiver requests, privacy policy, records retention, repositories; direct ISO/PO reports; retain original records.
173	09	Lexington	H	11/06/2012	Remedial Actions: maintain investigational drug list; provide electronic copy to the Pharmacy service; verify exemption categories; document materials and participation of all members in meeting minutes for IRB teleconferences; maintain current and previous membership rosters. Case closed.
174	09	Lexington	R	1/06/2012	Remedial actions: SOPs must be developed for all RDC subcommittees. CASE CLOSED.
175	07	Augusta	I	12/03/2012	Remedial actions: Unencrypted VA laptop w/o waiver; Personal laptops onsite for research w/o permission; EILs; HIPAA Authorization template missing required elements; incomplete or non-existent waiver of HIPAA Authorizations; PO review; SOPs; undocumented research data repository
176	17	VA South Texas HCS	A	12/04/2012	Remedial Actions: Establish procedures for reporting noncompliance; ensure that deviations are scientifically justified; update whistleblower policy; ensure that all IACUC members participate in the Occupational Health Program
177	17	VA South Texas HCS	S	12/04/2012	Remedial Actions: review of weekly access records; establish procedures for reporting; semiannual inventory of hazardous chemicals; document the multidisciplinary vulnerability assessment; SRS membership; review the research security plan; establish an MOU for the use of the IBC
178	04	Wilkes-Barre	R	12/12/2012	Remedial Actions: Harmonize local policy with regulations, conduct all aspects of annual reviews, proper committee procedures (vote count, quorum). CASE CLOSED.

TABLE 3. ONSITE REVIEWS OF BIOSAFETY LEVEL 3 (BSL-3) RESEARCH LABORATORIES

ORO conducts routine and for-cause onsite safety and security reviews/inspections at the nine VA facilities operating BSL-3 research laboratories. Inspections may be either announced or unannounced. Where deficiencies are identified, ORO requires that the facility develop a remediation plan and monitors implementation of the plan until remediation is complete.

Summary

- 6 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- 1 = New Cases – April 1 through June 30
- 0 = New Cases – July 1 through September 30
- 0 = New Cases – October 1 through December 31
- 1 = New Cases in Calendar Year
- 7 = Total Cases (Continuing Plus New) in Calendar Year

Case	Region	Date of Review	TABLE 3. ONSITE REVIEWS OF BSL-3 RESEARCH LABORATORIES (FULL REPORT AVAILABLE UPON REQUEST)
1	Midwest	February 2012	Remedial actions: Verify operational functionality annually; evaluate personnel access status semi-annually; review security plan annually; correct programmatic deficiencies promptly; document meeting activities fully. CASE CLOSED
2	Northeast	October 2010	Remedial actions: SOPs for inventory software, anesthesia of rodents for sample collection; reporting noncompliance; R&DC review of applicable SOPs per local requirements. CASE CLOSED
3	South	April 2011	Remedial Actions: Verify BSL-3 facility design and operational parameters on annual basis; annual review of BSL-3 safety, security, and emergency response SOPs; annual drills to evaluate the BSL-3 safety, security, and emergency response; post appropriate signage to entrances of labs.
4	Northeast	June 2011	Remedial Actions: Propagate M. tuberculosis cultures under BSL-3 containment; decontaminate Powered Air Purifying Respirator prior to removal from BSL-3 lab; install hands-free operated washing sink in D-305; install ANSI compliant eyewash in labs.
5	Northeast	September 2011	Remedial Actions: Modify BSL-3 ventilation system to provide sustained negative directional airflow; install ANSI-compliant eyewash.
6	West	November 2011	Remedial actions: Weekly review of facility egress records for the BSL-3; appropriate containment for centrifuge in BSL-3 laboratory; laboratory signage to include biosafety level and other relevant information. CASE CLOSED.
7	South	May 2012	Remedial actions: No remedial actions were identified. CASE CLOSED

TABLE 4. ONSITE TECHNICAL ASSISTANCE REVIEWS

ORO onsite technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Summary

- 3 = Cases Continuing from Previous Calendar Year
- 11 = New Cases – January 1 through March 31
- 6 = New Cases – April 1 through June 30
- 7 = New Cases – July 1 through September 30
- 15 = New Cases – October 1 through December 31
- 39 = New Cases in Calendar Year
- 42 = Total Cases (Continuing Plus New) in Calendar Year

Case	VISN	Facility	Focus	Date of Review	TABLE 4. ONSITE TECHNICAL ASSISTANCE REVIEWS
1	15	St Louis	H	12/13/2011	Remedial actions: Complete required training; prepare training and follow up audit plan for study staff; approval of study amendment by CIRB. Remedial actions complete. Case closed.
2	23	Minneapolis	E	12/14/2011	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
3	08	VA Caribbean HCS	H	12/14/2011	Remedial actions: Completion of the 100% re-review of the research portfolio, review and approval of the IRB SOP. CASE CLOSED
4	01	VA Boston Healthcare System	E	01/10/2012	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED.
5	10	Cleveland	E	01/24/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED

Case	VISN	Facility	Focus	Date of Review	TABLE 4. ONSITE TECHNICAL ASSISTANCE REVIEWS
6	21	VA Northern California HCS	R	01/24/2012	Technical assistance provided regarding the content of the R&DC SOP and related documents, R&DC review and approval requirements for individual projects, R&DC review processes for programmatic oversight, and procedures related to the management of research.
7	08	VA Caribbean HCS	E	01/27/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
8	17	VA North Texas HCS	E	1/28/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan and progress on 2011 triennial human subjects' auditing requirements. CASE CLOSED
9	09	Lexington	P	02/02/2012	Technical assistance visit on-site to review HRPP and RDCP, documentation in the IRB meeting minutes, recusals of members with conflicts of interest, maintenance of quorum, and ongoing mentoring.
10	18	New Mexico VA HCS	E	02/08/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
11	21	VA Northern California HCS	R	02/13/2012	Provided Technical Assistance regarding the ongoing need for specific R&DC and program policies and SOPs, and the historical context concerning the addition of specific policy statements following previous ORO Routine and For-cause reviews. CASE CLOSED.
12	07	Birmingham	S	02/14/2012	Technical assistance: Review of VHA Handbooks 1058.01, 1200.06 and 1200.08; review of VHA Directive 2009-026; regulatory requirements, RCO audit requirements, relationship between VA and affiliate institutions and use of MOUs. CASE CLOSED
13	16	Houston	E	02/28/2012	Technical Assistance Visit: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED.
14	08	Bay Pines	E	03/20/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
15	09	Lexington	E	04/10/2012	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed auditing plan and progress on 2012 triennial human subjects' auditing requirements. CASE CLOSED.
16	17	VA South Texas HCS	E	04/23/2012	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan and progress on triennial human subjects' auditing requirements. CASE CLOSED
17	23	Sioux Falls	E	05/16/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
18	23	VA Nebraska/ West Iowa HCS	A	6/19/2012	Technical Assistance: Document IACUC review and assessment of annual overheat test; document IACUC review of deviations from the Guide during semi-annual program evaluations and reports submitted to the Institutional Official; Add biological indicator test to sterilization QA processes. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 4. ONSITE TECHNICAL ASSISTANCE REVIEWS
19	08	VA Caribbean HCS	E	6/20/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED.
20	22	VA Southern Nevada HS	P	06/20/2012	Technical assistance: ORO recommends new MOU between VALLHCS and VASNHS for use of the VALLHCS IRB and RDC; clearly defined roles for the VASNHS ACOS/R and PO; IRB members should receive additional human subjects protection training; RCO should have access to electronic IRB records. CASE CLOSED.
21	01	Providence	H	08/08/2012	Technical Assistance: Research engagement; limited data sets vs. de-identified data human biological samples; IRB determination of non-human subject research and exempt categories of human subjects research; oversight by SRS and R&DC for exempt studies. CASE Closed.
22	07	Atlanta	E	08/14/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan. CASE CLOSED
23	07	Atlanta	E	08/15/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan. CASE CLOSED
24	18	Phoenix VA HCS	M	08/21/2012	Technical Assistance: The Federal Policy on Research Misconduct; VHA Handbook 1058.2 ("Research Misconduct"); and applicable sections of VA Handbook 0700 ("Administrative Investigations"). CASE CLOSED.
25	22	VA San Diego HS	E	08/28/2012	Technical Assistance: To review audit plan, SOP, and research program interpersonal communications with the RCO. CASE CLOSED
26	17	VA Central Texas HCS	E	09/19/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan and progress on triennial human subjects' auditing requirements. CASE CLOSED
27	11	Detroit	M	09/25/201 2	Technical Assistance: The Federal Policy on Research Misconduct; VHA Handbook 1058.2 ("Research Misconduct"); and applicable sections of VA Handbook 0700 ("Administrative Investigations"). CASE CLOSED.
28	18	Southern Arizona VA HCS	H	10/15/2012	Technical Assistance: Implementation of policies and procedures relating to the forming of an internal IRB. CASE CLOSED
29	20	Boise VAMC	E	10/16/2012	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
30	08	Orlando VAMC	H	10/23/2012	Technical Assistance: SOP and template revisions; documentation of IRB meetings. CASE CLOSED.
31	08	Orlando VAMC	R	10/23/2012	Technical Assistance: R&D organizational chart and SOP revisions. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 4. ONSITE TECHNICAL ASSISTANCE REVIEWS
32	07	Columbia	E	11/06/2012	Technical Assistance conducted with final Onsite TA Visit Report issued on November 14, 2012. CASE CLOSED
33	21	VA Sierra Nevada HCS	E	11/15/2012	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
34	03	VA New York Harbor HCS	P	11/19/2012	Technical Assistance: key issues addressed were improved IRB processes incl. voting practices, timely IRB minutes, expedited review of amendments with minor changes; education re: risk assessment; improved PO and ISO review process; improved protocol continuing review process.
35	03	VA New York Harbor HCS	R	11/26/2012	Technical Assistance: Key issues addressed, R&DC meeting organization; priorities for committee. review and discussion; MOU review responsibilities; actions requiring voting.
36	05	DC VAMC	E	11/29/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan and progress on 2011 triennial human subjects' auditing requirements. CASE CLOSED
37	03	VA New York Harbor HCS	P	12/10/2012	Technical Assistance: IRB disaster recovery after Hurricane Sandy, IRB oversight, procedures and processes. CASE CLOSED
38	08	Orlando VAMC	E	12/13/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan and progress on 2011 triennial human subjects' auditing requirements.
39	03	VA New York Harbor HCS	P	12/17/2012	Technical Assistance: R&DC Membership, R&DC oversight, procedures and processes, research staff tracking of committee actions. CASE CLOSED.
40	22	VA San Diego HS	H	12/19/2012	Technical Assistance. Advice provided regarding: the IRB and R&DC SOPs; the management/documentation of IRB activities; R&DC program oversight; electronic portfolio management (IMedRis); and additional topics presented by the ACOS/R. CASE CLOSED
41	01	Manchester	P	12/20/2012	Technical Assistance. Guidance provided regarding: the R&DC responsibility and authority; R&DC SOPs; the management/documentation of research review activities; R&DC program oversight; and additional topics requested by the MCD. CASE CLOSED
42	20	VA Puget Sound HCS	E	3/26/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, evaluated and addressed current auditing plan and progress on 2011 triennial human subjects' auditing requirements. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Certain compliance cases can be evaluated and managed remotely through written communications with facility leadership and facility compliance personnel. Among these reviews are remote reviews of apparent noncompliance that have been identified by sources external to the facility's HRPP. Such sources include, but are not limited to, apparent noncompliance identified by ORO, by other VA offices, by government regulatory agencies, and by industry sponsors. Table 5 summarizes ORO's remote reviews of apparent noncompliance identified by such external sources. NOTE: Cases under the jurisdiction of additional offices (for example, OIG or FDA) or involving physical infrastructure improvements may remain open for extended periods.

Summary

- 22 = Cases Continuing from Previous Calendar Year
- 48 = New Cases – January 1 through March 31
- 30 = New Cases – April 1 through June 30
- 40 = New Cases – July 1 through September 30
- 52 = New Cases – October 1 through December 31
- 170 = New Cases in Calendar Year
- 192 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	07 MA	Atlanta	I	06/16/2010	ORO was notified that a physician's assistant recorded patient data on a personal laptop for unknown purposes; then left the VA. Data return was requested. Destruction of the information could not be confirmed.	Remedial Actions: OIG criminal investigation; results pending.
2	22	VA San Diego HS	I	08/23/2010	ORO found that VASI and research data and records for 4 alcohol/alcoholism VA studies may have been destroyed (in violation of the records retention policy), disclosed, and/or relocated without authorization when PI left the VA and moved the studies to the academic affiliate.	Remedial Actions: Inventory of all records generated for the 4 VA studies; no definitive inventory of what remains in possession of affiliate; return of some original documents to VA; PO assessment of privacy risk; ORD, VHA Privacy, and OGC to follow-up as necessary. CASE CLOSED
3	12 NE	Hines	H	06/03/2011	RIPP Associate Director notification of possible non-compliance in study of educational materials for spinal cord injured veterans. Facility IRB apparently approved a verbal HIPAA Authorization for mobility impaired SCI patients.	Remedial actions: NERO inquiry underway. Remedial actions pending review of facility reply to inquiry. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
4	04	VA Pittsburgh HCS	I	10/20/2011	NSOC reported disclosure of audio recordings of 17 Veteran subjects to a non-Va employee through unencrypted email. Facility also reported incident to the NERO. Case linked to NERO DSS# 0081-646-H because NERO will provide primary oversight of incident.	Remedial actions: This practice is no longer taking place; the recordings have been deleted; staff education on proper information handling. CASE CLOSED
5	06	Durham	I	10/25/2011	NSOC reported a Research Assistant WOC employee removed full name/SSN, address, phone number (9 Veterans) from VA to affiliate; asked non-study student to make calls. Purpose recruitment in PTSD, addiction study, but protocol states recruitment at VA. Primary issues HRPP; SRO to open/manage H case.	Remedial actions: Documents were securely shredded; recruitment voluntarily suspended; staff reeducation on protocol adherence and importance of veteran's privacy; IRB determined PI will reassess and rewrite SOPs that would synchronize with facility SOPs and policies. CASE CLOSED
6	22	VA San Diego HS	I	11/03/2011	NSOC reported theft of a backpack belonging to a research WOC employee. The backpack contained forms with PII of three Veterans enrolled in a prostate cancer study.	Remedial actions: Three veterans were informed of the breach and offered credit protection services. CASE CLOSED
7	07	Tuscaloosa	H	11/14/2011	Anonymous Report--a terminated employee alleged that a Study Coordinator was added to three protocols without IRB Approval, scope-of-practice, or credentialing.	Remedial Actions: RCO to review protocols to ensure all study staff appropriately added, credentialed and have scopes. CASE CLOSED
8	06	W.G. (Bill) Hefner VA Medical Center	I	11/16/2011	NSOC reported electronic entry of incorrect SSN on a VA ICD and HIPAA authorization form that was subsequently signed by the Veteran intended to be enrolled. The Veteran did receive a copy of the form with another Veteran's SSN (deceased) and has stated he will return the forms to the VA.	Remedial actions: Veteran A returned the paperwork containing deceased Veteran B?s PHI, completion of enrollment paperwork by the correct veteran; Counseling, retraining and oversight of new research employee; CIRB determined no further action required beyond actions taken. CASE CLOSED
9	20	VA Puget Sound HCS	I	11/21/2011	NSOC reported vulnerability in what was thought to be a secure email system between the VA, an affiliate research institution and possibly 25 other sites related to bone marrow transplant studies. Research protocols permit transmission by fax not via email/list serv. AIB determined no breach of VASI	Remedial Actions: Affiliate immediately inactivated the listserv; AIB completed; transmit VASI by email only with encryption; improve information security/privacy training for research staff; increase RCO staff; enhance PO/ISO audits; prepare new MOU with affiliate.
10	06	Durham	H	11/22/2011	Study sponsor identified potential genetic abnormalities from study drug treating peripheral artery disease. Drug permanently discontinued and all subjects monitored. 5 subjects at site were on the drug.	Actions: Discontinue drug administration; Unblind subjects; Long-term monitoring for effects. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
11	11	Indianapolis	H	11/23/2011	For cause review remote as a result of MWRO noticing a possible pattern of VHA Handbook 1058.01 noncompliance by the affiliate IRB in terms of how apparent noncompliance is reviewed and the timelines of their reporting.	Remedial actions: Submission of a systemic noncompliance report with regards to affiliate IRB review and reporting of noncompliance reports; joint review by VA and affiliate as to IRB processes and procedures. Remedial actions completed. CASE CLOSED.
12	20	VA Puget Sound HCS	H	12/01/2011	DSMB report to facility providing notification of suspension of one treatment arm of a Phase 3 prostate cancer study due to higher toxicity rate (other arm remains open); more information from sponsor to follow.	Remedial actions: Local enrollees contacted, study drug discontinued, standard care continued; IRB approval of study continuation without suspended treatment arm; sponsor-directed modification of protocol and ICD.
13	06	Hampton	H	12/05/2011	Privacy Compliance Assurance review discovered a lack of HIPAA waiver for an exempt retrospective chart review of antipsychotic medication adherence. The missing waiver was discovered shortly after initiation of data collection.	Remedial Actions: HIPAA Waiver obtained for data going forward; IRB to approved use of data previously collected; Facility revised IRB review & approval checklists: Revised OP & ISO checklist: RCO to conduct a final QA of documents. CASE CLOSED
14	11	Indianapolis	I	12/05/2011	NSOC reported unencrypted transmission via email and fax of research subject logs containing VA patient PII to the affiliate without valid HIPAA Authorization. Number of Veterans affected was 167.	Remedial actions: Data transmissions were stopped immediately upon discovery; affiliate will de-identify data currently in system; affiliate will no longer receive patient identifiable data; RCO to monitor action plan. CASE CLOSED
15	18	New Mexico VA HCS	I	12/09/2011	NSOC reported transmission of an internal unencrypted email with attachments containing unredacted PHI. The document received unredacted was subsequently destroyed.	Remedial actions: Employee self-reported; employee reminded to use encryption or only send redacted copies; IRB staff and employee removed unencrypted email from mailboxes; clarified that email was not internal; facility has clear procedures to send PHI to affiliate IRB. CASE CLOSED
16	06	McGuire (Richmond)	H	12/12/2011	Sponsor of gene therapy for Crohn's Disease notified site of external drug reactions and discontinued high dose (4 units) but continued the low dose (1 unit)- enrollment suspended until protocol amended. No local SAE's.	Remedial actions: Protocol amendment; Single subject reconsent; Enrollment suspended; No additional dosing. Sponsor final decision to close study drug arm. CASE CLOSED
17	01	Providence	H	12/15/2011	Study of veterans in persistent vegetative states is monitoring distance recruitment procedures for veteran who is from a vulnerable population.	No non-compliance. CASE CLOSED
18	21	VA Northern California HCS	H	12/16/2011	Sponsor/monitor identified noncompliance; a research subject received an excluded concomitant medication while on protocol	IRB review determined the noncompliance was unanticipated and study related, but not serious. The IRB directed the PI to remove the Co-PI, sign all CPRS progress notes, ensure that procedures are conducted by qualified personnel. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
19	12	Madison	H	12/22/2011	Continuing and serious noncompliance discovered during an affiliate protocol audit; one previous incident involving a VA subject in which lab work was missing was determined not to be serious/continuing noncompliance.	Remedial actions: 3 month audit of study team's work; report of self-audit by study team; report of the audit findings that have been reported to the IRB; staff training; proposal on future study management. CASE CLOSED.
20	00	VA Central Office	H	12/22/2011	Funds for CIRB-approved, NIH-sponsored SPRINT study (blood pressure intervention trial) were transferred through VA to the primary VA facility and being administered by its NPC. The NPC engaged in the research without the required IRB oversight.	Remedial Actions: Assess engagement of NPCs; develop MOU for IRB oversight; Brief VHACO Institutional Official; IRB determined issue did not involve noncompliance.
21	03	VA Hudson Valley HCS	H	12/27/2011	SMART Audit of a mental health study found that copies of signed ICD and HIPAA were not given to 23 subjects immediately following the consent process.	Remedial Actions: Copies of ICD and HIPAA distribution to the enrolled subjects; Have a process in place to ensure all future participants receive copies immediately following consent; Staff review 1200.05 and receive additional hands on training in the consenting process CASE CLOSED
22	20	VA Puget Sound HCS	H	12/28/2011	NSOC reported noncompliance case involving DNA testing on samples containing PII without informed consent. ORO CO RIPP team requested that WRO manage this HRPP case.	Remedial actions: PI instituted a QA plan to ensure that DNA testing is only performed with consent; the IRB determined that the event was not serious and did not pose risk to subjects.
23	06	McGuire (Richmond)	H	01/06/2012	Sponsor of new diabetes drug notified site of enrollment suspension due to lack of efficacy and increased adverse events. 6 locally enrolled, 5 finished study, 1 off study drug in follow-up. Two events of syncope (only one possibly related) no other SAE's.	Remedial Actions: Consent form revised; Subject letter sent; Only subject completed study so reconsent not required; Enrollment reopened. CASE CLOSED
24	17	VA Central Texas HCS	H	01/06/2012	Multiple protocol deviations (inadequate documentation of study-specific activities) determined to be serious but not continuing.	IRB review and acceptance of investigator corrective actions, with a requirement for supplemental oversight - quarterly reports for the next two quarters. CASE CLOSED
25	10	Cincinnati	H	01/09/2012	FDA terminated an IND study due to non-submission of required annual reports to FDA; removal of red blood cells (RBCs) from the study subject, labeling the cells with biotin in vitro and then re-infusing the labeled cells back.	Remedial actions: IND termination by FDA; PI suspended all subject research activities; Review by Affiliate IRB Chair, Research Compliance, General Counsel. IND application resubmitted to FDA. PI corrective action plan reviewed. Study suspended on Clinical Trials website. CASE CLOSED
26	23	Minneapolis	H	01/09/2012	NSOC reported Misused Physical or Verbal Information. Researcher published one subject's name and diagnosis in a publication named VA Research Currents (Dec. 2011/Jan 2012)without appropriate signed authorization.	Remedial actions: PI education. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
27	06	W.G. (Bill) Hefner VA Medical Center	I	01/11/2012	NSOC reported loss of one HIPAA Authorization and two other documents due to damage of United Parcel Service (UPS) package during shipment. It was subsequently determined that two Veteran's HIPAA Authorizations with names and full SSNs were missing.	Remedial actions: UPS issued claim number for damaged package; letter of notification with offer credit protection services mailed to two Veterans; cease including SSNs on mailed documents. CASE CLOSED
28	06	Durham	I	01/19/2012	NSOC reported unencrypted transmission of email from VA to PI's account at the affiliate. The email contained a file with 68 names and SSNs and was deleted within 5 minutes. Affiliate employs up to date firewalls, anti-virus measures and Windows updates at least monthly.	Remedial Actions: Review and revise the research team's data handling procedures; detailed data handling re-training conducted by PI to research staff member who transmitted email. CASE CLOSED
29	16	Houston	H	01/25/2012	Novartis suspended study enrollment due to PBM warning of increased risks found on another related trial of the chronic heart failure study drug. IRB approval of an amended consent form is required before enrollment may resume.	Remedial actions: The one study participant at facility completed treatment five months ago, and the IRB has agreed with the PI's plan to notify the participant by mail.
30	06	McGuire (Richmond)	H	01/26/2012	Sponsor of a Hepatitis C drug study notified all sites of manufacturing quality control issues. Enrollment suspended. All current subjects to continue with existing stocks.	Remedial actions: Enrollment hold; current subjects notified; amendment to modify enrollment. Analysis by sponsor has corrected manufacturing problems. Study to re-open. Subject reconsented. CASE CLOSED
31	22	VA Long Beach HS	I	01/30/2012	NSOC reported transmission of unencrypted information containing PHI outside the VA protected network to two VA patients. The information was sent to the intended recipients.	Remedial actions: Employee counseling training, and application for PKI; verified email remained within VA; email removed from sender and recipient email boxes. CASE CLOSED
32	17	VA South Texas HCS	I	01/31/2012	NSOC reported lost or misplaced research consent form of a non-Va subject. Facility ACOS determined within the 5-day reporting window that the missing ICD was not a VA document. Facility noncompliance report not required.	Remedial actions: Facility confirmed the missing ICD was not a VA document. CASE CLOSED.
33	05	DC VAMC	I	02/01/2012	NSOC reported one Veteran's ICD was missing from a Rheumatoid Arthritis Registry protocol. No misuse has been reported. The report also stated that no media attention is anticipated.	Remedial actions: PI found the misfiled missing ICD within 5 business days; verified by Research Compliance Officer. CASE CLOSED
34	18	New Mexico VA HCS	I	02/01/2012	NSOC reported transmission within the VA of an unencrypted mail containing PII of 14 research participants.	Remedial actions: Remedial training of staff person; deletion of email. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
35	11	Ann Arbor HCS	I	02/02/2012	NSOC reported affiliate research server containing VA research information collected under 5 protocols(first/last name, address) was hacked by an email spambot. DTA and HIPAA Authorizations in place. Investigation revealed no evidence of lost, altered or compromised VA data.	Remedial actions: Close coordination between VAMC and affiliate to assess and resolve issue; more stringent server security controls deployed; IRB authorized PIs to inform subjects of shutdown. CASE CLOSED
36	03	VA Hudson Valley HCS	H	02/03/2012	SMART Monitor audit identified enrollment of a non-veteran employee in a CSP study assessing the genetics of functional disability in schizophrenia and bipolar disorder	Remedial Actions: Re-educating study staff on the inclusion and exclusion criteria; data collected will not be submitted for analysis; PI and staff will undergo training by CSP Coordinator; review of VHA Handbooks for roles and responsibilities of the PI and study staff CASE CLOSED
37	04	VA Pittsburgh HCS	I	02/03/2012	NSOC reported that 527 research solicitation postcards containing Veteran's names and addresses were inadvertently prepared using the affiliate's return address instead of the VA facility. None have been returned as yet. Past postcard return rate have low percentage.	Remedial actions: Addressing error identified and corrected; PI asked local post office to contact them if postcards are located. CASE CLOSED
38	01	VA Connecticut HCS	I	02/06/2012	NSOC reported five completed ICDs and HIPAA Authorizations were missing and are likely misfiled. Subsequently determined 6 were actually missing and that 5 of the 6 documents were found misfiled. PI believes the 6th is also misfiled or inadvertently shredded.	Remedial actions: One Veteran will be offered credit protection services; responsible staff member let go due to disorganization and unreliability; PI improving document storage and organization. CASE CLOSED
39	12 NE	Hines	H	02/07/2012	VA NSOC0546985 A VA Researcher disclosed date of birth information on a VA Patient without proper HIPAA authorization.	Remedial actions: Inadvertent case duplication. CASE CLOSED
40	11	Battle Creek	I	02/08/2012	NSOC ticket initially reported affiliate server had been hacked; this facility is one of three affected VA facilities. If breach did occur, compromised data would include subject first name, phone number and birth year. Investigation revealed no evidence that VA data was lost, altered or compromised	Remedial actions: One or more affiliate servers automatically shut down upon automated intrusion signal; more stringent security controls deployed on server; IRB approved methods to consent and inform subjects of server security breach. CASE CLOSED
41	11	Saginaw	I	02/08/2012	NSOC ticket initially reported affiliate server had been hacked; this facility is one of three affected VA facilities. If breach did occur, compromised data would include subject first name, phone number and birth year; investigation revealed no evidence VA data was lost, altered or compromised.	Remedial actions: One or more affiliate servers automatically shut down upon automated intrusion signal; more stringent security controls deployed on server; IRB approved methods to contact and inform applicable research subjects of the server security breach. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
42	11	Detroit	I	02/09/2012	NSOC reported affiliate research server containing VA research information in a mental health study was hacked by an email spambot originally from Ukraine. Investigations concluded no patients at this facility had been consented into this study.	Remedial actions: Investigations determined no patient information from this facility had been stored on the affected server. CASE CLOSED
43	11	Detroit	H	02/10/2012	ORO was notified that a VA human subject's PHI in a mental health study being released to an off-site location (affiliate) under an invalid HIPAA authorization.	Remedial actions: None at this time. IRB determines event is not considered serious or non-compliance. CASE CLOSED.
44	22	VA Long Beach HS	I	02/13/2012	NSOC reported unencrypted message containing full names, hone phone numbers, gender, age and ethnicity of 3 Veterans who responded to research study fliers. Unencrypted email was sent within VA network and to a PI at the affiliate. No evidence of data breach.	Remedial actions: Responsible staff counseled; confirmation of email deletion; education provided by ISO on VA approved email encryption technologies. CASE CLOSED
45	17	VA North Texas HCS	I	02/13/2012	NSOC reported unencrypted transmission of email containing PHI of 7,500 patients; including date and type of surgery, patient name and full SSN. Transmission path was within VA network. Per subsequent facility report, email was non-research-related.	Remedial actions: Incident was determined to be non research-related and therefore not an ORO case. CASE CLOSED
46	21	VA Northern California HCS	H	02/14/2012	Externally identified SAE (identified by sponsor monitor) reported by facility. A subject in a treatment study for atrial fibrillation experienced atrial fibrillation and required hospitalization. The PI was aware of the event but did not report to IRB as required.	Remedial actions: IRB recommended R&DC evaluate the training standards for clinical research coordinators; PI education that PI has responsibility for reporting SAEs even if has delegated to a study coordinator. Case closed.
47	16	Central Arkansas VHS	I	02/15/2012	NSOC reported transmission of internal unencrypted email related to the Million Vet Program (MVP). One Veteran's home address and full name was contained within the message.	Remedial actions: Sender attempted to recall message but was unsuccessful; email subsequently deleted from recipient's account; employee retraining; PKI transmission of future sensitive information. CASE CLOSED
48	11	Ann Arbor HCS	I	02/16/2012	NSOC reported unencrypted email that include one patient's PHI (full name and telephone #) to other research team members within the VA system and at the affiliate.	Remedial actions: Email deleted from all recipient mailboxes; research team reminded to encrypt messages with sensitive information; staff re-education; development of alternate communication method; revised protocol procedures. CASE CLOSED
49	10	Cincinnati	I	02/16/2012	NSOC reported ISO found a VA employee provided unauthorized electronic access to a new research WOC employee to complete required training and left the WOC employee unattended. Facility confirmed that PHI was not involved.	Remedial actions: WOC employee ceased training and logged off computer; VA employee's service was notified; other actions pending. No PHI involved in incident. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
50	03	VA Hudson Valley HCS	I	02/16/2012	NSOC reported inadvertent transmission of unencrypted internal email containing one Veteran's PHI (DOB, full name and full SSN) for potential enrollment in a CSP mental health study. Recall attempt was successful.	Remedial actions: Recipients delete the message; sender reviewed the Privacy and Freedom of Information Act (FOIA) policies. CASE CLOSED
51	02	VA Western New York HCS	H	02/17/2012	Sponsor-instituted enrollment suspension in a Phase II investigational new drug study of complicated intra-abdominal infections. Suspension due to potential rapid resistance to drug. No subjects enrolled at this facility.	Remedial Actions: Study closed at facility. Although study had obtained IRB approval, no subjects had signed consent forms or enrolled in this study at this facility. CASE CLOSED
52	10	Dayton	H	02/24/2012	Complaint received by VA Office of Inspector General on unauthorized blood draws from an anesthesia study. PI's response was that he had verbal consent from the patients in question.	Remedial Actions: Study suspended; Administrative Investigation Board convened to investigate unauthorized blood draws. CASE CLOSED
53	01	VA Boston Healthcare System	I	02/29/2012	Two non-profit corporation owned servers used for VA research were not located in an OIT controlled FISMA compliant computer room. The ISO determined there was no PHI stored on the servers.	Remedial actions: Servers were relocated to an OIT controlled server room, tagged, and entered into the property accountability system. CASE CLOSED
54	23	Minneapolis	I	03/01/2012	NSOC reported transmission of an internal unencrypted email containing one Veteran's PHI. It was subsequently verified that the email remained within the VA email system.	Remedial actions: PO recommended remedial actions to the individual who made the unauthorized transmission; NSOC ticket was resolved/closed. CASE CLOSED
55	12 NE	Hines	H	03/02/2012	IRB termination of approval in two obesity studies under the direction of the same PI.	CASE CLOSED Remedial Actions: Study terminated. One year sanction against conducting research implemented for this PI. Study was closed, all participants notified.
56	23	Minneapolis	I	03/05/2012	NSOC reported VA researcher sent spreadsheets containing PHI (dates of birth and dates of labs) from his affiliate VA account to the affiliate statistician. The spreadsheet contained data on 3497 subjects.	Remedial Actions: Data removed from affiliate server; sanitization of portable IT equipment; VA and affiliate agreed on a sanitization process of affiliate server space. CASE CLOSED
57	22	VA San Diego HS	H	03/05/2012	NSOC report identified the conduct of unapproved research by a physician who collected data on 367 Veterans. The data was entered on a personal home computer and shared outside of the VA.	Remedial actions: Physician admonished to not use or publish data; and Data returned to VA and/or destroyed. Case Closed.
58	05	DC VAMC	I	03/06/2012	VHA Issue Brief dated 3/6/12 outlined loss of VA Surgical Quality Improvement Program (VASQIP) dataset containing scrambled SSNs and dates of surgery by a facility PI (surgical study of perioperative hyperglycemia). Dataset had been stored on a hard drive which had apparently been destroyed.	Remedial actions: Data destroyed in part due to storage device technical failure; ORO concluded the dataset never left the VA protected environment. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
59	06	Durham	I	03/06/2012	NSOC reported internal unencrypted email containing PHI (zip codes connected to subject IDs) of 2,068 subjects in a post-deployment mental health database study.	Remedial actions: Data immediately deleted from sender and recipient's accounts; sender retraining; email privacy requirement reminders sent to all staff; staff reminded to use share drive instead of data transmissions via email. CASE CLOSED
60	09	Louisville	H	03/06/2012	ORO was notified of pneumonia study suspension due to lack of MCD and CRADO approval for international research. Data security issues may also be an issue. Subsequent RCO For-Cause audit found lapse in RDC review (administrative error).	Remedial actions: Suspension; ISO and PO review of data ownership and disclosures; RCO for-cause regulatory audit; RDC to use tracking system that automatically notifies staff of annual review date; PI receive renewal packet 30 days prior to expiration; RCO to monitor further incidents. CASE CLOSED
61	09	Louisville	H	03/07/2012	For-cause review remote as a result of noncompliance reporting and review issues discovered during a routine, on-site HRPP review. Timelines for reporting and review of the reports were not compliant with VHA Handbook 1058.01.	Remedial actions: IRB determined noncompliance was not serious or continuing; CASE CLOSED.
62	06	McGuire (Richmond)	H	03/07/2012	Sponsor of Hepatitis. C study drug instructed facilities to stop using the two highest doses and only use the lowest. One participant at the facility was switched with no adverse events reported.	Remedial actions: Dosage modification for one facility subject; protocol amendment to implement additional safety reporting for all enrolled subjects; additional monitoring along with a stopping rule. In addition, sponsor is requiring additional safety labs at W8 and W10. CASE CLOSED
63	06	McGuire (Richmond)	H	03/08/2012	Sponsor notified site that Hepatitis C study drug causing unacceptable raised liver enzyme levels. Study drug stopped and standard of care treatment given. Two subjects asymptomatic will be followed long term.	Remedial actions: Two subjects onsite stopped study drug and continued with background therapy. Will be followed long-term for the remainder of the study; protocol amendment to reflect changes. Subject reconsented as sponsor is supplying background therapy for the remainder of the study. CASE CLOSED
64	01	VA Boston Healthcare System	I	03/09/2012	A non-VA server used for VA research was hacked. A thorough investigation was conducted, including referral to the OIG and NSOC for threat analysis. Multiple technical experts determined no possibility of VA data breach.	Remedial actions: Removal of Non-OIT IT staff computer room access and OIT staff will escort if access necessary; removal of administrative access to servers not connected to air gap network. CASE CLOSED
65	16	Houston	I	03/15/2012	NSOC reported that a PI conducted a self-initiated review of consent forms and discovered that pages from two separate ICDs were missing. The missing pages contained Veteran's PHI (full name and last 4 SSN).	Remedial actions: Two (2) Veterans will be sent general notification letters; perform period spot checks to ensure compliant consent and record retention processes; bi-weekly research team meetings; amend the protocol to include telephone script and verbal consent. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
66	09	Huntington	I	03/16/2012	NSOC reported a research staff person allowed a patient to self-enter data on a website using the employee's access. Employee stated the patient was observed during the entire process.	Remedial actions: ISO will provide training to staff; ORO subsequently determined no PHI loss, breach, or disclosure was involved. CASE CLOSED
67	07	Columbia	I	03/19/2012	NSOC reported transmission of internal unencrypted email attachment containing PHI (exclusive of name or SSN). Risk category determined to be low.	Remedial actions: Recipients fully deleted email; Compliance audit of research study found no issues with protocol or staffing; staff retraining. CASE CLOSED
68	04	VA Pittsburgh HCS	I	03/19/2012	NSOC reported a PI obtained reports containing patient PHI through a process not contained within a protocol and not approved by the IRB. In addition, the employees who accessed CPRS to obtain the data were not approved by the IRB to conduct this task.	Remedial actions: IRB Chair education meeting and stand-down with research staff and involved employees; SOP in development for accessing clinical data by researchers; PI modification of protocol for recruitment screening will include Biostatisticians CASE CLOSED
69	20	Portland VAMC	H	03/23/2012	NSOC reported facility PO discovered that PII of five veterans in a level of amputation study is stored electronically outside of the VA without approval.	Remedial Actions: Deletion of the information that had been stored outside the VA; Revision of the study protocol, ICD, and HIPAA Authorization. CASE CLOSED
70	01	Bedford	I	03/29/2012	NSOC reported that a facility employee discovered patient research information (informed consents, progress notes, handwritten notes, study surveys) mistakenly thrown into the recycled trash. Documents were never out of VA control and the probability of unauthorized disclosure is next to zero.	Remedial actions: Documents secured and appropriate storage planned. CASE CLOSED
71	18	New Mexico VA HCS	I	04/02/2012	NSOC reported PI records File cabinet containing records with PHI was moved w/o PI or research staff knowledge during a 2011 remodeling project. PI left facility without notifying research service or transferring study responsibility. Cabinet later found, but was completely empty.	Remedial actions: Notification letter will be sent to 90 identifiable Veterans out of total 116 affected individuals; credit monitoring for 90 participants; new SOP for clearing station; study now inactive and pending closure; 26 participants remain unidentified. CASE CLOSED
72	23	Minneapolis	I	04/03/2012	NSOC reported transmission of unencrypted email containing an attachment regarding 106 subjects. Recipients were internal except one message was sent to an affiliate's email account. ORO to determine if attachment contained PHI.	Remedial actions: Emails containing PHI have been deleted; PI plan to use a secure limited access drive for study team; encrypt all emails with sensitive information. CASE CLOSED
73	18	Phoenix VA HCS	I	04/09/2012	NSOC reported that hard copy documents containing PHI were sent by inter-office mail without utilizing a privacy envelope. The documents were exposed minimally to one VA employee who promptly reported the incident. Report stated no data breach occurred.	Remedial actions: Data were fully recovered; education provided to relevant employees; mail routing issues were resolved. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
74	17	VA North Texas HCS	I	04/13/2012	NSOC reported NPC employee was accessing VA systems without appropriate background check or suitability process. In addition, another employee knowingly provided his/her login credentials to NPC employee. Facility investigated and determined no PHI was transmitted, removed, stolen, or destroyed.	Remedial actions: Facility report and local inquiries clarified the incident scope that no PHI had been accessed or compromised. CASE CLOSED
75	17	VA North Texas HCS	H	04/16/2012	ORO review of IRB minutes found unreported facility concerns regarding adequate pharmacy staffing and resources and raised questions regarding the ability to safely conduct investigational drug studies in compliance with all rules and regulations.	Remedial actions: The IRB determined that the actions of the research pharmacist constituted serious but not continuing noncompliance. The IRB approved the RAP. CASE CLOSED.
76	06	Asheville	I	04/17/2012	NSOC reported new occupants of a former research office found research records that had not been removed. The records were in a locked file cabinet and the office door was locked. New occupants unlocked file cabinets but no data breach occurred.	Remedial actions: Documents secured and retrieved by Research staff. Per NSOC desk, does not meet criteria for data breach. CASE CLOSED
77	03	VA Hudson Valley HCS	I	04/20/2012	NSOC reported research assistant sent an email containing CSP protocol amendments and attachments containing Veteran's PHI/PII in a study of mental health genetics. VISN Director, CIRB, OIG, CO Issue Brief submitted. OIG investigation found no veteran/research PHI was transmitted due to VA blocking.	Remedial Actions: The research assistant's network access and employment were terminated; study is now closed at this site; OIG determined no compromise of VASI. CASE CLOSED
78	12 NE	Hines	I	04/27/2012	NSOC reported internal unencrypted email containing PHI (dates and cause of death) to other VA study team members.	Remedial actions: Recipients instructed to double delete email. CASE CLOSED
79	08	Tampa	I	04/30/2012	NSOC reported transmission of "unblinded blast email" to private external email addresses of all 324 consented study participants (active duty soldiers) on an approved study. All participant e-mail addresses were visible in the message; however no PHI was included.	Remedial actions: Education provided to PI; use of "blast" emails was approved prior; however the "blind carbon copy" (Bcc) feature was required by VA IRB amendment in May 2012; DOD IRB also required the same Bcc requirement. CASE CLOSED
80	22	VA Long Beach HS	I	05/02/2012	NSOC reported that two completed ICDs forms were mistakenly removed from their secure storage location while the PI was on leave and are missing. PII was involved but doesn't meet criteria for credit protection services. It is presumed the ICFs were inadvertently shredded.	Remedial actions: Document security education to staff; RCO verify proper storage; file cabinet keys only to authorized study staff; project is closed. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
81	01	VA Boston Healthcare System	I	05/08/2012	NSOC reported a VA issued laptop missing from a Research investigators office. Laptop is encrypted, but has not been used for five years. Facility provided clarification that the laptop only contains SAS datasets.	Remedial actions: No PHI was contained on the laptop; therefore, noncompliance did not occur. CASE CLOSED
82	06	Durham	I	05/09/2012	NSOC reported some identifiable information (ages >90) was retained in a dataset after de-identification. The dataset was then stored on the same server as the affiliate, can be viewed by affiliate researchers. Affiliate data manager was only person who had accessed the data.	Remedial actions: Dataset corrections to ensure proper de-identification; store only correct file on the shared server (VA and affiliate); deletion of unencrypted email. CASE CLOSED
83	22	VA Long Beach HS	P	05/16/2012	ORO onsite review of R&DC found what appeared to be indications that an investigator undertook prohibited research activities including international research involving autoimmune disease in pregnant women and neonates.	Remedial actions: R&DC subcommittee investigation in response to ORO query; all concerns resolved without evidence of noncompliance; case closed.
84	12	Chicago HCS	I	05/17/2012	NSOC reported a research employee was using personal email account for VA-related issues. Investigation by ISO and PO subsequently determined no VA PHI was sent through the personal email account.	Remedial actions: Education provided to employee to discontinue using personal email account. CASE CLOSED
85	23	VA Nebraska/ West Iowa HCS	I	05/21/2012	NSOC reported unauthorized disclosure of PHI when research gave a Veteran another Veteran's medication. The medication was returned unopened.	Remedial actions: Notification letter to Veteran whose PHI was disclosed; reinforcement of policy to double-check names prior to release of study medication. CASE CLOSED
86	06	Durham	I	05/24/2012	NSOC reported collection of PHI (consisting of dates) not approved in the protocol and apparent transmission of this PHI to the affiliate. Only de-identified data were to be entered into affiliate database.	Remedial Actions: Data entry has stopped; data was transferred in a secure manner, but the transfer was in violation of protocol; data deleted from active database and moved to inactive status. CASE CLOSED
87	01	VA Boston Healthcare System	I	05/24/2012	NSOC reported missing/stolen Netbook controller used by a PI as a stand-alone device. The unencrypted Netbook was OE and not connected to either the VA network or the network of the PI.	Remedial actions: Non-VA equipment; not an incident. CASE CLOSED
88	07	Columbia	H	05/25/2012	NSOC Reported HIPAA form not signed by subject that failed to meet screening criteria. No PHI disclosed. No data breech.	Remedial Actions: None. No PHI disclosed. No data breech. CASE CLOSED
89	08	VA North Florida/ South Georgia HCS	I	05/25/2012	NSOC reported one laptop and five Palm Pilots were missing during a routine inventory. Facility subsequently reported neither the laptop nor the Palm Pilots were ever used to collect or store PHI.	Remedial Actions: Mandated 100% inventory of all IT items; ensure all devices are properly backed up, encrypted, and turned in if no longer used. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
90	11	Indianapolis	I	05/30/2012	ORD was notified that facility was unable to locate CSP 560 subject records, including subject specific source documents and informed consent forms.	Files were subsequently located and the records have been (and remain) in a secure double locked research specific storage room at the VA
91	03	VA New Jersey HCS	I	05/30/2012	NSOC Report: Eleven names with full SSN were on a research consent log with signature date; log was misplaced but never lost	Remedial actions: Document storage SOPs put into place to prevent future incidents. CASE CLOSED
92	23	Sioux Falls	H	06/04/2012	RCO audit found one subject enrolled in a heart failure management study who met exclusion criteria.	Remedial Actions: PI removed the subject from the study. Remedial actions complete, CASE CLOSED.
93	12	Madison	H	06/05/2012	Affiliate IRB and Eastern Cooperative Oncology Group reported enrollment of ineligible VA subjects and missed study labs for four participants enrolled in this multiple myeloma trial.	Remedial Actions: Study is now closed at the VA; remaining PI's studies restricted to 6 month continuing review and must have co-PI added; PI to receive additional human subjects training; studies to receive quarterly audits; participants notified of closure.
94	18	Phoenix VA HCS	I	06/05/2012	NSOC reported discovery in a public restroom of research subject's copy of ICD and HIPAA Authorization that were within an undisturbed sealed envelope. Appears to have been left behind by the subject.	Remedial actions: Facility investigation found no loss of VA PHI; no remedial actions required as not a reportable event; facility will continue efforts to reach the subject and return the envelope. CASE CLOSED
95	20	VA Puget Sound HCS	I	06/08/2012	NSOC reported transmission of an internal unencrypted email containing the name of one Veteran former research participant (now deceased).	Remedial Actions: Staff member education regarding transmission of PHI. CASE CLOSED
96	20	Boise VAMC	H	06/11/2012	An external VA IRB found during an expedited continuing review that a multi-site study concerning cognitive process and diagnostic reasoning lacked IRB approval from collaborating affiliate universities.	Remedial Actions: A review determined that the affiliate university was not engaged in research and that noncompliance had not occurred. Case closed.
97	07	Tuscaloosa	I	06/11/2012	NSOC reported internal transmission of unencrypted email containing one Veteran's PHI. User immediately recalled the message.	Remedial Actions: User reeducation; user will utilize automatic encryption option and deselect encryption for emails not containing VASI/PHI. CASE CLOSED
98	18	Phoenix VA HCS	I	06/12/2012	NSOC reported mis-faxed master study subject list containing PHI for 91 enrolled participants. It was subsequently determined that the fax went to a local charity and was only seen by two employees.	Remedial Actions: All 91 participants will be sent notification letters; The Research PO recovered the information from the charity. CASE CLOSED
99	04	Clarksburg	I	06/13/2012	NSOC reported a VA staff physician gave his CPRS access information and his affiliate research access code to a nurse who entered CPRS progress notes on his behalf. Subsequently determined no PHI was transferred from CPRS to the affiliate.	Remedial Actions: The physician's codes have been changed; Information Security and Privacy training to the MD and nurse; new Rules of Behavior signed. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
100	07	Columbia	I	06/13/2012	NSOC reported a PI transmitted an external unencrypted email message to his account at the affiliate medical school and to a co-investigator. The email contained first and last initial and last 4 SSN of the study participants.	Remedial Actions: Unencrypted email with PHI was deleted from VA and affiliate email systems; email encryption training to the CoPI. CASE CLOSED
101	11	Ann Arbor HCS	H	07/02/2012	ORO notified that audit found 6 ICDs missing page 1 of the ICD and 6 missing HIPAA authorizations in a Vitamin D deficiency study.	Remedial Actions: Research staff provided re-education of consent process, project manager will audit completed ICDs within 7 days; no HIPAA reconsent since these subjects were not enrolled; prepare tracking document for ICD re-audit in 3 months. CASE CLOSED.
102	15	VA Kansas City Medical Center	I	07/02/2012	NSOC reported transmission of internal unencrypted email containing PHI of 62 individuals. No data breach.	Remedial Actions: All copies deleted from all Outlook folders; CASE CLOSED.
103	23	Minneapolis	H	07/17/2012	ORO notified of the suspension of PI privileges to conduct research at VA facility. PI was not compliant in record keeping and carrying out basic protocol and ICD processes in a brain cognition study.	Remedial Actions: Completion of new IRB application; Establishment of adequate document management processes for both essential regulatory documents; Creation of a master list of subjects enrolled to date and a plan to maintain it going forward.
104	00	VA Central Office	H	07/17/2012	CIRB reported enrollment suspension of a PTSD study at a facility due to potential safety concerns identified by CSP internal monitoring involving enrolling ineligible subjects and delay in SAE reporting.	Remedial Actions: LSI to report all SAEs and protocol deviations; RCO to conduct an audit; a qualified co-investigator delegated to oversee enrolled subjects.
105	01	Bedford	I	07/18/2012	NSOC reported that an envelope containing research subject's PHI and protocol name on the outside was inadvertently processed through the US Postal Service instead of being dropped off for placement in the hospital's safe. Envelope contained "unblinding" info for use in case of subject emergency.	Remedial Actions: Staff to visually confirm placement of unblinding envelopes in safe; protocol will be revised to include this procedure; affected Veteran will receive HIPAA notification letter. CASE CLOSED
106	15	VA Kansas City Medical Center	H	07/18/2012	CIRB suspends enrollment of this PTSD study due to patient safety concerns: enrollment of ineligible participants and reporting of SAEs. The LSI also had study enrollment suspended for the Million Veterans Program and a depression outcomes study which are both CSP studies.	Remedial Actions: ACOS/R is developing an oversight and follow-up plan to ensure the safety of participants currently enrolled in the PTSD study; replace new LSI. Remedial actions complete. CASE CLOSED.
107	23	Minneapolis	I	07/19/2012	NSOC reported a research supervisor permitted the sharing of network user accounts. This was a policy violation; no data breach occurred.	Remedial Actions: Facility subsequently reported that the access description was inaccurate and the individual did not inappropriately access any Government system. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
108	07	Birmingham	I	07/20/2012	NSOC reported research study surveys with PII for two subjects were sent via United Parcel Service (UPS) but never received. UPS eventually discovered and delivered the package.	Remedial Actions: Certified by VACO Mental Health Services that the surveys were related to training program evaluation activities and not research; credit protection and HIPAA notification letters not required. CASE CLOSED
109	01	VA Boston Healthcare System	H	07/24/2012	NSOC reported that during a research media encounter, a TBI/PTSD researcher permitted a photograph to be taken of a brain scan where the procedure date was visible in the image.	Remedial Actions: Staff education, VA Form 5345 provided to staff with education about its required use if PHI is to be released.
110	06	Durham	I	07/25/2012	NSOC reported a subject inadvertently took the subjects' sign-in sheets with his handouts when leaving the group meeting. The sign-in sheets contained names and study IDs of 49 participants.	Remedial Actions: Subject returned all the sign-in sheets 5 days later; affected participants will be sent notification letter; procedure for sign-in sheets revised. CASE CLOSED
111	22	VA Greater Los Angeles HS	I	07/30/2012	NSOC reported inadvertent disclosure of subject name to the research sponsor. Sponsor has since de-identified the report.	Remedial Actions: Re-education to PI and staff; ensure new staff are trained; report training to IRB; develop checklist; PI to verify no PII/PHI prior to faxing; credit protection services not required. CASE CLOSED
112	12 NE	Hines	I	08/03/2012	NSOC reported stolen Research computer with the name, DoB, and SSN of 36 subjects. Computer was recovered.	Remedial Actions: Development of an internal security plan (immediate transfer from the biomedical device computer to an encrypted thumb drive; then to a secured study-specific folder on research server); random data external audits; cable lock computer to cart. CASE CLOSED
113	07	Augusta	H	08/07/2012	ORO identified IRB approval of PI's study of caloric needs among obese spinal cord injured patients expired. Research Service failed to notify PI; ACOS/R erroneously notified PI that the study was approved by the IRB and R&DC.	Remedial Actions: Study closed. PI must take continuing education and work with a mentor prior to conducting other research studies. CASE CLOSED.
114	04	VA Pittsburgh HCS	I	08/07/2012	NSOC reported an ICD containing name and last 4 of SSN was found on a VA shuttle bus. It was believed that the Veteran left his own information.	Remedial Actions: PO confirmed documents were destroyed. CASE CLOSED
115	03	Northport	I	08/10/2012	NSOC reported study team erroneously entered three screen failures name, date of birth, date of service to sponsor's electronic database. The entries were deleted from the database.	Remedial Actions: Confirmed that screening data has been deleted; study team has undergone remedial training and reminded that all approved protocol procedures (i.e. obtaining informed consent prior to research) be followed; document consent prior to data transmission. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
116	20	Portland VAMC	I	08/10/2012	NSOC reported transmission of internal unencrypted electronic mail containing PHI for one Veteran research participant. This case outlines the same occurrence as #0092-648-I because two separate NSOC tickets were filed. Also relates to WRO 0091-648-H for human subjects protection issue.	Remedial Actions: Email senders and recipients instructed to retract and/or delete unencrypted messages; retraining provided to study team regarding email encryption requirements. Note that remedial actions are the same for each of the three DSS cases related to this occurrence. CASE CLOSED
117	21	San Francisco VAMC	I	08/13/2012	NSOC reported missing study files for one participant. It is likely the documents may be misfiled.	Remedial Actions: Systematic search conducted by research study staff and the misplaced study file was located within the overall study participant folders; incident did not involve unauthorized disclosure or loss of PHI. CASE CLOSED
118	03	Bronx	I	08/14/2012	NSOC reported 5 subjects' PHI was sent to an affiliate central database without obtaining informed consent or HIPAA Authorization.	Remedial Actions: Coordinating Center confirmed all data has been deleted; study team received re-training on study procedures. CASE CLOSED
119	12 NE	Hines	I	08/14/2012	NSOC reported transmission of internal unencrypted email containing a password for study CDs.	Remedial Actions: Sender requested that recipient delete message from all mailboxes. CASE CLOSED
120	19	VA Salt Lake City HCS	I	08/16/2012	NSOC reported OIT personnel installed an unauthorized File Transfer Protocol (FTP) client (Filezilla) in the research department. It was subsequently determined that VASI was never out of VA control or transferred outside VA.	Remedial Actions: OIT resolved. CASE CLOSED
121	02	VA Western New York HCS	I	08/16/2012	NSOC reported two medical students were collecting data containing PHI for two projects on a personal laptop and transmitting the spreadsheet via a personal email account. It was subsequently determined the research had not been approved by the IRB; HRPP case 0060-528-H opened by NERO.	Remedial Actions: ISO scanned laptop and removed all data; education to medical students on use and security of VA data; PI terminated from all current/future research at facility. One of PI's 2 active studies was terminated; other was suspended and may re-open with new PI.
122	06	McGuire (Richmond)	I	08/22/2012	NSOC reported that boxes of research study forms and supporting documents were found in a locked dialysis storage closet. The records were noted to be 12 years old.	Remedial Actions: Boxes were immediately retrieved for proper storage in the research storage area. CASE CLOSED
123	05	DC VAMC	I	08/23/2012	NSOC reporting two missing VA-issued research laptops that were turned into the IRM for updates. Investigation revealed that both missing laptops were found in the OI&T work area and were never out of VA control.	Remedial Actions: Reported to VA Police and ISO; Upon investigation, both laptops were located in a IT support space. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
124	12 NE	Hines	I	08/23/2012	NSOC reported a research employee was disposing of VASI with names, DOB, SSNs into an unlocked shred bin.	Remedial Actions: Bin secured immediately; PI met with facility mgmt to obtain secure bins; staff to check that shred bins are locked prior; PI held lab specific meeting with staff on disposal of VASI; AO/R reminded all research staff via email of VASI disposal procures. CASE CLOSED
125	16	Shreveport	H	08/23/2012	ORO was notified that a subject took 40 extra doses of the study medication Polyphenon E (Green Tea) in a prostate cancer study. Subsequent liver function studies were within normal limits. Enrollment of an ineligible subject also occurred.	Remedial Actions: Patient education on taking medication; ICDs signed on day obtained; patients screened in real time only; patient must bring study medications to first visit; pen must be used in medical record; reason for withdrawal must be noted.
126	15	Columbia	H	08/28/2012	RCO regulatory audit of treatment based cardiac rehabilitation protocol for enrollee eligibility errors; missing inclusion/exclusion documentation; ineligible subject enrollment; inconsistent data points.	Remedial actions: PI voluntarily halted active enrollment. IRB votes to terminate study. PI to appeal. CASE CLOSED.
127	06	McGuire (Richmond)	H	09/04/2012	Sponsor notified facility that an investigational Hepatitis C drug has been placed on partial clinical hold by FDA because of possible cardiac risks. One subject at facility ended study drug 6 months ago. The subject will be notified and have EKG.	Remedial Actions: Subject notified; Reconsent not required; EKG done and was normal. CASE CLOSED
128	07	Charleston	I	09/07/2012	NSOC reported the loss of 14 case studies by a physician and researcher. Case studies consisted of participant CRFs and corresponding source documentation, including PHI. Files were last seen with Study Coordinator who left VA employment.	Remedial Actions: Veterans were identified and offered credit monitoring; former study coordinator contacted but no further details were provided; verified that former coordinator's other research folders were accounted for. CASE CLOSED
129	09	Memphis	H	09/07/2012	ORO was notified of programmatic noncompliance on a autoimmune arthritis study for incorrect protocol assignment of exemption status, missing PO/ISO review, missing HIPAA waiver, missing verbal consent approval, and use of non-Veterans.	Remedial Actions: further education for IRB reviewers; PO will now review all protocols including exempt. Remedial actions complete. Case Closed.
130	18	Phoenix VA HCS	I	09/07/2012	NSOC reported a previously unaccounted for sponsor laptop was missing. It was subsequently returned by a former NPC employee.	Remedial Actions: A loan agreement between sponsor and NPC will be executed; sponsor-owned equipment will be inventoried; education to current staff; evaluation of hard drive for PHI.
131	20	VA Puget Sound HCS	I	09/12/2012	NSOC reported unencrypted internal email containing a HIPAA Authorization with unspecified PHI.	Remedial Actions: No data breach. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
132	17	VA South Texas HCS	I	09/17/2012	NSOC reported theft of a personal laptop and one paper document containing PHI that belonged to a WOC. The laptop was not encrypted and the WOC was not authorized to store VASI on her personal laptop.	Remedial Actions: Credit monitoring for one research participant; Employee was reprimanded and subsequently resigned; unanticipated problem report submitted to IRB; PI conducted extensive retraining for all research staff; IRB approved PIs extensive retraining agenda. CASE CLOSED
133	06	Durham	I	09/19/2012	NSOC reported the original ICD containing PHI for one patient was missing. Patient and pharmacy copies exist; also the document was scanned into CPRS. It is suspected that the original document was misfiled.	Remedial Actions: Participant informed of missing document and offered credit protection services; search underway for missing ICD; SOPs were updated; signed copy of the original ICD was scanned into CPRS. CASE CLOSED
134	18	Phoenix VA HCS	I	09/19/2012	NSOC reported a Veteran was inadvertently given a CPRS printout containing PHI for another Veteran with the same last name.	Remedial Actions: The Veteran whose PHI was disclosed was offered credit protection services; Veteran A returned Veteran B's CPRS print out; Research Staff counseled on minimum necessary use and recording of PHI and not over printing CPRS chart data. CASE CLOSED
135	11	Indianapolis	H	09/20/2012	Affiliate clinical trials monitoring committee found expired ICDs were used in an affiliate cancer biomarker study; 21 subjects did not sign or date the ICDs correctly; and 3 staff who were obtaining consent were not on the protocol.	Remedial Actions: PI voluntarily suspended enrollment until amendment is approved by IRB to update staff list; a Project Manager will provide oversight at all future outside events.
136	02	Syracuse	H	09/20/2012	Sponsor audit found five investigational drug(cetuximab) vials could not be accounted for on a Phase III Lung Cancer trial. Other findings include logs did not reflect the correct number of vials, dose of each treatment and investigational drug refrigerator not adequately labeled.	Remedial Actions: Drug vials located and disposed of as per local policy; appropriate labeling of investigational drug refrigerator; log update to reflect vial inventory and dose for each treatment date; review of other protocols dispensing drugs; audit of all studies approved to dispense drugs.
137	12 NE	Hines	I	09/21/2012	NSOC reported nurse practitioner performing research for her advanced degree took research study material home with her. Data was in hard copy only; not shared outside of the VA. Per PO/ISO review, data contained some HIPAA identifiers but no names.	Remedial Actions: Paperwork for this closed study is now stored in the Research Department; PO determined HIPAA notification letters not required; PI education. CASE CLOSED
138	02	Albany	I	09/25/2012	NSOC reported two Regulatory Research study binders were found in a hallway. The binder contained PHI (names, phone numbers, DOB and some clinical information) of 41 participants in a closed study.	Remedial Actions: The binders were immediately secured; determined HIPAA notification letters and credit monitoring not required; PI no longer with the VA. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
139	01	Bedford	I	09/26/2012	NSOC reported transmission of an internal unencrypted email with attachments containing subject PHI (VA employees/staff) including full SSN.	Remedial Actions: Employee follow-up PKI training. CASE CLOSED
140	18	New Mexico VA HCS	H	09/27/2012	VA CIRB-determined serious noncompliance during continuing review of a CSP combat trauma PTSD study local site application. A study coordinator dispensed study medication outside of her scope of practice when the research pharmacist was not available.	Corrective Actions: determination of no physical harm to subject; study coordinator reprimanded, prohibited from dispensing (or assisting in dispensing) drug, not permitted unescorted entry to pharmacy. CASE CLOSED.
141	06	Durham	I	10/02/2012	NSOC reported the occurrence of an unencrypted email with PHI of 3003 subjects sent from a VA account to an affiliate account.	Remedial Actions: Place the enrollment log in a password-protected folder; staff member who sent email was counseled and has re-taken VA Human Subjects Protection training; email deleted from all locations for both sender and recipient. CASE CLOSED
142	17	VA North Texas HCS	H	10/03/2012	WRO found, during review of another ORO case 0057-549-H, consent for 5 of 8 subjects was not obtained prior to study participation.	Remedial Actions: Program to review ORO reporting requirements; respond to ORO inquiry. CASE CLOSED.
143	21	VA Palo Alto HCS	H	10/11/2012	Sponsor notified facility of an urgent safety concern with study examining the antiviral efficacy, safety, and tolerability of various drug combinations for the treatment of Hepatitis C infection	Remedial Actions: One subject on study drug stopped study medication; the IRB determined that the problem was unexpected, related to the research, and harmful. CASE CLOSED.
144	11	Ann Arbor HCS	I	10/12/2012	NSOC reported an unencrypted internal VA email was sent without PKI and contained PHI on approximately 4000 patients.	Remedial Actions: Email deleted from both sender and receiver mailboxes in all locations; email resent using PKI. CASE CLOSED
145	23	Minneapolis	I	10/17/2012	NSOC reported transmission of an internal unencrypted email containing an attachment with four research subjects' data.	Remedial Actions: No data breach. CASE CLOSED
146	12 NE	Hines	H	10/19/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. No SAEs reported for VA subjects.	Remedial Actions: Study coordinator instructed all participants to stop study drug immediately and sent sponsor letter; study close-out procedures will be completed. CASE CLOSED
147	06	Salem	H	10/19/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. No SAEs reported for VA subjects.	Remedial Actions: Study team contacted subjects to stop study drug immediately; Final study visits completed 12/06/12; No local AE's which led to study closure. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
148	03	VA New York Harbor HCS	H	10/19/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. No SAEs reported for VA subjects.	Remedial Actions: One patient was active at this site. He has been contacted and study medication stopped.
149	23	VA Neb do not use	H	10/23/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. No SAEs reported for VA subjects.	Remedial Actions: Discontinue the study medication, provide subjects follow-up information and conduct clinical follow-up of former subjects.
150	04	VA Pittsburgh HCS	H	10/26/2012	Sponsor terminated a multisite study on chronic kidney disease and diabetes due to safety concerns (excess SAEs and mortality)	Remedial Actions: Subjects contacted and asked to stop taking the drug; subjects encouraged to see their primary care physicians prior to the 4-week follow-up; written notification sent to the subjects subsequent to a phone call reiterating the importance to stop taking the study drug. CASE CLOSED
151	00	VA Central Office	H	11/06/2012	ORD issue brief to early terminate medication of CSP #565 on treatment of diabetic nephropathy due to unexpected side effects of study medications.	Remedial Action: Participating sites notified
152	12	Chicago HCS	I	11/07/2012	NSOC reported that a former research employee has data stored offsite and the former researcher affiliate site is reluctant to release the data (electronic and hard copy) back to the VA.	Remedial Actions: Since VA still owns the data, arrangements are being made for placing the data under appropriate VA controls.
153	18	Southern Arizona VA HCS	I	11/13/2012	NSOC reported a non-GFE unencrypted laptop containing 73 research subjects PHI (names, SSNs, contact/health information) was stolen from a research monitor employed by the sponsor. A valid ICD and HIPAA Authorization was signed by each subject authorizing the sponsor as recipient of the PHI.	Remedial Actions: All subjects notified and offered 1 year credit monitoring; VHA Privacy Office determined data on the stolen laptop was not VA PHI.
154	00	VA Central Office	H	11/13/2012	CIRB reported a possibly related SAE involving a fall with two fractures in a CSP systolic blood pressure intervention trial	CIRB preliminary determination of serious, unanticipated and possibly related SAE. Based on additional information regarding blood pressure and posture change, CIRB final determination SAE not related to research. CASE CLOSED

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
155	21	VA Northern California HCS	I	11/13/2012	NSOC reported six research staff in leased space were using the VA Internet from a local account on MAC computers to remotely connect to the affiliate's email program and server. The staff members have not been cleared to use the VA network. Incident did not involve PHI or VASI.	Remedial Actions: OIT will remove the local accounts; VA computer use and network access suspended from this lease space; VA computers will be collected by facility IT staff and the hard drives erased.
156	09	Memphis	H	11/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial actions: Study team to stop study drug and transition subjects to standard of care.
157	23	Minneapolis	H	11/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks.
158	17	VA North Texas HCS	H	11/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks.
159	06	McGuire (Richmond)	H	11/15/2012	DMC for CSP study notified facility that two-drug study treatment in a diabetic nephropathy study was stopped by sponsor for safety concerns. In addition, the combination therapy failed to demonstrate efficacy in lowering risk of kidney disease progression.	Remedial Actions: Participants notified by phone and certified letter; advised to discontinue study medication; return to facility for exit study visit.
160	04	VA Pittsburgh HCS	H	11/15/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Study participants to be contacted and instructed on what drugs to stop taking; arrange exit visit; evaluate for safety and transfer participants to standard clinical care as soon as possible; send notification of study termination to participants; documentation in CPRS

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
161	12 NE	Hines	H	11/16/2012	Sponsor terminated CSP #565 study due to safety concerns including acute kidney injury and hyperkalemia. (Study was to assess the effect of combination of an angiotensin converting enzyme inhibitor and an angiotensin receptor blocker on progression of kidney disease in patients with diabetes and proteinuria.)	Remedial Actions: Study staff to notify participants; study close-out procedures pending.
162	06	Durham	H	11/20/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial actions: CSP study closeout procedures completed. No adverse events. CASE CLOSED.
163	05	VA Maryland HCS	H	11/21/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial actions: PI letters and calls to notify participants to cease taking study drug and consult primary care physicians for clinical management 30-day close out visits. Reported closure to OHRP, IRB approved CAP. CASE CLOSED
164	08	Tampa	H	11/23/2012	CSP reported terminating the Nephron-D study CSP 565 due to safety concerns.	Remedial Actions: Study Treatments will be terminated as soon as feasible. All participants will be transferred to standard clinical care within 6 weeks.
165	21	VA Northern California HCS	H	11/28/2012	HIPAA related noncompliance identified by ORO during a routine on-site HRPP review and clarified by an RCO audit in a study of non-healing diabetic foot ulcers.	Remedial Actions: RCO provided training to the PI and staff regarding consenting procedures and WRO reminded of 1058.01 reporting requirements. CASE CLOSED
166	11	Indianapolis	H	11/29/2012	CSP DMC recommended termination of a VA sponsored diabetes study due to risk associated with study drug. Facility had 35 subjects enrolled.	Remedial Actions: Study team to stop study drug and transition subjects to standard of care.
167	21	San Francisco VAMC	I	11/29/2012	NSOC reported that data on an encrypted NPC was rendered inaccessible due to system failure. The exact nature of the inaccessible data is not known at this time; an investigation is underway.	Remedial Actions: The matter has been assigned to an internal VA forensics team.
168	12	Milwaukee	H	11/30/2012	CSP is terminating a diabetic neuropathy study because of subject safety concerns. This study was sponsored by the VA.	Remedial Actions: 56 subjects to be contacted with instructions to terminate study drug; Subjects to be brought into facility for study exit visit and follow-up. Remedial actions completed. CASE CLOSED.

TABLE 5. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
169	15	VA Kansas City Medical Center	H	11/30/2012	CSP Coordinating Center notified facility of the DMC's recommendation to close CSP Study 565 (treatment of diabetic nephropathy) due to subject safety concerns.	Remedial actions: Subjects to be taken off study drug; subjects to complete study exit visit;
170	09	VA Tennessee Valley HCS	H	11/30/2012	DMC recommended termination of CSP diabetic nephropathy study due to increased risk to subjects.	Remedial Actions: Subjects to be evaluation for safety, taken off study drug and directed to standard of care; subjects to attend a study exit visit. CASE CLOSED.
171	10	Cleveland	H	12/03/2012	DMC notified facility of termination of CSP 565 diabetic nephropathy study because of subject safety issue.	Remedial actions: Subjects to be taken off study drug and moved to standard of care treatment; Subjects to attend a study exit visit.
172	15	VA Kansas City Medical Center	H	12/03/2012	Pharmaceutical sponsor notified facility of termination due to safety concerns of investigational drug study involving diabetic patients with Stage 4 chronic kidney disease.	Remedial Actions: Sponsor termination of study; subject notification to stop study drug and complete exit procedures.
173	23	VA Nebraska/ West Iowa HCS	I	12/03/2012	NSOC reported research employee mailed two Veteran's records to a sponsor without properly redacting information.	Remedial Actions: Employee contacted sponsor and requested packet be returned unopened. Sponsor's action pending.
174	12	Milwaukee	H	12/04/2012	Sponsor notified facility that DMC recommended termination of Pharmaceutical sponsored investigational drug study involving diabetic patients with Stage 4 chronic kidney disease due to safety concerns.	Remedial actions: Sponsor termination of study; Subject contact for discontinued use of study drugs and scheduled exit follow-up with PI. CASE CLOSED.
175	07	Charleston	H	12/05/2012	Facility reported that CSP is terminating the Nephron-D study CSP 565 due to safety concerns.	Remedial Actions: Study Treatments will be terminated as soon as feasible. All participants will be transferred to standard clinical care within 6 weeks.
176	07	Columbia	H	12/05/2012	CSP reported terminating the Nephron-D study CSP 565 due to safety concerns.	Remedial Actions: Study Treatments will be terminated as soon as feasible. All participants will be transferred to standard clinical care within 6 weeks.
177	15	St Louis	H	12/05/2012	DMC recommended termination of a CSP diabetic nephropathy study because of a subject safety concern.	Remedial Actions: Subjects to terminate study drug; subjects to attend a study exit visit.
178	20	Portland VAMC	I	12/06/2012	NSOC reported transmission of internal unencrypted email containing PHI.	Remedial Actions: Message recall and deletion from all mailboxes. CASE CLOSED
179	22	VA Loma Linda HS	H	12/07/2012	DMC reported subject safety issue related to one of the investigational agents in a CSP diabetic kidney disease study.	Remedial actions: Subjects to be taken off study drug; subjects to complete a study exit visit.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
180	10	Cincinnati	H	12/11/2012	Pharmaceutical sponsor notified facility of DMC's termination due to safety concerns of an investigational drug study involving diabetic patients with Stage 4 chronic kidney disease.	Remedial Actions: Sponsor requested termination of study, stop subject enrollment and use of investigational drug; study close out pending.
181	23	Iowa City	H	12/13/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. Unclear how many SAEs involved VA subjects.	Remedial Actions: Subjects notified to stop taking study medication.
182	20	Portland VAMC	H	12/13/2012	Early Termination of a VA SCP study (#565), in response to a directive from the CSP Coordinating Center.	CSP Coordinating Center notified facility of study closure for safety concerns; the IRB approved the close-out procedures, allowing early termination of CSP #565.
183	08	VA Caribbean HCS	H	12/13/2012		
184	23	Iowa City	H	12/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks.
185	01	VA Connecticut HCS	H	12/14/2012	Sponsor terminated CSP #565 study due to safety concerns related to high potassium levels and acute changes in kidney function with combination treatment. Study was to assess the effect of two-drug combination treatment for diabetic kidney disease.	Remedial Actions: Study staff notified 2 participants by certified mail and will schedule for study exit visit. CASE CLOSED
186	15	VA Kansas City Medical Center	H	12/17/2012	FDA correspondence requests PI to delay further dosing and places a clinical hold on the study of cocaine-reinforced behavior.	Remedial Actions: CASE CLOSED.
187	20	VA Puget Sound HCS	I	12/17/2012	NSOC reported research packet including medical information was sent to the incorrect Veteran; further information pending.	Remedial Actions: Veteran will be sent a notification letter; Research staff reminded to verify addresses and the contents of all research packets prior to mailing.
188	01	VA Boston Healthcare System	I	12/18/2012	NSOC reported an unauthorized individual attempted (with refusals) to connect "hundreds of times" to the Million Veteran Program production server. It also appears the individual somehow changed the local security policy to allow him to act as part of the operating system.	Remedial Actions: Individual removed from role; individual's access disabled; other actions pending.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
189	01	VA Boston Healthcare System	I	12/18/2012	NSOC reported permissions on a research server were not limited to appropriate personnel; one file on this server contained passwords.	Remedial Actions: The share permissions have been corrected and the service account passwords have been changed; other actions pending.
190	22	VA Greater Los Angeles HS	I	12/18/2012	NSOC reported four VA research consent forms containing PHI for a CSP CIRB study sent via UPS were received and signed for by research administration staff; however the package was subsequently lost and could not be located.	Remedial Actions: The four individuals will be sent HIPAA notification letters; other actions pending.
191	23	VA Nebraska/ West Iowa HCS	H	12/18/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks.
192	20	Portland VAMC	H	12/31/2012	NSOC reported that RCO found PHI was collected from 700 subjects without the appropriate IRB approval.	Remedial Actions: Case closed with linkage to 0102-648-H, in which management will be tracked to resolution

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

The Director of each VA research facility is required to report promptly to ORO any serious or continuing noncompliance in the facility's research program. ORO requires that the facility develop an acceptable remediation plan and monitors implementation of the plan until remediation is complete.

Summary

- 78 = Cases Continuing from Previous Calendar Year
- 50 = New Cases – January 1 through March 31
- 54 = New Cases – April 1 through June 30
- 60 = New Cases – July 1 through September 30
- 56 = New Cases – October 1 through December 31
- 220 = New Cases in Calendar Year
- 298 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	07	Augusta	A	03/03/2008	Facility reported IACUC did not have nonscientist member Oct/Nov 2006; HVAC deficiencies were not corrected in a timely manner, and IACUC members had not completed all training requirements.	Remedial Actions: Appointing nonscientist to IACUC; re-review of affected protocols; correcting HVAC problems; and completing IACUC member training.
2	10	Cleveland	A	11/17/2009	Facility reported that the 12 hour light cycle for the ARF housing rats and mice was nonfunctional and the lights had been on continuously for a period of time (at least 3-4 wks). The automatic light cycle failed during ARF renovations. No animal harm resulted.	Remedial actions: Continue to monitor the 12 hour ARF light cycle manually until installation of a permanent electronic monitor; purchase a monitoring system for the ARF or upgrade the lighting system to include a monitoring and alert system. CASE CLOSED
3	22	VA Greater Los Angeles HS	A	07/26/2010	Facility reported multiple noncompliance problems in canine research, including excessive weight loss, lack of timely reporting, unapproved protocol modifications; inappropriate medication acquisition; poor husbandry; lack of compliance with veterinary orders; inadequate record keeping.	Remedial Actions: Veterinary care; education of PI, study team, animal staff; extended IACUC monitoring/follow-up; clinical veterinary monitoring plan; veterinary review of insulin pump and blood sampling operations; communications plan; medication log; unrestricted veterinary access. CASE CLOSED

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
4	22	VA San Diego HS	A	11/30/2010	Facility reported lab inspection found post-operative rats in spinal cord injury/regeneration studies: housed in unapproved laboratory overnight; inadequate monitoring; missing or inadequate documentation; and performance of unapproved: surgical procedures, test substance, use of hazardous agent.	Remedial actions: responsible lab member suspended from all animal studies till further notice; formal audits of all PI's ACORPS; assess animal care; retraining. Audits revealed further noncompliance. Remediation is in progress. CASE CLOSED
5	21	VA Palo Alto HCS	A	12/17/2010	Facility reported unanticipated loss of five caged rats in a metabolic syndrome study due to leak in VMU ceiling water pipe.	Remedial actions: leak stopped by Engineering Service; replace piping; VMU impact assessment. Transferred to RSAW 02/11/11 Temporary external heater has been installed. CASE CLOSED
6	21	San Francisco VAMC	S	01/19/2011	Facility reported safety incident involving a chemical.	Remedial actions: Revision and SRS approval of the standard operating procedures involving the use of the hazardous chemical. CASE CLOSED
7	17	VA North Texas HCS	A	02/27/2011	Facility reported failure in the HVAC affecting one section of the VMU. All affected protocols involved mice and rats.	Remedial actions: Custom fabrication of damaged coils repairs are in progress. CASE CLOSED
8	03	Bronx	A	03/10/2011	Facility reported tail biopsies were being performed on conscious adult mice without IACUC approval.	Remedial actions: IACUC investigate incident IACUC recommend VMO and PI receive counsel; additional training for the technician; IACUC must approve all animal procedures prior to initiation; incident and actions reviewed by the IACUC CASE CLOSED
9	05	DC VAMC	H	03/11/2011	Facility reported an unanticipated problem with inpatient pharmacy vaccine refrigerator (temps too high); Study meds from 2 studies were stored there; sponsor instructed PI to destroy meds	Remedial Actions: Study medications are now stored in the research pharmacy refrigerator; temp monitored manually -daily; Facility Management Service formed Integrated Project Team (IPT) meeting weekly.
10	04	VA Pittsburgh HCS	H	03/11/2011	Facility reported Project Suspension (MRSA rates in spinal surgery): PI used IRB-unapproved method to obtain patient names; non-approved staff attempted to receive PII and send list of names to non-VA email acct. RCO Audit to occur before IRB can review PI's request for study closure.	Remedial Actions: 1. RCO completed the for-cause audit of the study. There were no major findings; 2. IRB accepted the audit report; 3. No further response required from PI but PI must complete all research training requirements to conduct future research. CASE CLOSED
11	12 NE	Hines	H	05/19/2011	Facility reported-Inflammation in Family Caregivers of TBI study-HIPAA Authorizations not obtained (5 subj.). Pt. identifiers collected for screening/recruitment by interviews using partial HIPAA Waiver	Remedial Actions: PI will contact individuals who agreed to be in study and obtain the Authorizations. PO notified. All outstanding HIPAA Authorizations obtained.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
12	16	Oklahoma City	H	05/25/2011	Facility reported PI audited her own study and found HIPAA authorizations were missing for seven participants in a tobacco-induced cancer study. PI is trying to contact participants to obtain signed authorizations.	Remedial actions: PI to obtain HIPAA authorizations or request a waiver; reported deviations to IRB.
13	04	VA Pittsburgh HCS	H	05/25/2011	Facility reported employee conducted unauthorized employee health behaviors research. Data collected from the surveys of employees was to be used for the employee's master's thesis work. All surveys destroyed by employee, no data saved, analyzed.	Remedial Actions: IRB Chair and supervisor made with the student to ensure he/she is educated in VHA requirements to conduct research; 2. Patient Care Services have procedures in place to educate nursing students that they must meet VHA requirements to conduct research. CASE CLOSED
14	02	Syracuse	H	05/26/2011	Facility reported substantive protocol change in PTSD OEF/OIF Veterans substance misusing study implemented without prior IRB approval. Breathalyzer administered prior to consent.	Remedial Actions: = compliance review of enrollment activities completed; RCO audit of this study and another OEF/OIF study completed; PI training completed; PI report finalized. Enrollment reinstated.
15	09	Lexington	I	05/27/2011	Facility reported a PI's personally owned laptop containing PHI was possibly used for unauthorized research; also found paper documents, other electronic files (CDs, floppy paper, slides) and patient films. OIG is investigating. Reported involved 1,900 Veteran's PHI.	Remedial actions: AIB completed; notification letters to all Veterans; electronic media was sanitized by IRM; case diagnostic information was shared without direct identifiers. CASE CLOSE
16	09	Lexington	H	06/16/2011	Facility reported that a personally owned laptop containing PHI (>500 VA patients) possibly used for unauthorized research; Incident Response Team gathering information; AIB starting to investigate Privacy and Research aspects; OIG is investigating.	Remedial actions: AIB determined PI conducted research and shared PHI inappropriately; IRM destroyed all e-files and computer was wiped clean; IRB/RDC actions postponed pending AIB results. CASE CLOSED.
17	02	Syracuse	A	07/08/2011	Facility reported suspension of two mouse protocols due to ongoing misconduct investigation of NIH funded research activities at the affiliate.	Remedial Actions: P.I.'s facility access terminated; mice placed on hold until alternative use is determined; notified relevant external agencies CASE CLOSED
18	22	VA Greater Los Angeles HS	A	07/12/2011	Facility reported several incidents of HVAC failures within the animal facility. One incident affected approximately 430 mice. No mice died.	Remedial actions: Sepulveda alarm system reprogrammed to contact VMU staff during future HVAC failures; exhaust fans set in "fail-off" position; VMU staff trained to operate manual exhaust shut off. CASE CLOSED
19	02	VA Western New York HCS	H	07/26/2011	Facility reported Conflict of Interest (COI) on three different protocols with PIs employing family members. VISN Office, National Association of Veterans Research and Education Foundation (NAVREF), Non-Profit Program Office (NPPO) and Regional Counsel were consulted.	CASE CLOSED Remedial Actions: ACOS/R&D asked all PIs to declare any COI issues by 7/21/11. Focused RCO Audits have been initiated; VISN Director initiated ABOI - report in with 3 recommendations: Policies and procedures (both COI and WOC) are revised, appointments for non-profit staff reviewed.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
20	01	Providence	H	08/09/2011	Facility reported: 4 missing consents(of 18 reviewed), 14 consents missing signature or date of person obtaining consent, and no HIPAA Authorizations in a cost analysis study of non-invasive DNA collection methods.	Remedial Actions: Study suspended; no work on samples until valid consent and HIPAA obtained pending IRB review; RCO training for both students and PI completed; RCO satisfied recruiting is being done correctly; RCO conducted regulatory audit.
21	12	Chicago HCS	S	08/22/2011	Facility reported water leak and flooding of the 6th and 7th floors of the R&D Department. One employee reported respiratory issues after the incident but no flooding in the VMU and no animals compromised.	Remedial Actions: notify MCD; Evacuation and inspection of 7th floor; VMU evacuation; removal of water and debris. CASE CLOSED
22	03	VA New Jersey HCS	H	08/29/2011	Facility reported lack of SRS annual review and approval for an oncology clinical trial.	Remedial actions: Study closure submitted; audit of all human research studies in need of SRS review.
23	03	VA New Jersey HCS	R	08/29/2011	Facility reported failure of SRS review for animal study since 2004.	Remedial actions: PI submitted materials for SRS review; study approved by SRS Aug 15, 2011; IACUC reviewed and approved; next continuing review date will be included in ACOS notification letter; audit for other instances underway.
24	07	Atlanta	H	09/16/2011	Facility self report of VA funded study Behavioral and Neuroimaging changes after cognitive rehab. conducted at affiliate and at VA. Subjects (# unknown) consented using affiliate's ICD only.	Remedial Actions: IRB approved plan to re-consent new and active study subjects with VA ICDs. RCO, PO and ISO monitoring progress. Actions completed. Case closed.
25	07	Atlanta	H	09/16/2011	Facility self report of VA funded study of memory rehabilitation. Subjects enrolled w/ affiliate approved ICDs at affiliate (# subjects unknown)	Remedial Actions: IRB determination for re-consenting active and new study subjects w/ RCO,PO and ISO monitoring progress. All actions taken. Case Closed
26	03	Bronx	H	09/16/2011	Facility self report of two biopsies in a Hepatitis C research study that were conducted outside of VA without approval; monetary reimbursement issues, reporting issues.	Remedial Actions: Privacy discussion with PO; secure data at outside facility and agreement written; budgetary issues to be resolved; enrollment suspended; liver biopsies suspended for research purposes. CASE CLOSED
27	05	Martinsburg VA Medical Center	H	09/23/2011	Facility reported that a PI of a vascular study left the VA without notification and did not seek IRB approval for a new PI. IRB subsequently approved the new PI. Data previously collected cannot be used.	Remedial actions: Update the process for PIs leaving VA employment. CASE CLOSED
28	08	VA North Florida/ South Georgia HCS	H	09/23/2011	Facility reported a change of PI to co-PI which did not assign appropriate roles to the PI and 16 subjects were consented without PI's appropriate scope of practice, this is a behavioral study of wheelchair use.	Remedial actions: Training to both PIs was conducted; The study was stopped and the subjects were notified. The IRB determined not serious not continuing. The study is now closed. CASE CLOSED.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
29	15	VA Kansas City Medical Center	H	09/27/2011	Facility reported MCD suspension of enrollment of new subjects in a trial of anticoagulant use for atrial fibrillation. Suspension based on PI history of non-compliance over the past year and results of two RCO audits of PIs other studies.	Remedial actions: Request RCO regulatory audit; complete master log; report all SAE's to the IRB; update VA pharmacy prescriber form and FDA Investigator form 1572. MCD suspension lifted 1/4/2012. Remedial actions complete. Case closed.
30	15	VA Kansas City Medical Center	H	09/27/2011	Facility reported suspension of enrollment of new subjects in a study of Type II diabetes and cardiovascular deaths. Suspension based on IRB findings of Investigator noncompliance in past year and results of two RCO Audits.	Remedial actions: Change in PI; implemented staff changes/protocol training; allow enrollment 1 subject with new PI and Sponsor monitor oversight. Suspension lifted January 2012; PI RAP to address delay of subject contact. Remedial actions complete. CASE CLOSED.
31	15	VA Kansas City Medical Center	H	09/27/2011	Facility reported suspension of enrollment of new subjects in a trial of Type II Diabetes and cardiovascular outcomes. Suspension based on IRB findings of Investigator noncompliance in past year and results of two RCO Audits.	Remedial actions: Change in PI 9/1/11, PI initiated process changes and training of staff, future PI noncompliance may warrant research privileges revoked by MCD, allow enrollment 1 subject on trial basis with new PI and Sponsor monitor oversight. Remedial actions complete. CASE CLOSED.
32	10	Cleveland	H	10/04/2011	Facility reported IRB approved administrative termination of DNA Banking Substudy to CSP#565, a diabetic kidney disease study involving a onetime blood draw. Termination resulted from expiration of the IRB approval period.	Remedial Actions: All records and data associated with study do not have IRB approval and may not be used or accessed. IRB determined subj. not at risk due to study termination. RCO audit to ensure no additional study data or samples sent. ACOS contacted CSP Study Coordinating Center. Case Closed
33	10	Cleveland	H	10/04/2011	Facility reported IRB approved administrative termination of the retrospective chart review study "Intra-operative Predictors of Adverse Outcomes" due to lapse in continuing review (third occurrence). Study closed to enrollment and in data analysis.	Remedial Actions: IRB determined all records and data associated with study do not have IRB approval and may not be used or accessed. Systemic issues re: communication of pending continuing reviews addressed by R&DC.
34	11	VA Illiana Healthcare System	H	10/04/2011	Facility reported that IRB failed to accurately document approvals, and Research Service failed to maintain requirements and protocol binders.	Facility in process of program closure by end of December, 2011. Program closed January 24, 2011.
35	01	VA Connecticut HCS	H	10/19/2011	Facility reported medication administration error in a blinded treatment study of skeletal related events in Prostate Cancer patients. No severe side effects are expected; decision made to not unblind the participant.	Remedial Actions: IRB to review this event at October 20, 2011 meeting. CASE CLOSED

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
36	03	Bronx	H	10/21/2011	Facility reported that a PI (Hepatitis C study) was using a Non-VA facility for liver biopsies. Privacy issue. PI faxed PHI/PII to the offsite location (two Veterans); stated it was discussed with pts but it wasn't documented in chart or included in the HIPAA Authorization.	Remedial Actions: PI to meet with PO; secure data at outside facility and agreement written; budgetary issues to be resolved; enrollment suspended; liver biopsies suspended for research purposes; 2 Veterans will be offered credit protection services. CASE CLOSED
37	04	VA Pittsburgh HCS	H	10/21/2011	Facility reported unauthorized transmission to affiliate of 17 audio recordings for 9 subjects in a depression prevention study. The personnel that reviewed the audio tapes had no WOC appointment and were not credentialed and privileged. Case linked to RIPP DSS#0079. NERO providing primary oversight	Remedial actions: PI provide written confirmation audio/video taping not used in any active protocols; if method used, submit UPR, and confirm VAPHS appointment, credentialing and training of tape recipients, modify protocol to state consent must be obtained prior to taping. CASE CLOSED
38	08	Bay Pines	A	10/25/2011	Facility reported an incident of non-compliance when mice were left unattended for over an hour during behavioral restraint procedure.	Remedial actions: IACUC notified PI of incident; IACUC developed action plan; PI ensure proper coverage of all animals; PI provide documentation of monitoring; PI's experiments will be independently validated for compliance; staff training on ethical treatment of animals. CASE CLOSED
39	09	VA Tennessee Valley HCS	H	10/26/2011	Facility reported that as part of a NIH funded study, 3 human skin punch biopsies collected at the affiliate were processed using VA time, VA resources and equipment, and VA space without prior approval by the VA IRB.	Remedial actions: Immediately stop research activities at VA; PI educated on VA requirements; submission of new protocol to VA RSS/IRB/RDC for approval. CASE CLOSED.
40	21	San Francisco VAMC	H	10/28/2011	Facility reported the recruitment of subjects from a study population not approved by the IRB for a simulation of coronary artery bypass graft study.	Required actions: Cease noncompliant enrollment, modify protocol, identify mechanism to prevent recurrence. CASE CLOSED.
41	08	VA North Florida/ South Georgia HCS	A	10/31/2011	Facility reported unanticipated loss of life in rats.	Remedial Actions: Husbandry staff training; revise procedures for health monitoring to ensure timely veterinary notification; submission of protocol amendment to revise endpoint criteria. CASE CLOSED.
42	16	Houston	H	11/03/2011	Facility reported that CIRB suspended multi-site Hepatitis C and Depression study due to use of an amended ICD without prior approval.	Remedial actions: Study suspended; complete audits of study files at all sites; re-consent of participants enrolled with the unapproved ICD
43	00	VA Central Office	H	11/04/2011	Facility reported suspension of IRB approval of a Hepatitis C study due to a finding that a local study site appeared to have forged IRB approval of an amended informed consent document. Suspension effective at all 4 study sites.	Remedial actions: RCO audits at all 4 sites; reconsent subject; training; LSI action plan and weekly progress report. OIG decided not to investigate case as the individual left VA.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
44	22	VA Greater Los Angeles HS	H	11/04/2011	Facility reported a CIRB suspension of a multisite study of hepatitis C and depression. The facility is a local site in this multisite study and was not directly involved in the noncompliance that resulted in the CIRB suspension.	Remedial actions: Local RCO performed requested audit of the local study file and reported to the VHA CIRB and the local R&DC; no further local action required; CIRB study suspension to be managed by ORO CO; local case closed.
45	10	Cleveland	H	11/10/2011	Facility Self Report of noncompliance based on IRB audit of VA Merit Review study of pressure ulcer assessment in spinal cord injured patients; 8 ICDs without IRB stamp; 1 HIPAA auth. not signed; 8 subjects not given copies of ICD signature pg; (10) missing CPRS documentation and staff training.	Remedial Actions: PI and Study Coordinator IC education; CPRS Documentation; Obtain HIPAA authorizations; Use current IRB stamped ICD version; study staff training; providing copies of authorizations to research subjects; Study closure w/ letter to subjects on study status; no data use. CASE Closed
46	06	Durham	H	11/10/2011	Facility reports facility recruitment-only study for larger affiliate study of a computer-based intervention for PTSD and addiction had unauthorized VA PHI removed from facility and taken to affiliate. An affiliate student also cold-called prospective subjects and one lodged a complaint with VA PO.	Remedial actions: Facility PO, ISO, HRP Coordinator, RCO provided education (approved transport & disposal of VA PHI) to the PI and staff; PI will reassess & rewrite policies that synchronize use of PHI. CASE CLOSED
47	20	Portland VAMC	A	11/16/2011	Facility reported investigation of mouse death during experimental Plasmodium infections. Work conducted by technician not on protocol. Mice ordered and received under other protocol. IACUC determined incident not to be reportable.	Remedial Actions: Amendments to add technical to protocol and transfer animals to protocol; Increased monitoring frequency of mice and increased blood sampling to monitor parasitemia. CLOSED CASE
48	06	W.G. (Bill) Hefner VA Medical Center	I	11/17/2011	Facility reported discovery of old research study files containing subject's names and some identifiers in storage room locked cabinets. Non-research related documents were also found. Incident Response Team (IRT) immediately notified. Data breach involved approximately 2,766 individuals.	Remedial actions: Room immediately secured; all documents inventoried; inventory submitted to ORO; Regional Counsel and OIG were notified; VA removable media were recovered; 162 Veteran research subjects will be sent credit monitoring letters; referred to Regional Counsel for action. CASE CLOSED
49	16	Fayetteville	H	11/21/2011	Facility self-reported that their representative to the IRB of Record (located at another VA facility) did not meet the 5/8 VA employment requirement for IRB membership.	Remedial actions: Replaced ineligible member, IRB checked minutes, quorum was not lost on votes for review items during the period when the 5/8 VA requirement was in effect.
50	16	Central Arkansas VHS	H	11/23/2011	Facility self-reported that the PI conducted PTSD research collected data and enrolled participants after IRB approval lapsed.	Remedial actions: PI - Prioritize communications from the IRB; Reconsent two participants recruited during lapse; IRB - automate expiration notices through IRBNet Facility - self-report to OHRP

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
51	20	Portland VAMC	H	11/29/2011	Facility reported that the linking document between the data and the identifiers for a closed dialysis and depression study had not been destroyed, and the data were not deidentified.	Remedial Actions: Training for the PI; other actions pending. CASE CLOSED.
52	20	VA Puget Sound HCS	H	11/30/2011	Facility reported that a PI did not implement IRB required actions following a previous determination of consent related serious noncompliance (case #0070-663-H) in a pulmonary study.	Remedial Actions: Administrative hold and audit of all PI's protocols; re-consenting; CPRS notations; training. All corrective actions completed. Case closed.
53	11	Indianapolis	P	12/02/2011	Facility reported full time VA employee/part time affiliate was using non VA time and effort while conducting human research at affiliate without RDC approval.	Remedial actions: PI education; CASE CLOSED
54	05	VA Maryland HCS	H	12/05/2011	Facility reported affiliate audit found IRB approval expired 3 times; incorrect ICD used for 8/100 subjects; the "evaluation to consent" form was not completed or present for 14/100; documentation of the consent process was not present for 100/100 participants (cardiac arrhythmia risk study).	Remedial Actions: VA conducted audit with same findings; PI reported deviations; change in facility personnel with creation of new Research Service position; new SOPs established to ensure compliance with ORO reporting. CASE CLOSED.
55	05	VA Maryland HCS	H	12/05/2011	Facility reported source documentation was not available to verify study eligibility (hip fracture study) prior to enrollment of 5/5 subjects; IRB approval expired 3x-no research conducted during lapse; witness signature missing; study procedures not performed; HIPAA signed after data collection	Remedial Actions: PI retrained; PI updated SOPs; PI reported deviations to IRB. CASE CLOSED
56	01	VA Connecticut HCS	H	12/06/2011	Facility reported omitted HIPAA Authorization for 20 of the 20 subjects enrolled to date in a lung surgery observational study.	Remedial Actions: IRB asked RCO to perform a Good Clinical Practice audit; IRB allowing use of data collected since PHI will not be disclosed outside of VA; RCO to monitor next 10 enrollments to ensure proper ICD and HIPAA Authorization processes. CASE CLOSED
57	08	Bay Pines	H	12/07/2011	Facility reported a protocol violation in using unapproved interview scripts and failure to consent 3 provider subjects for an evaluation of housing program for homeless Veterans.	Remedial actions: Study suspension during the IRB's investigation and review. The RCO audited all informed consents and the PI's study binder. PI decided to close the study due to noncompliance determined serious by the IRB. Reporting to OHRP completed. CASE CLOSED.
58	08	Tampa	H	12/09/2011	Facility reported failure to report an unanticipated SAE in a phase II myeloma drug study.	Remedial actions: The PI submitted a report after education was received from the RCO. The IRB determined the noncompliance as serious, non-continuing. The R&DC accepted and reported to OHRP. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
59	20	VA Puget Sound HCS	H	12/12/2011	Facility self-reported serious noncompliance. One subject was enrolled in a lapsed COPD protocol.	Remedial actions: Development and implementation of a plan by study staff to track IRB approvals and ensure critical study information is disseminated to all study staff. CASE CLOSED.
60	16	Central Arkansas VHS	H	12/15/2011	Facility reported suspension of PI's research privileges based upon "ongoing global serious and continuing noncompliance..." in multiple studies.	Remedial actions: PI's research privileges suspended by Acting ACOS/R, terminated two studies, suspended one; PI will not be reinstated until all contingencies on listed studies are satisfied and privileges are restored. CASE CLOSED
61	05	DC VAMC	S	12/16/2011	Facility reported an incident in which the Animal Research Facility Manager was injured while transporting waste to the dumpster. The manager experienced severe bruising on her left leg and upper torso. She received medical treatment from Occupational Health.	Remedial actions: Loading ramp dock closed; stop research staff from handling hazardous animal waste; contract a vendor to remove all hazardous waste; install dumpster closer to the Animal Research Facility. CASE CLOSED
62	16	Central Arkansas VHS	A	12/16/2011	Facility reported an incident in which several mice were found dead due to inadequate husbandry procedures.	Remedial actions: VMU supervisor re-emphasize the need to follow husbandry SOPs; staff retraining; greater oversight of animal care staff; develop a protocol to help monitor animal care technicians. CASE CLOSED
63	21	San Francisco VAMC	S	12/16/2011	Facility reported an incident in which a postdoc fellow was injured while working under the fume hood using isoflurane and paraformaldehyde. The postdoc suffered a needle stick and loss of consciousness.	Remedial actions: Notified Environmental Health and Safety, Engineering, Personnel Health, and the SRS Chair; continue to monitor and follow up with the postdoctoral fellow's health care provider. CASE CLOSED
64	08	VA Caribbean HCS	H	12/19/2011	Facility reported the PI failed to submit the continuing review materials requested by the IRB. The IRB terminated this human papilloma virus knowledge assessment study after risk assessment was obtained and signed by the Chief of staff and the PI.	Remedial Action: Study termination; RCO audit of this closed study. CASE CLOSED.
65	08	VA Caribbean HCS	H	12/19/2011	Facility reported the PI failed to submit the continuing review materials requested by the IRB. The IRB terminated this study after risk assessment was obtained and signed by the Chief of staff and the PI on an sleep apnea study.	Remedial actions: The IRB terminated this study after risk assessment was obtained and signed by the Chief of staff and the PI. RCO audited the closed study and had no findings. CASE CLOSED.
66	08	VA Caribbean HCS	H	12/19/2011	Facility reported: a. The Principal Investigator (PI) failed to submit the continuing review materials requested by the IRB. b. The IRB terminated this study after risk assessment was obtained and signed by the Chief of staff and the PI on a multiple sclerosis study.	Remedial Actions: The IRB terminated this study after risk assessment was obtained and signed by the Chief of staff and the PI. No Activity was ever started. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
67	08	VA Caribbean HCS	H	12/19/2011	Facility Reported: The PI failed to submit the continuing review materials requested by the IRB; and the IRB terminated this study after risk assessment was obtained and signed by the Chief of Staff and the PI on a sleep apnea associated with erectile dysfunction study.	Remedial actions: The IRB terminated the study after a risk assessment was reviewed. Training needs were assessed and a plan developed.
68	05	VA Maryland HCS	H	12/20/2011	Facility reported noncompliance discovered during SRO's HRPP recent visit. A chronic heart failure study addressing depression and biobehavioral processes did not have R&DC approval.	Remedial actions: PI will submit to R&DC for approval; Enrollment stopped until R&DC approval is obtained. CASE CLOSED.
69	04	VA Pittsburgh HCS	H	12/21/2011	Facility reported a study of sedentary overweight Veterans" was suspended by the IRB2 due to the failure of investigator to make modification to the protocol and provide a response to the IRB comments in a timely manner.	Remedial Actions: Modification to protocol to revise exclusion criteria, consent form, waiver of HIPAA authorization and to include power analysis Remedial actions have been completed. Case closed
70	04	VA Pittsburgh HCS	H	12/21/2011	Facility reported nurse coordinator conducted an active protocol (Ischemic Foot Ulcer Study) without required credentialing and privileging.	Remedial Actions: IRB2 has reminded R&D Office that conduct of research without credentialing, privileging, scope of practice is a violation of VHA and local policies; R&D Office instructed to thoroughly review CVs of individuals requesting approval to conduct research. CASE CLOSED
71	04	VA Pittsburgh HCS	H	12/21/2011	Facility reported PI of ischemic foot ulcer study failed to report one or more SAEs within the required timeframe. Determined by IRB that SAEs not study related and did not represent serious problem involving risks to subjects or others. Study closed.	Remedial Actions: IRB determined no corrective actions necessary since study closed; PI will be reminded for future studies to follow local and VHA policies for recording and reporting SAEs. CASE CLOSED
72	04	VA Pittsburgh HCS	H	12/21/2011	Facility reported programmatic non-compliance wherein the Clinical Trials Center (CTC) has failed to meet the requirements of reporting non-serious, unanticipated adverse events according to facility SOPs.	Remedial Actions: IRB SOP updated for AE reporting; CTC staff reviewed the VAPHS AE reporting policy and attend the education session that addressed the requirements. CASE CLOSED
73	04	VA Pittsburgh HCS	H	12/21/2011	Facility reported the IRB failed to report non-compliance (Case #0062-646-H) within 5 days of identification in a study of MRSA rates in spinal surgery. Case linked Case #0062-646-H	Remedial Actions: IRB reminded that any non-compliances identified must be reported with 5 days; IRB1 and IRB2 have adopted a status report charting system to ensure that there is a continuous scrutiny and updated actions to resolve non compliance issues until closed. CASE CLOSED
74	09	VA Tennessee Valley HCS	A	12/21/2011	Facility reported a temporary lapse in animal husbandry. The species affected were mice and rats.	Remedial actions: Revision and modification of the weekend coverage schedule; employee training regarding unscheduled leave policy. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
75	02	Albany	H	12/23/2011	Facility reported apparent informed consent and HIPAA authorization documentation noncompliance on human subject protection for a suicide study.	Remedial Actions: RCO audit. CASE CLOSED
76	18	Phoenix VA HCS	H	12/23/2011	Facility reported protocol change implemented prior to IRB approval.	Remedial actions: IRB review of the requested protocol change (and the associated noncompliance); PI reports all unapproved activities. CASE CLOSED.
77	18	Phoenix VA HCS	H	12/23/2011	Internal pre-audit (prior to the RCO audit) of an asthma study identified delinquent SAE reports and self-reported by facility to ORO.	Remedial actions: Remedial training for PI regarding reporting requirements and timeframes; IRB did not require any protocol changes as the 4 AE and 2 SAE were not study related. CASE CLOSED.
78	09	Memphis	H	12/29/2011	Facility reported PI non-compliance with reporting requirements in study on progressive tinnitus management with cognitive behavioral therapy. PI reported SAE (death by suicide) 30 days after discovery.	Remedial actions: IRB deemed event not related to research participation; IRB notified PI of SAE reporting requirements. CASE CLOSED
79	06	Durham	S	01/04/2012	Facility reported an unauthorized student lacking proper training doing research in the lab during a routine safety inspection. The student was instructed to stop all research activity until WOC status and training were completed.	Remedial actions: Student prevented further access; PI submit written report to SRS; PI develop a checklist of requirements for new staff; future staff not allowed lab entrance prior to written approval from Occupational Health and RCO. CASE CLOSED.
80	01	Providence	S	01/04/2012	Facility reported a WOC student splash with a research sample (bacterial broth) onto her face, neck, and hands. The student was wearing a lab coat but no safety glasses.	Remedial actions: Eyewash protocol initiated; Employee Health notified and a health assessment performed; spill area locked down and cleaned; eyewash area cleaned and disinfected; worker counseled on proper PPE; change of syringe type to prevent future occurrences. CASE CLOSED
81	20	VA Puget Sound HCS	A	01/06/2012	Facility reported failure to meet a deadline to correct a major deficiency involving the HVAC heat valves failing in the off position so that animal rooms cannot overheat. To date, no rooms have overheated no animals have been hurt. The species housed are mice, rats and chickens.	Remedial actions: Facility upgrading of heat valves underway; completion dates set for January 12, 2012 and March 31, 2012. CASE CLOSED
82	16	Central Arkansas VHS	H	01/13/2012	Facility reported research on cardiac stents was conducted by Cardiology Fellows with Service Chief's concurrence but without IRB and R&DC approval	Remedial actions: None - IRB and R&DC determined that the activity was not research

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
83	20	VA Puget Sound HCS	H	01/13/2012	Facility self reported apparent serious noncompliance in the failure to obtain compliant HIPAA authorization and maintain documentation required by an IRB approved protocol for 26 out of 26 subjects enrolled in a pulmonary function protocol.	Remedial actions: The IRB required audits of all of the PI's protocols; PI and staff must be retrained. All corrective actions completed. Case closed.
84	05	DC VAMC	H	01/18/2012	Facility self-reported 30 subjects signed unstamped ICDs in a unfunded, minimal risk study with medical students & residents completing surveys to assess their attitudes & self-perceived skills at the beginning and end of their internal medicine rotation.	Remedial Actions: PI will not reconsent subjects; PI will allow subjects option to withdraw their data. CASE CLOSED.
85	01	VA Connecticut HCS	A	01/20/2012	Facility reported an incident of inadequate husbandry practices involving mice.	Remedial actions: Training of husbandry personnel; increase monitoring by research staff. CASE CLOSED
86	23	St Cloud	H	01/23/2012	Facility reported apparent programmatic non-compliance for use of one of the boards of the IRB of record which was not listed on the facility FWA.	Remedial actions: FWA amended to add IRB-B; other actions pending. Closed.
87	23	Minneapolis	H	01/24/2012	Facility reported apparent human subject programmatic noncompliance. IRB reports affiliate VA protocols reviewed by IRB panel not listed on affiliate VA FWA.	Remedial Actions: Revise FWA to include both IRB panels. CASE CLOSED.
88	17	VA South Texas HCS	I	01/24/2012	Facility reported 1 missing laptop and 1 missing desktop computer. Both computers had been entered onto inventories. NSOC report subsequently submitted stated no PHI/PII was stored on either computer.	Remedial actions: No data breach occurred since no PHI/PII was stored on either computer. CASE CLOSED
89	03	Bronx	S	01/25/2012	Faculty reported a needle stick experienced by a WOC employee while performing an autopsy on a Hepatitis C patient. The autopsy was being conducted for research purposes and was supervised by VA staff.	Remedial actions: Employee taken to employee health and treated; follow up lab testing and monitoring implemented; all appropriate committees notified; SRS conducting ongoing surveillance. CASE CLOSED
90	01	VA Boston Healthcare System	A	01/25/2012	Facility reported an incident of non compliance whereby appropriate post op analgesia was not supplied when surgery was performed on 3 rats. The IACUC suspended the survival surgery portion of the protocol.	Remedial actions: Survival surgery portion was suspended; employee involved was suspended from conducting survival surgery on all protocols; PI to provide description of circumstances that resulted in noncompliance; appropriate oversight organizations notified. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
91	07	Atlanta	H	01/29/2012	Facility reported that data (CBC blood tests) on 11 subjects from study on Improving Outcomes for Family Caregivers of Heart Failure Patients stored at affiliate but not documented in HIPAA authorizations.	Remedial Actions: Privacy Officer notified; NSOC Report issued. Amend HIPAA, reconsent subjects; additional information security training for study team; affiliate IRB and VHA research compliance office evaluate process for improvement. CASE CLOSED
92	22	VA Long Beach HS	H	01/30/2012	Facility reported that a subject did not sign a screening ICD for a human stent graft system study. The subject failed the requisite screening procedure and was not enrolled in the study.	Remedial actions: Education of PI and study staff regarding the requirement to obtain informed consent for all research procedures, including screening; refresher education for IRB regarding reporting requirements. CASE CLOSED
93	12 NE	Hines	H	02/01/2012	Facility reported 5 missing HIPAA Authorizations in a CDC study of HIV patients.	Remedial Actions: HIPAA Authorizations are being obtained; RCO to conduct audits every 3 months; development of plan to prevent future occurrences. CASE CLOSED
94	09	Memphis	H	02/01/2012	Facility reported external SMART audit of a diabetic nephropathy study results included 2 SAE's unreported to the IRB; delayed reporting to IRB of 9 SAE's; no HIPAA waiver for recruitment on file.	Remedial actions: Submit 2 unreported SAE's to the CIRB; RCO provided SAE reporting education to PI and Study Coordinator. CASE CLOSED.
95	00	VA Central Office	H	02/02/2012	Facility reported a package mailed from the facility to study coordinating center in CA was damaged upon receipt, and items containing PHI were missing. Combat trauma PTSD study.	Remedial actions: UPS issued claim for damage shipment; notify affected subjects; provide justification for including SSN in consent and HIPAA. CASE CLOSED
96	08	Miami	A	02/03/2012	Facility reported non-adherence to research protocol involving mice. The approved protocol was to examine new cancer therapies but the mice were being purchased and used to conduct research on an unapproved neurological study.	Remedial actions: IACUC ordered PI to stop noncompliant research; PI to submit report summarizing noncompliant animal research activities; PI to submit a new ACORP covering neurological research. CASE CLOSED
97	07	Charleston	H	02/09/2012	Facility reported that a veteran subject engaged in a sexual relationship with a study therapist at the affiliate. The NIDA-funded study involved treatment for OIF/OEF veterans with PTSD and substance abuse.	Remedial Actions: PI submitted report to affiliate IRB; Veteran being treated at facility Mental Health Clinic; Facility checking to see if other Veterans enrolled in study & seen by the therapist; Will notify licensing boards & OHRP; Will notify NIDA. CASE CLOSED.
98	22	VA Greater Los Angeles HS	H	02/13/2012	Facility reported PI did not submit PBM alert and sponsor safety information related to the drug Aliskiren to the IRB as required. IRB determined subjects were not at risk as the PI undertook appropriate actions.	Remedial Actions: Suspension of new enrollment for ongoing VA studies with this drug until consent is revised with new information. CASE CLOSED.
99	18	Phoenix VA HCS	H	02/15/2012	Facility reported that an SAE involving a human study involving current care for foot ulcer prevention was not reported within the require time frame.	Remedial Actions: Updated training for research staff to reinforce the requirements for reporting SAEs; recently developed SOP explaining this and other processes. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
100	21	San Francisco VAMC	H	02/15/2012	Facility self reported Unanticipated SAE in the discontinuation of enrollment in a prospective, multicenter safety and efficacy study of an implanted deep brain stimulation system for the treatment of tremors due to concerns performance and reliability of the device.	Required actions: Cease enrollment; Subject notification; and external reporting to OHRP and FDA. Case closed.
101	09	Louisville	H	02/17/2012	Facility self reported an activity of noncompliance for delayed reporting of facility change in AAHRPP status.	Remedial actions: report to ORO. Facility obtained full accreditation. IRB determined no further actions required. CASE CLOSED.
102	00	VA Central Office	H	02/17/2012	VHACO reported a facility research staff emailed the last page of ICD and a letter to a veteran to the VA coordinating center unencrypted.	Remedial actions: Report to PO and NSOC; delete unencrypted email; report to VACIRB.
103	07	Atlanta	H	02/22/2012	Facility reported that prostate study subject zip codes were stored at the affiliate without valid HIPAA authorization or notification in the ICD.	Remedial Actions: PO and ISO have been notified. NSOC ticket has been opened and closed. Revise the VA HIPAA form; Re-consent with amended HIPAA form or remove zip code data if unable to recontact; Info. Security/HIPAA training for PI and study staff. Zip codes removed. Case Closed.
104	01	VA Boston Healthcare System	H	02/22/2012	Facility reported PI of a COPD study self-identified failure to adhere to exclusion criteria for 3 enrolled participants.	Remedial actions: Report issue to coordinating site; new enrollments suspended; subjects not meeting inclusion criteria withdrawn and notified of occurrence.
105	15	VA Kansas City Medical Center	H	02/22/2012	Facility reported non-compliance of failure to adhere to the protocol-defined schedule of events in a diabetic vascular study. 34 study subjects had delays in their 9-month follow-up phone visits due to change in study personnel.	Remedial actions: New coordinator caught up with backlog within 3 months; RCO audit to be conducted after next protocol-defined follow-up phone visit. Remedial actions completed. Case closed.
106	05	VA Maryland HCS	A	02/27/2012	Facility reported incidents of noncompliance involving two research protocols. These included a lapse of IACUC approval in a study involving the use of mice, and a lapse in RD&C and SRS approval.	Remedial actions: PI acknowledgement that data collected during unapproved period is not to be used in publications; further non-compliance will result in suspension of research; increased post-approval monitoring. CASE CLOSED
107	08	Tampa	I	02/28/2012	Facility reported transmission of unencrypted email containing 35 Veteran's PHI in a kidney disease study. The message was sent within the VA network.	Remedial actions: Sender re-training related to encryption process; RCO clarified that email was removed from sender and recipient email mailboxes. CASE CLOSED
108	00	VA Central Office	H	02/28/2012	Facility reported serious noncompliance involving taking a subject's pictures with consent in a carcinoma chemoprevention trial.	Remedial actions: Pictures deleted from the study file and camera memory card as instructed by Nation CSP Coordinating Center; inform subject of mistake and actions taken.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
109	22	VA Greater Los Angeles HS	A	02/28/2012	Facility reported that a researcher performed surgeries in mice prior to being added to the research protocol.	Remedial actions: Submission of amendment to IACUC and SRS to add researcher to protocol; IACUC review of current procedures to add personnel.
110	12 NE	Hines	H	03/05/2012	Facility reported IRB continuing review audit identified documentation deficiencies in consent forms in study of neuropathy.	Remedial Actions: PI to develop checklist; RCO to audit next 10 subjects enrolled. CASE CLOSED
111	09	Louisville	H	03/07/2012	Facility reported R&DC approval for 8 non-VA science-only research protocols.	Remedial actions: RDC rescinded approval of protocols; facility contacted ORD regarding non-VA research being entered into ePromise; CASE CLOSED.
112	21	VA Palo Alto HCS	A	03/07/2012	Facility reported conduct of animal procedures by unauthorized personnel (species not specified)	Remedial action: Submission of a protocol amendment to add the lab member to the list of approved personnel. CASE CLOSED
113	21	VA Palo Alto HCS	A	03/07/2012	Facility reported inappropriate euthanasia techniques in rodents (species not specified).	Remedial action: All laboratory staff received retraining in proper euthanasia techniques by VMU supervisor. CASE CLOSED
114	11	Detroit	H	03/08/2012	Facility self-report concerning possible VA animal research being conducted off-site without off-site waiver.	Remedial actions: Case focus is animal research, case referred to RSAW. CASE CLOSED.
115	12	Chicago HCS	H	03/12/2012	Facility reported enrollment of non-eligible subjects, dosing errors, and numerous procedural deviations in an antiplatelet inhibition IND study. Issues were identified by the IRB during the continuing review process.	Remedial Actions: PI to notify human subjects office of sponsor monitoring visits; IRB is placing hold on approving any new research studies from PI; continuing reviews to be set at 6 month intervals. Remedial actions complete. Case closed.
116	08	Orlando VAMC	H	03/13/2012	Facility reported non-VA research promotional brochures were received and distributed by facility staff members from affiliate investigators seeking to engage the facility in a PTSD virtual reality study.	Remedial actions: Service Chiefs and IRB Chairperson immediately notified all personnel via email of current VA policy. A letter will be sent to the University IRB to remind them of VA policy. Further education to facility staff to prevent reoccurrence. CASE CLOSED.
117	12	Milwaukee	A	03/14/2012	Facility reports a resident performed a procedure on a guinea pig that was not included in the IACUC-approved animal protocol. The procedure was subsequently included in a protocol amendment and approved by the IACUC.	Remedial actions: PI self reported the violation, counseled research fellows not to make any changes to procedures unless an amendment is approved. IACUC investigated, determined that PI had taken appropriate measure and considered the issues resolved. ORO concurs. CASE CLOSED.
118	11	Detroit	A	03/15/2012	Facility reported possible off-site research without a waiver.	Remedial actions: Investigation is ongoing at this time. It was determined that animal work at this location does not require an off-site waiver.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
119	08	Miami	H	03/16/2012	Facility reported a research subject was photographed in a CSP skin cancer chemoprevention trial despite declining to sign consent for photography.	Remedial Actions: CSP advised deletion of photos. Procedure was developed to identify subjects that did not sign the photo consent form; the IRB suggested contacting the subject and informing him of the error and corrections that were taken. Participant informed. CASE CLOSED.
120	22	VA Greater Los Angeles HS	H	03/16/2012	Facility Self-Report informed of a 8-month delay in reporting a patient's death in August 2010 while participate in a heart disease study.	Remedial Actions: IRB determined the event was serious and possibly related to the study; and the delay in reporting was serious noncompliance. CASE CLOSED.
121	08	VA North Florida/ South Georgia HCS	H	03/20/2012	Facility self-reported that an investigational aortic stent failed during aneurysm repair surgery. The broken device was removed and surgery continued without incident.	Remedial actions: Broken stent removed and replaced. Device sent for evaluation to manufacturer where it passed evaluation. The IRB determined the event to be serious, unanticipated, and related to the research. CASE CLOSED.
122	16	Houston	P	03/21/2012	Research Service Line review of e-IRB database found PI of an orthopedic registry study started study without submitting for R&DC review; failed to obtain a valid HIPAA authorization from 55 Veteran participants; employed a non-VA coordinator to enroll Veterans; sent data to a non-VA institution	Remedial Actions: Administrative hold placed on study; PI to submit protocol to R&DC for review and approval before resuming research procedures; credit monitoring offers to Veterans; protocol amendment; ensure all VA research is conducted in accordance with VHA 1200.05.
123	05	VA Maryland HCS	H	03/22/2012	Facility reported that the RIPP review revealed that HIPAA authorization was not obtained correctly. This is a clinical demonstration dementia study with no randomization or group assignment.	Remedial actions: To be followed in RIPP Remedial Action Plan. CASE CLOSED
124	05	VA Maryland HCS	H	03/22/2012	Facility self-reported that the FDA issued changes to the study for increased risks. This is a Phase II clinical trial for men with a rising PSA funded by the Dana Farber Cancer Institute.	Remedial Actions: PI to submit protocol amendment and revised ICD; Enrolled participants will be reconsented; Previous participants will be notified of possible ovarian failure. CASE CLOSED.
125	06	McGuire (Richmond)	H	03/23/2012	Facility reported a TBI model systems study questionnaire was used multiple times but had not been approved by the IRB. The questionnaire was IRB approved for a separate TBI study with the same PI and overlapping study staff.	Remedial actions: Data will not be used; the questionnaire will be kept separate from the other study; staff will be retrained on the use of the questionnaires. CASE CLOSED
126	08	VA Caribbean HCS	I	03/23/2012	Facility reported temporary loss of a folder containing one Veteran's ICD form containing PHI and another form containing employee identifiable information. The folder was located within 20 minutes and returned to the appropriate staff.	Remedial actions: Staff orientation and retraining; Privacy/Information Security awareness campaign launched and walkthroughs to begin; offer credit monitoring services to Veteran. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
127	15	Columbia	A	03/27/2012	Facility reported a procedural deviation involving the lack of use of aseptic technique during survival surgeries in rodents.	Remedial actions: Compliance in the use of aseptic technique during surgery; VMO and IACUC post-approval monitoring
128	01	VA Boston Healthcare System	A	03/27/2012	Facility reported a suspension of two protocols due to significant non-compliance. The protocols involved the use of mice.	Remedial actions: Protocol suspension; PI to provide a written response addressing all non-compliance issues and remedial actions. CASE CLOSED
129	18	Phoenix VA HCS	H	04/02/2012	Facility reported serious noncompliance involving late reporting of a SAE in a multi-site, randomized controlled prospective clinical trial to explore if the use of online wound electronic medical record reduces amputations from diabetic foot ulcers	Remedial actions: Refresher training provided to Principal Investigator and staff.
130	06	W.G. (Bill) Hefner VA Medical Center	I	04/05/2012	Facility reported an incorrect SSN was entered onto an ICD in a genetics of mental health study and a copy was given to the incorrect Veteran.	Remedial actions: Participant will bring the form to the facility for destruction and sign another consent; explanatory note to file placed in participant folder; Veteran whose SSN was disclosed will be offered credit protection services; CASE CLOSED
131	23	Minneapolis	A	04/06/2012	Facility reported the use of wire bottom cages, which was not approved in the protocol. This protocol involved the use of rats.	Remedial Actions: Amendment of the protocol; development of a spreadsheet describing procedures; monitoring of protocol procedures and animal numbers by VMO, during animal ordering.
132	23	Minneapolis	S	04/06/2012	Facility reported the lack of an initial review and approval by the SRS, of a protocol using rodents.	Remedial Actions: Completion of a Research Protocol Safety Survey; protocol review and approval by the SRS.
133	19	VA Eastern Colorado HCS	H	04/06/2012	Facility reported 37/71 VA study subjects were found to have inadequate consent or HIPAA documentation in a human study involving 3D coronary angiography.	Remedial Actions: IRB determinations -the noncompliance was serious; data use not allowed for subjects with deficient consent and/or HIPAA; no further contact with VA study subjects; no further action required; case closed.
134	11	Indianapolis	H	04/11/2012	Facility reported IRB suspension of VA PET Scan study due to lack of adequate information needed to approve critical study amendment.	Remedial actions: Correction of IRB Continuing Review forms; justification for additional PET scan. Remedial actions complete. Case Closed.
135	03	VA New Jersey HCS	I	04/12/2012	Facility reported 2 veterans reported receiving letters from the VA that contained full SSN on the envelope. The error occurred during a MS Word mail merge with an Excel spreadsheet. Facility investigated and it is possible 73 total Veterans were affected.	Remedial actions: Credit monitoring services offered to 73 Veterans; PI will remove SSNs from database so Excel files will not contain SSN; PIs to review envelopes before being mailed. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
136	22	VA San Diego HS	A	04/16/2012	Facility reported conduct of animal activities without IACUC approval and failure to provide and/or document post-surgical care and monitoring for monitor animals (rats).	Remedial Actions: Retraining for the PI to include 1) re-attending VMU Orientation and 2) counseling with the VMO on Pre- and Post-Operative Recordkeeping; Audit of both active protocols. CASE CLOSED
137	22	VA San Diego HS	A	04/16/2012	Facility reported five cages of mice with marked dermatitis found during the Spring 2012 IACUC Semiannual Facility Inspection and were subsequently euthanized.	Remedial actions: Review of relevant SOPs pertaining to rodent health checks & documentation with all animal care staff; Termination of Animal Health Program Coordinator employment; formal corrective action plan from VMO presented to IACUC. CASE CLOSED
138	20	Portland VAMC	A	04/17/2012	Facility self report - PRELIMINARY. Facility reported deaths of 20 animals (mice) from parasitemia that were on a malaria study. IACUC is investigation.	IACUC determined that the incident was not reportable. CASE CLOSED
139	22	VA Greater Los Angeles HS	H	04/17/2012	Facility reported continuing noncompliance in a multi-site study of carbohydrate restriction among men on Androgen Deprivation Therapy for Prostate Cancer; 10 subjects received an additional DEXA (x-ray) scan that was not characterized in the protocol.	Remedial Actions: PI must respond to IRB inquiries; modify the protocol; notify and reconsent the subjects; notify the coordinating center. CASE CLOSED
140	15	St Louis	R	04/19/2012	Facility reported publications that did not go through Research Service which also lacked appropriate VA acknowledgement. Possible patent/intellectual property issues.	Remedial Actions: RDC sent email to research PIs detailing publications/ presentations/media interview requirements; topic added to quarterly PI meeting; RCO to conduct annual publications audit, OGC reviewing non disclosure of patent, forwarded to VHA Technology Transfer staff. CASE CLOSED.
141	17	VA North Texas HCS	A	04/19/2012	Facility reported implantation of unapproved euthanasia in rats.	Remedial Action: Repeat CITI-courses pertaining to IACUC approval processes; retraining on policies, guidelines and SOPs; submission of experiment reports for review until further notice; submit amendment for IACUC review & approval. CASE CLOSED
142	01	VA Boston Healthcare System	A	04/24/2012	Facility reported a protocol suspension related to a noncompliance involving the use of rats.	Remedial actions: Transfer of animals to a holding protocol; suspension of research procedures; submission and approval of a new protocol; use of a growth curve chart and monitoring; training of research staff. CASE CLOSED
143	01	VA Connecticut HCS	A	04/24/2012	Facility reported conditions that jeopardized the health or well-being of an animal (a mouse) and conduct of animal activities without IACUC review and approval.	Remedial actions: Adherence to IACUC policies regarding transfer of animals between protocols; IACUC approval of personnel handling animals; provision of food and water to animals; use of species-appropriate caging and separation practices; inspection of cages before they are returned. CASE CLOSED

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144	04	VA Pittsburgh HCS	H	04/24/2012	Facility reported a nursing undergraduate student conducted a retrospective chart review and used the de-identified information to prepare a manuscript for presentation to faculty members. Data were transferred and stored off-site without required authorization.	Remedial Actions: Transfer dataset collected without IRB approval to the custody of the RCO; for any future research, the individual, in addition to the required training and credentialing, should contact IRB office to schedule a meeting with the IRB chair. CASE CLOSED
145	08	Tampa	A	04/25/2012	Facility reported: Insufficient anesthesia; lack of analgesic administration; failure to adhere to principles of aseptic surgery; and use of outdated drugs (study of a mouse model of Alzheimer's Disease).	Remedial actions: Completion of web-based training courses; hands on surgical training; training with research pharmacist on use and storage of controlled drugs. CASE CLOSED
146	10	Cleveland	H	04/27/2012	Facility Self Report-IRB administrative termination of IRB #2006-044 Protocol Title: Mechanistically-based Optimization of UV Radiation Therapy in Psoriasis (VA Merit Funded) following lapse in Continuing Review and other serious non-compliance re: training, current IRB approved ICDs	Remedial Actions: Administrative termination of protocol; No data use or access; regulator audit by RCO; R&DC review of PI's status re: future research. Funding returned to CO. CASE CLOSED.
147	20	Portland VAMC	H	04/30/2012	Facility reported PII disclosure to the affiliate from 8 patients considered for enrollment in a study about the effects of Vitamin D on balance in persons with Parkinson's disease.	Remedial actions: Protocol was amended, and a revised ICD and HIPAA Authorization waiver requests was approved; IRB determined serious noncompliance had occurred. CASE CLOSED.
148	11	Ann Arbor HCS	H	05/04/2012	Facility reported initiation and completion of a "Perception study" in Veterans with Parkinson's Disease prior to obtaining RDC approval and ACOS/R notification. However, IRB contingent approval was granted.	Remedial Actions: IRB and RDC staff to reinforce approval process to facility/affiliate PIs; remediation with PI complete. CASE CLOSED.
149	06	McGuire (Richmond)	A	05/04/2012	Facility reported missing 5 x1ml vials of narcotic agent (Buprenorphine) on a dog study.	Remedial Actions: Identify measures to strengthen security; Police investigation; Research Service internal review; Official notifications of missing controlled substances; VMU Supervisor to assume interim custody of lock box and keys. CASE CLOSED
150	01	Providence	A	05/04/2012	Facility reported the death of four mice during the use of a hypoxia chamber.	Remedial actions: Monitoring of equipment; development of a daily log for use of hypoxia chamber; development of standard operating procedures for the use of chamber. CASE CLOSED
151	21	San Francisco VAMC	A	05/04/2012	Facility reported unanticipated adverse events associated with kainic acid administration in rats.	Remedial actions: Protocol amendment; PI and staff retraining; written assurance from PI to adhere to protocol endpoints and adverse event reporting. CASE CLOSED

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152	00	VA Central Office	H	05/09/2012	Facility reported serious noncompliance of repeated failure to follow study protocol.	Remedial actions: LSI to submit corrective action plan; study team education.
153	00	VA Central Office	H	05/10/2012	Facility reported a serious noncompliance involving a local site study coordinator sending emails containing PHI to her personal email address.	Remedial actions: Study closed at the site; study coordinator's VA employment terminated; request a copy of NSOC investigation report. CASE CLOSED
154	23	Iowa City	S	05/11/2012	Facility reported employee accident with minor injury (puncture wound)during sharps disposal.	Remedial actions: First aid; employee sent to occupational health clinic; lab meeting to ensure sharps containers are not overfilled. CASE CLOSED
155	12	Milwaukee	A	05/11/2012	Facility reported inappropriate euthanasia in 2 rats	Remedial actions: Additional training with demonstrated proficiency; thoracotomy to ensure irreversibility of procedure. CASE CLOSED
156	16	Oklahoma City	H	05/14/2012	Facility reported that a PI's internal audit of a statin and renal insufficiency study found multiple protocol deviations (omitted lab evaluations and omitted or incorrect procedures) and noncompliance (failure to obtain HIPAA Authorizations for two subjects).	Remedial Actions: PI submitted protocol amendment; PI suspended study to new enrollment; PI obtained 1 of 2 HIPAA Authorizations and resumed enrollment; PI to review VHA 1200.05 HRPP handbook; training for study team. IRB determined non-serious, not continuing.
157	17	VA North Texas HCS	H	05/15/2012	Facility reported local pharmacist misplaced randomization codes; dispensed active drug to 1st subject at recommendation of study coordinator (acquired pneumonia study) later learned pt was assigned to placebo; staff unblinding resulted; omitted labs at 28-day visit; delayed report to CIRB, ORO,	Remedial Actions: VA CIRB determined noncompliance was serious; PI and LSI were re-trained; and pharmacy oversight enhanced. CASE CLOSED.
158	19	VA Salt Lake City HCS	H	05/16/2012	Facility reported two cardiac studies had been suspended to new enrollment pending approval of the Corrective Action Plan required due to PI's previous SNC.	Remedial Actions: ICD revisions; include adequate placebo justification in IRB application; affiliate IRB must accept the PI's response/completion of the corrective action; issue start date of a 1-year improvement plan.
159	18	Phoenix VA HCS	H	05/17/2012	Facility reported serious noncompliance in the failure to obtain HIPAA authorization from 16 Veteran subjects enrolled in a randomized clinical trial of a neuropsychological intervention for overweight and obesity.	Required Actions: compliant approved HIPAA form developed; staff retrained; data use permitted; no further action required. Case closed.
160	05	VA Maryland HCS	H	05/18/2012	Facility reported that an affiliate School of Medicine employee falsified ICDs and collected the monetary compensation intended for participants.	Remedial Actions: Employee was fired; IRB chair suspended study; RCO will audit ICDs; PI verify all staff trained in proper consenting and interviewing. CASE CLOSED

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
161	07	Atlanta	H	05/19/2012	Facility reported unauthorized disclosure to affiliate of identifiable information (date of visit for study tests not indicated on HIPAA) of 104 subjects, for multi-site study HIV associated Emphysema; VA approved study, NIH funded.	Remedial Actions: Suspend enrollment for new subjects; amendment revisions regarding disclosure; study staff training; ICF and HIPAA revisions.
162	21	San Francisco VAMC	S	06/01/2012	Facility reported unauthorized protocol deviation involving a Use Authorization for Chemical of Extreme Acute Toxicity (UACEAT) for 1-methyl-4-phenol-1,2,3,6-tetrahydropyridine (MPTP).	Remedial Actions: Suspension of all lab work; SRS investigation; staff re-training; update training and inventory records; submission of new 'Use Authorization for Chemical of Extreme Acute Toxicity' application; laboratory re-inspection. CASE CLOSED.
163	01	VA Boston Healthcare System	A	06/01/2012	Facility reported Institutional Animal Care and Use Committee (IACUC) protocol suspension involving mice.	Remedial Actions: Protocol suspension; PI inquiry. CASE CLOSED
164	06	W.G. (Bill) Hefner VA Medical Center	H	06/01/2012	Facility reported that during an Informed Consent Process Monitor, the RCO found that 2 required elements of the Informed Consent were missing. The study is a needs assessment of Telegeriatrics Interdisciplinary Team Training Curriculum.	Remedial Actions: Missing consent elements added; all subjects reconsented; no further actions required by the IRB. CASE CLOSED
165	16	Houston	H	06/05/2012	Facility reported SNC on a Functional MRI (fMRI) study of comorbid PTSD patients; participant was scanned when he met an exclusion criterion(gunshot wounds/shrapnel/BBs).	Remedial Actions: PI retrained team, reviewed all participant records for correct application of inclusion/exclusion criteria; IRB and Acting MCD(IO)reported to OHRP
166	12	Hines do not use	A	06/06/2012	Facility reported unanticipated nonhuman primate death (Macaca fascicularis).	Remedial Actions: IACUC review of final necropsy findings; development of guidelines and paradigm for computerized recording of daily observations to flag at-risk animals. CASE CLOSED
167	16	Central Arkansas VHS	H	06/07/2012	Facility reported IRB-deemed continuing noncompliance for PI's repeated delayed SAE reports on a Phase III hepatocellular carcinoma randomized clinical trial. IRB also failed to report SAE to MCD and ORO within 5 business days.	Remedial Actions: PI must submit a RAP to ensure timely reporting of reportable events
168	16	Oklahoma City	R	06/11/2012	Facility reported non-VA research procedures (CPRS research notes blood draws) conducted by dually- appointed team members on three prostate cancer clinical trials	Remedial Actions: RCO educated PI and study team; other actions pending. CASE CLOSED.
169	18	Phoenix VA HCS	H	06/13/2012	Facility reported a cardiac study had been suspended to new enrollment until safety issues investigated and resolved.	Remedial Actions: IRB determined serious and continuing noncompliance occurred; required additional audits and monitoring of subject enrollment; PI must submit a written corrective action plan to prevent recurrence. CASE CLOSED

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
170	01	VA Connecticut HCS	A	06/13/2012	Facility reported an incident involving inadequate husbandry practices that resulted in the death a mouse.	Remedial actions: Investigation of incident; training for lab staff and caretakers on daily assessment of animal cages. CASE CLOSED.
171	23	Iowa City	A	06/14/2012	Facility reported an inaccurate account for a controlled substance. Protocol involved mice.	Remedial actions: Improvement of records; weekly audits of records; lab will return any unused drug to the VA pharmacy. CASE CLOSED
172	04	VA Pittsburgh HCS	S	06/15/2012	Facility reported overexposure of personnel to waste anesthetic gas. Species not specified.	Remedial Actions: Employee health evaluation; IACUC and IBC review of incident. CASE CLOSED
173	16	Houston	H	06/19/2012	Facility reported that a PI self-identified that 18 participants were enrolled on a TBI assessment protocol using an expired ICD. PI discovered the noncompliance during a pre-RCO audit review.	Remedial Actions: PI must generate notes to CPRS file documenting the issue, IRB reminder sent to use ICDs with current approval dates. CASE CLOSED
174	19	VA Salt Lake City HCS	A	06/19/2012	Facility reported a lapse of an annual review of a protocol involving the use of pigs.	Remedial Actions: PI will ensure that the annual review requirements are met; change of institutional policy to require annual renewals for all species. CASE CLOSED.
175	01	White River Junction	A	06/19/2012	Facility reported an incident involving unanticipated death of mice.	Remedial actions: Submission of an amendment to the protocol, record of the health conditions of mice at arrival, review of PI notification procedures and previsions for veterinary involvement. CASE CLOSED.
176	21	VA Northern California HCS	H	06/22/2012	Facility reported urine specimen was collected by unauthorized personnel.	Remedial Actions: PI and staff reminded of need for amendment approval before implementation; no further action needed. CASE CLOSED
177	12 NE	Hines	H	06/25/2012	Facility reported apparent noncompliance of 30 missing HIPAA Authorizations in a pressure ulcer study; many of whom were unable to sign due to spinal cord injury.	Remedial Actions: PI to obtain HIPAA Authorizations from 30 study participants but was unable to obtain 18 of the 30; IRB permitted PI to use data already collected from all 30 participants. CASE CLOSED
178	21	VA Palo Alto HCS	H	06/25/2012	Facility report PI self-identified missing HIPAA authorizations (4) in a psychotherapy and PTSD study.	Remedial Actions: No data use without compliant HIPAA authorization; only one of the four subjects was randomized; valid authorization obtained from the randomized subject; no indication of privacy breach.
179	18	Phoenix VA HCS	H	06/26/2012	Facility reported apparent discrepancies in PI signatures on ICDs in a study of diabetic limb amputations.	Remedial Actions: Allegations of forgery were confirmed and employee was terminated. The IRB determined serious and continuing noncompliance occurred and required the PI to develop an action plan to prevent recurrence. CASE CLOSED.
180	18	Phoenix VA HCS	H	06/26/2012	Facility reported study team self-identified that one subject was enrolled in a metabolic biomarker study using the ICD for a different study.	Remedial Actions: Subject re-consented; PI and staff re-trained. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
181	05	VA Maryland HCS	A	06/26/2012	Facility reported protocol deviations regarding the use of analgesics in rats and incomplete surgical and post-operative records.	Remedial Actions: Halt unapproved procedures; improvement of surgical and post-operative records. CASE CLOSED
182	15	VA Kansas City Medical Center	H	06/28/2012	Facility reported an unauthorized person obtained informed consent for one subject in a prostate cancer prevention study.	Remedial Actions: RCO to educate the study staff on the consenting and HIPAA process with specific attention to requiring IRB approval prior to proceeding on any study modifications and that protocol deviations need to be submitted in a timely manner. CASE CLOSED.
183	11	Indianapolis	H	07/02/2012	Facility reported that in a sponsored oncology drug study the wrong medication regimen was prescribed by a substitute, non-research nurse practitioner for a subject who did not meet inclusion criteria.	Remedial Actions: PI change in office practice for improved oversight: All study drugs will require PI approval prior to any drug administration. IRB staff training on reporting requirements. Update IRB reporting SOPs. CASE CLOSED.
184	15	VA Kansas City Medical Center	H	07/02/2012	Facility reported that during a pharmaceutical company sponsored anticoagulant study one subject received the wrong prescription.	Remedial Actions: The research pharmacist and the study team develop a plan to double check prescription orders. CASE CLOSED
185	10	Cincinnati	H	07/03/2012	Facility reported serious non compliance involving use of recruitment materials not approved by the IRB and improper recruiting of VA patients for PTSD clinical studies on two studies by one PI sponsored by the US Army Medical Research/DOD	Remedial Actions: Investigation to be reported to IRB and ORCRA for determinations; study placed on administrative hold, no recruitment; PI to notify subjects in writing; sponsors to be notified; modification of HIPAA and waiver of consent process reviewed by IRB and R&DC. CASE CLOSED
186	08	VA North Florida/ South Georgia HCS	H	07/05/2012	Facility reported that external SAE's unrelated to the angiography study being conducted at the facility were submitted at study close. IRB felt these should have been submitted within 5 days of discovery and determined serious noncompliance .	Remedial Actions: The R&DC discovered discrepancies between the IRB's determinations, minutes and notes and requested a re-review of the case. During re-review the IRB noted their mistake and retracted the determination of serious noncompliance. CASE CLOSED.
187	16	Houston	R	07/06/2012	Facility reported that Historical Review of Affiliate IRB-approved protocols revealed that a cardiac catheterization outcomes chart review was conducted by a VA PI without R&DC Review or ACOS/R Notification that VA research may begin. PI had previously submitted two other studies to the R&DC.	Remedial Actions: ACOS/R placed study on administrative hold pending PI's receipt of ACOS/R notification of R&DC and all subcommittee approvals and authorization to begin research.
188	17	VA South Texas HCS	H	07/09/2012	Facility reported that 6 subjects were enrolled in a diabetic foot ulcer study by an unauthorized PI using an unapproved ICD and while the study was on administrative hold.	Remedial actions: PI completed training; 6 subjects were dis-enrolled from the study. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
189	20	Boise VAMC	A	07/11/2012	Facility reported an adverse event involving mice in a streptococcal study.	Remedial Actions: IACUC investigation of event; analgesic treatment of affected mice. CASE CLOSED
190	03	VA New York Harbor HCS	H	07/11/2012	Facility reported disclosure of PHI of ten research subjects without a HIPAA authorization on a systolic blood pressure intervention trial.	Remedial Actions: Study coordinator educated and design problems corrected; data from involved participants permanently deleted from the database
191	03	VA New York Harbor HCS	I	07/13/2012	Facility reported inadvertent disclosure of PHI included with a shipment of nasal swab specimens (Personal Protective Equipment study) that were damaged during transit. Receiving non-VA lab destroyed list upon receipt.	Remedial Actions: Incident did not require notification or credit protection services; additional training for research staff regarding prohibition from disclosure of PHI to non-VA collaborators. CASE CLOSED
192	03	VA New York Harbor HCS	S	07/13/2012	Facility reported damage to a shipping container resulting in possible loss of biologic (nasal swab) specimens.	Remedial Actions: SRS investigation and root cause analysis; R&DC review; training for study staff; SOP for packing and shipping specimens. CASE CLOSED.
193	09	VA Tennessee Valley HCS	S	07/13/2012	Facility reported a chemical spill involving the research area.	Remedial Actions: Clean-up of spill; chemical waste removed to the waste storage facility
194	06	Durham	I	07/19/2012	Facility reported transmission of an internal unencrypted email containing PHI. No data breach occurred. Reported simultaneously to NSOC.	Remedial Actions: Unencrypted email with PHI deleted from all email boxes/folders; staff retrained on email encryption procedures. CASE CLOSED
195	23	Minneapolis	A	07/24/2012	Facility reported two incidents of inadequate post surgical monitoring, involving a rat protocol.	Remedial Actions: IACUC investigation; PI and research staff training; increased post-approval monitoring; revised SOPs. CASE CLOSED.
196	02	VA Western New York HCS	S	07/24/2012	Facility reported conduct of research by unauthorized personnel (no animal work reported).	Remedial Actions: SRS review of incident; completion of all research training requirements; submission of amendment to protocol. CASE CLOSED
197	12	Madison	A	07/25/2012	Facility reported unapproved animal research activity in mice.	Remedial Actions: IACUC investigation; suspension of protocol; resignation of PI as IACUC chair. CASE CLOSED.
198	08	Tampa	H	07/26/2012	Facility reported a PI initiated a retrospective chart review study concerning bone health in inflammatory bowel disease before R&DC approval and ACOS/R notification.	Remedial Actions: RCO educated the PI on current VA procedures. Report to OHRP completed. CASE CLOSED.
199	23	VA Nebraska/ West Iowa HCS	A	07/27/2012	Facility reported deviations consisting of procedures not included in the approved protocol using swine.	Remedial Actions: Submission of amendments; improved communication; consultation with funding agency regarding the use of the data obtained during the unauthorized procedures. CASE CLOSED

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
200	16	Central Arkansas VHS	P	07/30/2012	Facility reported that employees observed unsupervised shredding of research documents, authorized by the Health Science Officer for Research(acting AO/R).	Remedial Actions: Issue brief 7.13.12; including inventory of shredded items; NSOC report; staff informed of proper VA records disposal procedures; event is being evaluated to learn which processes failed. CASE CLOSED.
201	23	Iowa City	S	07/31/2012	Facility reported an incident involving an accidental use of formaldehyde. One employee reported transient eye irritation.	Remedial Action: Update of lab contact information; instruction on the disposal of chemicals; discontinuation of the use of cloth chairs; revision of chemical labels; discontinuation of the use of formaldehyde. CASE CLOSED
202	08	VA North Florida/ South Georgia HCS	H	07/31/2012	Facility reported that neither an original signed ICD or a full copy of the ICD was kept in the study records of one subject in a hemispatial neglect study; also reported the person who obtained consent was not listed as study staff.	Remedial Actions: Attempt made to obtain ICD copy from the subject but copy was never received; IRB determined that the subject's data could not be used. PI was not able to obtain consent. CASE CLOSED.
203	08	VA North Florida/ South Georgia HCS	H	07/31/2012	Facility reported that the Principal Investigator (PI) self reported to the IRB that they enrolled two subjects without obtaining a signed HIPAA authorization in a locomotor training study after spinal cord injury.	Remedial Actions: The enrollment was stopped, the Privacy Officer contacted and revisions to the ICD and HIPAA submitted to the IRB. Training and weekly audits have been initiated. CASE CLOSED.
204	16	Houston	A	08/01/2012	Facility reported unapproved procedures in a protocol using mice.	Remedial Actions: Demonstration of procedure technique; additional training. CASE CLOSED
205	20	Portland VAMC	H	08/01/2012	Facility reported unauthorized disclosure of (at least one individual's) PHI prior to obtaining consent and HIPAA authorization via transmission of an unencrypted email to the potential subject's VA provider personal email account.	Remedial Actions: ISO instructions to delete/retract the noncompliant messages; NSOC tickets closed - no data breach; PI plan to prevent recurrence accepted by IRB; staff retraining. CASE CLOSED.
206	20	Portland VAMC	I	08/01/2012	Facility reported transmission of an external unencrypted email containing PHI. Case linked with WRO 0091-648-H (unauthorized disclosure of PHI prior to informed consent and HIPAA Authorization, same subject).	Remedial Actions: Email senders and recipients were instructed to retract and/or delete the unencrypted messages; Study team to receive refresher training regarding email encryption. CASE CLOSED
207	04	VA Pittsburgh HCS	H	08/08/2012	Facility reported a subject enrolled in a CSP study for treatment of diabetic neuropathy did not adhere to the protocol; subject did not stop taking one of the study medications as instructed by staff. Subsequent labs revealed no adverse effects.	Remedial Actions: Subject re-educated on adhering to the study staff instructions; staff reviewed medication list with subject to ensure participant adheres to the study drug. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
208	06	Durham	A	08/09/2012	Facility reported an unanticipated death of rats following experimental treatment.	Remedial Actions: Animal toxicity grading to include death as an endpoint; staff re-training; demonstration of procedures; reporting of adverse events to IACUC; monthly progress reports. CASE CLOSED.
209	17	VA North Texas HCS	A	08/10/2012	Facility reported unapproved breeding of mice.	Remedial Actions: Submission of an amendment; separate protocol for breeding; annual tracking of breeding colonies. CASE CLOSED
210	12	Madison	H	08/13/2012	Facility reported in a Gulf War Veteran brain imaging study the results of urine drug screenings for 65 subjects were mistakenly entered into CPRS.	Remedial Actions: PI is removing the urine sample results from CRPS.
211	05	VA Maryland HCS	H	08/15/2012	Facility reported that 3000 subjects were screened instead of the approved 1000. This is a randomized clinical trial comparing Behavioral Treatment for Smoking Cessation in Schizophrenia to a standard smoking cessation treatment.	Remedial Actions: PI has implemented a process for weekly tracking of screening numbers; PI asked the IRB to raise the screening limit to 5000. CASE CLOSED
212	16	Central Arkansas VHS	H	08/21/2012	Facility reported that the wrong study medication was dispensed to a subject. The pharmacist realized the mistake the next day and told the subject to stop taking study drugs. The subject was in a study for treatment of diabetic nephropathy but was given blood pressure medication.	Remedial Actions: All research pharmacy staff received in-service training focusing on adherence to pharmacy policy: filling one prescription at a time and completing the drug accountability log prior to dispensing any study drug. CASE CLOSED.
213	22	VA Greater Los Angeles HS	A	08/21/2012	Facility reported a deviation from the approved anesthetic in a protocol using rats.	Remedial Actions: IACUC investigation; protocol amendment to include urethane as anesthetic. CASE CLOSED
214	22	VA Greater Los Angeles HS	A	08/21/2012	Facility reported unapproved restraint procedures in a protocol using rats.	Remedial Actions: Submission of an amendment; veterinary consultation for the design and implementation of new restraint; IACUC monitoring. CASE CLOSED
215	02	VA Western New York HCS	H	08/23/2012	Facility reported that PO detected unapproved research (during Environment of Care Rounds) and unauthorized use of PHI by two medical students. The students were collecting data from CPRS for an unapproved research study of Clostridium difficile Infection in the Intensive Care Unit.	Remedial Actions: PI and medical student counseled and education conducted, PI's studies suspended. PI suspended from conducting research for 3 year period.
216	06	McGuire (Richmond)	H	08/24/2012	Facility reported via NSOC that a medical record of non-vet was sent by the patient to the research team prior to obtaining consent and HIPAA. This is an open label drug study for ulcerative colitis. Upon presentation of consent/HIPAA subject declined enrollment.	Remedial Actions: New policy that redacted subject medical records only sent to sponsor after subject consent; Training at next coordinator's meeting mandated by IRB. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
217	08	Tampa	H	08/24/2012	Facility reported one adverse event on a pilot study regarding a therapy system for treatment of split thickness donor sites was reported late by the PI to the IRB.	Remedial Actions: Additional training to the study team and the PI was provided. CASE CLOSED.
218	01	VA Boston Healthcare System	H	08/27/2012	Facility report describes pervasive non-compliance with a specific PI who is responsible for 8 active studies in the area of behavioral health. Non-compliance includes informed consent issues.	Remedial Actions: All PI's studies suspended to new enrollment until remedial actions addressed; PI and study staff education; Mock Informed Consent training; PI assurance of adequate time/resources to properly run 8 studies; identify person with secondary responsibility to assist PI.
219	19	VA Eastern Colorado HCS	A	08/27/2012	Facility reported protocol deviation involving weight loss in pneumocystis-infected mice.	Remedial Actions: IACUC review of incident; submission of protocol amendment. CASE CLOSED
220	01	White River Junction	A	08/30/2012	Facility reported temperatures outside the normal range, affecting mouse rooms in the VMU.	Remedial Actions: SOP for animal care staff; communication with Facilities Management Service. CASE CLOSED
221	04	VA Pittsburgh HCS	A	08/31/2012	Facility reported inappropriate post-operative analgesia in mice.	Remedial Actions: IACUC investigation; submission of ACORP amendment; verification of remedial training on protocol compliance and post-procedural analgesic administration. CASE CLOSED
222	08	VA Caribbean HCS	H	09/05/2012	Facility reported the failure to report 8 protocol deviations to the IRB in a timely manner in a study of Vitamin E and Memantine in Alzheimer's Disease.	Remedial Actions: The IRB requested the PI to retrain all research staff on local policy on reporting requirements regarding protocol deviations and to provide evidence of the completion of the training to the IRB. Evidence provided. CASE CLOSED.
223	08	Bay Pines	H	09/10/2012	Facility Reported damage by a water leak to research documents; these included R&D protocol related information and nonprofit files related to research and education.	Remedial Actions: All salvageable material has been moved to a secure location and restoration of documents was completed. CASE CLOSED.
224	22	VA Greater Los Angeles HS	H	09/10/2012	Facility reported that 3 subjects, who failed to meet inclusion criteria, were enrolled and underwent study procedures in a DoD lung cancer pathogenesis protocol(additional bronchial brushings, blood draws and nasal brushing in a study limited to current or former smokers).	Remedial Actions: Suspension of enrollment rescinded with PI acceptance of corrective actions to ensure that only smokers are enrolled. Case closed.
225	22	VA Greater Los Angeles HS	H	09/10/2012	Facility reported that an unapproved ICD was used to enroll 13 subjects in an Alzheimer's study.	Remedial Actions: Study terminated due to PI noncompliance and disregard for IRB processes. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
226	07	Columbia	A	09/12/2012	Facility reported three expired IACUC protocols involving mice and rats.	Remedial Actions: Suspension of research activities; IACUC investigation with follow-up report for corrective actions; use of spreadsheet to track approval and expiration dates. CASE CLOSED.
227	07	Charleston	H	09/13/2012	Facility loss of 16 case studies by a physician and researcher	Remedial Actions: Missing 16 participants CRF and corresponding source documentation, including PHI; RISP Team will follow in Case Number 0024-534-I.
228	00	VA Central Office	H	09/15/2012	Facility reported serious noncompliance in a combat trauma PTSD study involving deviating from scope of practice and dispensing medication without appropriate oversight.	Remedial Actions: Review study team scopes of practice, IND management procedures/SOP, and pharmacy security
229	12	Chicago HCS	S	09/17/2012	Facility reported an unauthorized transport of chemicals between laboratories.	Remedial Actions: Laboratory closure; disposal of chemicals. CASE CLOSED.
230	16	Houston	H	09/17/2012	Facility reported that a PI initiated research without R&DC approval or ACOS/R notification. The study involves a review of Veterans' medical records to identify the current level of treatment effectiveness from patients who were enrolled in Substance Dependence Treatment Program.	Remedial Actions: Administrative Hold placed; PI instructed to cease all research activities, including abstract and manuscript preparation and presentation of any data; the Administrative Hold will be upheld until required documents are received and reviewed. CASE CLOSED.
231	16	Houston	H	09/17/2012	PI conducted research without R&DC approval and submitted a manuscript for publication using the research. This retrospective study involving 35 patients aimed at helping elucidate the efficacy of the posterior surgical approach using several objective and subjective criteria.	Remedial Actions: PI instructed to cease all research activities; Administrative Hold to be continued until all required documentation is completed, reviewed by relevant committees and PI is notified of approval to initiate research.
232	08	Orlando VAMC	R	09/17/2012	Facility reported a lapse in training by an Ex-officio non-voting member of the R&DC.	Remedial Actions: The Ex-officio non-voting member completed the training; Research discontinued the use of the internal tracking database and modified TMS to include all required research training. CASE CLOSED.
233	09	Louisville	H	09/20/2012	Facility reported one ICD for this musical intervention study scanned into CPRS by non-study staff.	Remedial Actions: Standard Operating Procedure on the consenting process will be furnished to the study staff. The RCO will review the consent process with the study staff. Remedial actions complete, CASE CLOSED.
234	18	Phoenix VA HCS	H	09/24/2012	Facility reported consent-related noncompliance and signatory fraud in a lower extremity chronic ulcers in adults with diabetes mellitus wound care study.	Remedial Actions: Signatory fraud corrected with appropriate notes to file, re-education of staff, and dismissal of the perpetrator - no further action required; corrective action plan requested for consent-related noncompliance. CASE CLOSED

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235	18	Phoenix VA HCS	H	09/24/2012	Facility reported protocol deviations (blood specimens drawn outside of protocol timeframe) and possible privacy breach (subject initials were disclosed to the sponsor without being described in the ICD) in a molecular biology study.	Remedial Actions: Protocol and ICD were revised to increase protocol timeframe for samples; ICD revised to indicate disclosure of initials to sponsor. CASE CLOSED
236	18	Phoenix VA HCS	H	09/24/2012	Facility reported the duplicate enrollment of an individual in an online medical record to Reduce Limb Amputations in Persons with Diabetes study.	Remedial Actions: develop corrective action plan; provide re-training of proper consenting procedures; implement monitoring of consent process
237	17	VA North Texas HCS	H	09/24/2012	Facility reported two subjects in a bariatric surgery study were enrolled using a non-VA ICD; and PI was delinquent in training.	Remedial Actions: PI will complete required training; undergo refresher training on the consent process; and obtain informed consent from two subjects using a VA 10-1086 ICD. CASE CLOSED.
238	16	Central Arkansas VHS	H	09/26/2012	Facility reported a serious unanticipated adverse event when a subject experienced altered mental status on September 10. The last dose of study medication was taken September 27, 2010. Designated IRB reviewer made a preliminary determination that this was serious, unanticipated, possibly related.	Remedial actions: None. CASE CLOSED
239	08	Tampa	R	09/26/2012	Facility reported a bench protocol and an animal protocol without R&DC and ACOS/R approval and notification to initiate the studies. None of the studies have initiated research.	Remedial Actions: The R&DC and ACOS/R took appropriate actions in sending the required approval and notification letters, respectively. In addition, both principal investigators have not initiated research. The PIs received procedural refresher training. CASE CLOSED
240	20	VA Puget Sound HCS	H	09/26/2012	Facility reported that a PI used unapproved recruitment strategies to contact 55 Veterans for enrollment into a psychological intervention study for distress/impairment in OEF/OIF/OND Veterans.	Remedial Actions: Retraining of the PI regarding subject recruitment, Privacy and Information Security and HIPPA authorization; Subject notification; and request consent for use of picture and/or voice. PO review completed. Case closed.
241	08	Tampa	H	09/27/2012	Facility reported that study team realized that incorrect consent form was downloaded for an audiology questionnaire study and 36 participants were consented on an unstamped consent form.	Remedial Actions: PI and staff were provided with training on VHA policy; a systematic renaming of approved documents was developed to use in the storing of documents by the IRB. CASE CLOSED.
242	00	VA Central Office	H	09/28/2012	Facility reported study procedures in a colonoscopy study were initiated at 4 local sites prior to R&DC approval.	Remedial Actions: Obtain local R&DC approval; education for site study personnel; PI to review investigator responsibilities in VHA policy.

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243	22	VA Long Beach HS	S	10/01/2012	Facility reported unauthorized access into a BSL-3 Laboratory	Remedial Actions: Notification of MCD; VA Police service investigation; Review of access records; Research Security Subcommittee review; training regarding access to research building; follow-up with employee health.
244	06	Durham	A	10/05/2012	Facility reported unanticipated loss of animal life. Two mice died of postoperative hypothermia due to a nonfunctioning heating table.	Remedial Actions: IACUC review of incident; repair heating table; staff must ensure proper functioning of equipment prior to use. CASE CLOSED.
245	16	Jackson	H	10/05/2012	Facility reported non-compliance involving conducting research without current IRB approval. The study is an evidence-based pilot project related to a Resource Care Map for Rural Elderly Caregivers.	Remedial Actions: Reconsent 5 subjects; Submit amendment to increase size; Education from IRB and RCO provided to PI; PI must submit a mentor to IRB for approval.
246	09	Lexington	A	10/05/2012	Facility reported a missing NOT-OD-09-035 Agreement form for use of DMR subsequent to FCR protocol review (species not specified).	Remedial Actions: Protocol re-review and approval by IACUC; SOP revision. CASE CLOSED.
247	07	Atlanta	H	10/09/2012	10/9/12-Facility reported (today)that PI self-audit of study "Behavioral and Neuroimaging Changes after Cognitive Rehab in T131 & MCI"IRB #000273 (VA Career Development) discovered 9 subjects signed the wrong version of IDC and 6 signed ICD but not HIPAA Authorizations	Remedial Actions: Explanatory letters sent to subjects along w/ reconsent by mail; PI team Privacy re-training; PI revised practices for ensuring correct versions ICD and HIPAA used. CASE CLOSED
248	09	Louisville	H	10/09/2012	Facility reported that 9 ICDs were not provided to the Research Office for inclusion into the subject's medical record in an influenza treatment and prevention study.	Remedial Actions: Place the 9 ICDs into the subject's medical record; review SOP for consenting process with study staff. CASE CLOSED.
249	08	Bay Pines	S	10/11/2012	Facility reported a lapse in SRS continuing review.	Remedial Actions: SRS review; enhanced database monitoring for protocol continuing reviews; reminders to all PI's for timely submission of documents for continuing review. CASE CLOSED.
250	10	Cleveland	H	10/11/2012	Facility reported data collection in a colonoscopy study was initiated prior to RDC approval.	Remedial Actions: VA CIRB determined study team may use data gathered prior to RDC approval.
251	22	VA Greater Los Angeles HS	H	10/11/2012	Facility reported vendor deviated from substance abuse protocol; interviewer did not report thoughts of suicidal ideation; and re-contacted subject who had withdrawn and requested no further contact.	Remedial Actions: PI suspended enrollment; IRB is working with the PI to institute safeguards so that the protocol is implemented as designed. All corrections implemented (new contract vendor); case closed.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
252	15	VA Kansas City Medical Center	A	10/11/2012	Facility reported high number of rat death when using Propofol, Dexmedetomidine and Fentanyl as an anesthetic.	Remedial Actions: IACUC review; substitute pentobarbital as the anesthetic agent. CASE CLOSED.
253	20	VA Puget Sound HCS	A	10/11/2012	Facility reported animals being held under an expired protocol, animal numbers being exceeded on two protocols.	Remedial Actions: Improved recordkeeping; improved communication; amend protocol to increase animal numbers; transfer animals to another protocol. CASE CLOSED
254	11	Indianapolis	H	10/12/2012	University IRB reported unanticipated problem involving risks to subjects or others in this lung cancer study which is closed to enrollment. Several cases of interstitial lung disease were noted in other studies using the same drug - tivantinib.	Remedial Actions: None. Case closed.
255	21	VA Palo Alto HCS	H	10/15/2012	Facility reported PI's QA audit found missing HIPAA authorization for one subject enrolled in a CSP project evaluating chemotherapy treatments for subjects who are at high risk for cancer relapse.	Remedial Actions: remedial education and prohibited use of research data without a revised HIPAA authorization permitting use of the (previously collected) data. Case closed.
256	08	Tampa	A	10/16/2012	Facility reported two IACUC approved protocols involving the use of mice without SRS and R&DC approval.	Remedial Actions: Submission of protocols for approval; training; halt of activities until written notification from ACOS is received. CASE CLOSED
257	07	Charleston	R	10/18/2012	Facility reported the R&DC inadvertently closed a study that remained open with the Affiliate IRB.	Remedial Actions: Study to be reviewed at next R&DC meeting; Acting RCO to perform regulatory compliance audit of study prior to next R&DC meeting; create a plan to cross-reference close-out procedures between IRB and R&DC.
258	16	Oklahoma City	H	10/19/2012	Facility reported 10 Subjects did not sign ICDs.	Remedial Actions: All ten research participants signed the ICDs. CASE CLOSED.
259	16	Oklahoma City	H	10/23/2012	Facility reported incorrectly signed HIPAA form (corrected very quickly) in a vein graft angioplasty study.	Remedial Actions: None. CASE CLOSED.
260	17	VA Central Texas HCS	A	10/23/2012	Facility reported inappropriate post-operative analgesia, lack of aseptic techniques and incomplete controlled drug logs for surgical procedures in rats.	Remedial Actions: IACUC investigation; submission of protocol amendment; training; improved documentation of controlled substance and post-operative records; PI verification of analgesic administration; observation of animal procedures by veterinary staff. CASE CLOSED.
261	17	VA Central Texas HCS	H	10/23/2012	Facility reported that a creative arts (music) therapist apparently conducted unapproved sleep research on 40-50 inpatient Veterans.	Remedial Actions: Employee instructed to cease activity and secure records; and ISO secured non-VA equipment with PHI and reported to NSOC. CASE CLOSED.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
262	02	Syracuse	H	10/29/2012	Facility reported that a skin cancer quality of life study was suspended by R&DC due to PI being noncompliant with education requirements.	Remedial Actions: Study suspended; PI to complete required education requirements. CASE CLOSED
263	07	Atlanta	H	11/01/2012	Facility reported serious continuing noncompliance re: PET scan study for PTSD (closed to enrollment). PI did not inform IRB and R&DC of IND for [O]15; did not submit annual reports to FDA; and did not submit project to FDA as amendment to IND.	Remedial Actions: PI training; report filed with FDA; Clinical trials audit to be conducted; PI and study team training completed before new submissions accepted.
264	07	Atlanta	H	11/01/2012	Facility reported serious continuing noncompliance re: PET scan study for PTSD prevention in Iraqi Veterans (closed to enrollment). PI did not inform IRB and R&DC of IND for [O]15; did not submit annual reports to FDA; and did not submit project to FDA as amendment to IND.	Remedial Actions: PI training; report filed with FDA; Clinical trials audit to be conducted; PI and study team training completed before new submissions accepted.
265	07	Atlanta	H	11/01/2012	Facility reported serious continuing noncompliance re: PET scan study of memory and hippocampus in twins w/ PTSD (closed to enrollment). PI did not inform IRB and R&DC of IND for [O]15; did not submit annual reports to FDA; and did not submit project to FDA as amendment to IND.	Remedial Actions: PI training; report filed with FDA; Clinical trials audit to be conducted; PI and study team training completed before new submissions accepted.
266	04	Clarksburg	H	11/05/2012	Facility reported IRB suspended industry sponsored atrial fibrillation study of DU-176b Versus Warfarin. Suspension due to documentation backlog related to staff turnovers (sponsor monitors and facility coordinators).	Remedial Actions: Study suspension; IRB audit of documentation; report to FDA, OHRP and Sponsor; other actions pending.
267	01	VA Connecticut HCS	H	11/07/2012	Facility reported a new PI over-enrolled subjects into a health Outcomes study for Veterans receiving mental health care services. PI subsequently enrolled eight additional subjects after being notified to cease enrollment.	Remedial Actions: PI to submit amendment for additional subjects; PI and staff to obtain continuing education; data not to be used from the 8 subjects enrolled after cease enrollment notification.
268	11	Ann Arbor HCS	H	11/09/2012	Facility reported noncompliance for an unfunded protocol involving the analysis of dietary labeling of oral chemotherapy prescriptions. The PI modified the approved study and added a sub-study that did not receive IRB or RDC approval.	Remedial Actions: Study presentation withdrawn from medical conference; all research activities and the unapproved sub-study stopped; cannot use database for any research. Suspension lifted, PI RAP completed; education of PI/staff on conducting VA research.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
269	16	Central Arkansas VHS	H	11/09/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Pending.
270	06	Durham	A	11/13/2012	Facility reported an unanticipated death of rats following experimental procedure.	Remedial Actions: Submission of a modification to protocol; training. CASE CLOSED.
271	16	Houston	A	11/13/2012	Facility reported an incident in which personnel not approved in the protocol participated in surgical procedures in sheep.	Remedial Actions: Amendment to the protocol; training. CASE CLOSED.
272	23	Iowa City	H	11/15/2012	Facility reported that the affiliate IRB appointed a new PI to this VA depression study who did not have appropriate credentialing or training.	Required Actions: PI credentialing and training not completed/not possible, protocol terminated and all VA data transferred to Research Office. Case closed.
273	01	Providence	H	11/16/2012	Facility reported that enrollment on a CSP study (A Point of Care Randomization Study Comparing Insulin Administered Using a Sliding Scale vs a Weight Based Basal-Bolus Regimen) has been temporarily stopped by the coordinating site due to unanticipated problem related to a clinician not following a	Remedial Actions: Enrollment temporarily stopped at participating sites; revisions to CPRS screens to mitigate similar problems in future
274	22	VA Loma Linda HS	H	11/16/2012	PI of CSP 565(Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) failed to report incarceration of subject to. CSP later halted Protocol 565 due to high potassium levels and acute kidney function changes.	Remedial Actions: Detention authorities must be contacted to discontinue incarcerated subject from continuing study drugs.
275	07	Charleston	A	11/21/2012	Facility reported unanticipated loss of animal life in mice.	Remedial Actions: IACUC review; laboratory technician employment termination. CASE CLOSED.
276	06	Durham	I	11/21/2012	Facility reported that during a routine annual ICF audit the study staff found that a signed ICF for one research participant could not be located. The ICF was not scanned into CPRS as the study participant is not a veteran and does not have a CPRS record.	Remedial Actions: It was verified the ICF was not misfiled; Research participant contacted and asked to verify if the original ICF picked-up by accident but did not respond; credit protection services or HIPAA notification not required; staff reminded of IC documentation policies. CASE CLOSED

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
277	23	Iowa City	H	11/21/2012	Facility reported three full-time VA staff incorrectly listed as study staff on three affiliate university ophthalmologic studies; one VA staff consented two university subjects without authorization.	Remedial Actions: Remove VA personnel from affiliate university protocol rosters. Remedial actions competed, case closed.
278	21	VA Palo Alto HCS	S	11/21/2012	Facility reported a lapse of SRS approval with continuation of research activities.	Remedial Actions: SRS approval of research activities. CASE CLOSED.
279	08	Tampa	S	11/28/2012	Facility reported transfer of protocol without IBC.	Remedial Actions: SRS review; establish an MOU between JAHVH and the affiliate IBC to cover all future studies. CASE CLOSED.
280	08	Tampa	H	11/29/2012	Facility reported research conducted without obtaining HIPAA Authorizations on 80 participants in a homeless index study based on interviews.	Remedial Actions: Pending.
281	01	VA Boston Healthcare System	H	11/29/2012	Facility report of two Traumatic Brain Injury and Stress Disorder studies that recruited participants whose age exceeded the parameters in the eligibility criteria.	Remedial Actions: PI and study staff education. Self-audits with IRB reporting required.
282	09	Memphis	H	11/30/2012	Facility reported serious programmatic noncompliance of 75 WOC appointments have expired; 13 other's status is unknown; 3 appointments have been expired for more than 2 years.	Remedial Actions: Human Resources and Research Service are reviewing WOC appointments for accuracy. 81.5% completion rate as of 1/2/13.
283	02	Syracuse	A	11/30/2012	Facility reported discovery of a mouse carcass in a cage that had been autoclaved	Remedial Actions: The technician was retrained on operating procedures for ensuring an accurate accounting of all animals in the cage and an additional new log sheet is being initiated to provide another step in preventing this type of incident in the future. CASE CLOSED.
284	18	Phoenix VA HCS	H	12/04/2012	Facility reported release of a partial recruitment list of subjects who failed pre-screening without consent or HIPAA authorization in a diabetic foot ulcer study.	Remedial Actions: Recovery of disclosed information
285	07	Augusta	A	12/06/2012	Facility reported non-approved procedure performed on mice.	Remedial Actions: Reviewed the ACORP; retraining; Orientation for Animal Users refresher course. CASE CLOSED.
286	04	VA Pittsburgh HCS	H	12/06/2012	Facility reported that the IRB failed to report that the PI had failed to report a SAE within three days of becoming aware of the SAE. The study is a Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with recurring or Metastatic Head and Neck Cancer.	Remedial Actions: Pending

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
287	02	VA Western New York HCS	H	12/11/2012	Facility reported unanticipated problem related to safety in a CSP treatment study of kidney function in diabetic patients.	Remedial Actions: Subjects contacted via certified letter; Study close-out procedures underway at facility.
288	21	San Francisco VAMC	A	12/17/2012	Facility reported possible unapproved procedures (skin biopsies) in mice.	Remedial Actions: IACUC investigation; suspension of animal privileges for research staff member(s) involved.
289	01	White River Junction	H	12/17/2012	Facility reported a UPR in a study of veterans with mild TBI and/or PTSD funded by US Army Medical Research and Materiel Command. Randomization occurred correctly but dispensation was incorrect (due to technical problem) for 2 of 3 study treatment arms. No AEs occurred that required unblinding.	Remedial Actions: Randomization list updated for two of the three treatment arms, technical check developed to ensure randomization and dispensation match; PI education provided regarding reporting responsibilities.
290	16	Central Arkansas VHS	H	12/18/2012	Facility reported IRB suspended this investigator initiated retrospective chart review study on anti-diabetic agents and colorectal cancer. Suspension was due to repeated lapses in IRB approval.	Remedial Actions: PI to complete VA-required research training on schedule as required.
291	16	Central Arkansas VHS	H	12/19/2012	Noncompliance was discovered during an audit of a previously reported noncompliance event. A death, determined to be NOT related, was not reported in a timely manner.	Remedial Actions: Pending.
292	16	Houston	H	12/20/2012	Facility self-reported that the affiliate suspended a protocol after it found that the protocol file was not current as it applies to IND and FDA documentation. The study measures changes in Dopamine when Modafinil is used as a Treatment for Cocaine Dependence.	Remedial actions: Pending.
293	16	Central Arkansas VHS	H	12/20/2012	Facility reported two subjects enrolled in this study received study medication from the wrong kit. The study assesses the effectiveness and safety of 12 versus 30 months of dual anti-platelet therapy in subjects undergoing percutaneous coronary intervention with drug-eluting or bare metal stent.	Remedial Actions: Revision of the dispensing SOP; audit of all active study drug binders; education of pharmacy staff. All items previously completed. CASE CLOSED.
294	21	VA Central California HCS	H	12/20/2012	Facility reported 19 subjects enrolled in a cardiac study were not paid for participating as stipulated in the ICD, constituting continuing noncompliance.	Remedial Actions: Pay remaining study subjects; Develop policy instructing PIs how to obtain funds to pay study subjects; Update ICD to include subject withdrawal information.
295	10	Cleveland	A	12/26/2012	Facility reported controlled substance (ketamine cocktail) inventory discrepancy.	Remedial Actions: SRS and IACUC review; return controlled substance cocktail to Pharmacy Services. CASE CLOSED.

TABLE 6. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
296	21	San Francisco VAMC	A	12/28/2012	Facility reported protocol suspension due to unapproved procedures (implantation of mini osmotic pumps) in mice.	Remedial Actions: IACUC review and protocol suspension.
297	17	VA North Texas HCS	H	12/28/2012	Facility reported a voluntary local PI suspension of enrollment of a vein graft study, pending review by DSMB and IRB.	Remedial Actions: suspend enrollment; IRB/DSMB review pending
298	04	VA Pittsburgh HCS	H	12/28/2012	Facility reported survey participants were able to review survey responses on a Share Point that was supposed to be accessed by study investigators only on a study of the problem of bullying in healthcare.	Remedial Actions: Pending

TABLE 7. REMOTE REVIEWS OF COMPLIANCE OFFICER (RCO) AUDITS

VHA facility-based Research Compliance Officers (RCOs) must conduct annual informed consent audits and triennial regulatory audits of all research studies. The director of each research facility is required to report promptly to ORO any apparent serious or continuing noncompliance identified in these audits. ORO conducts remote reviews of these reports, requiring that the facility develop an acceptable remediation plan and monitoring implementation of the plan until remediation is complete.

Summary

- 79 = Cases Continuing from Previous Calendar Year
- 41 = New Cases – January 1 through March 31
- 85 = New Cases – April 1 through June 30
- 75 = New Cases – July 1 through September 30
- 47 = New Cases – October 1 through December 31
- 248 = New Cases in Calendar Year
- 327 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	12 NE	Hines	H	02/28/2011	RCO audit of muscle stimulation in ventilated patients study found consent and HIPAA irregularities, inadequate progress note documentation and on-study death that was not reported to the IRB.	Remedial actions: RCO provided education to PI and Study Coordinator; protocol amendment was submitted; IRB approved HIPAA waiver and made determinations on data use. CASE CLOSED.
2	12 NE	Hines	H	03/01/2011	RCO audit of cataract study found "test" data collected on 11 cataract surgery patients without ICD or HIPAA Authorization prior to IRB and R&DC approval. One omitted HIPAA Authorization; 1 unreported adverse event; multiple other irregularities.	Remedial actions: study closed, education provided to PI and others in Ophthalmology Dept. For future studies, mentor assigned, experienced coordinator will be assigned, audit frequency would increase. CASE CLOSED.
3	08	Miami	H	03/10/2011	RCO triennial audit found protocol violation regarding use of unapproved screening survey tool and unapproved inclusion/exclusion criteria in a dry eye syndrome study.	Remedial actions: An amendment was submitted and approved to include the new survey tool and the new inclusion/exclusion criteria, no new risks identified by the IRB. OHRP report completed. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
4	12 NE	Hines	H	03/11/2011	RCO audit found ICD irregularities in all consent forms in study of educational materials for spinal cord injured veterans including missing times and/or dates; use of ICD with expired IRB stamp; No HIPAA Authorizations obtained.	Remedial actions: Obtain re-consents and HIPAA Authorizations; HIPAA waiver granted for the study and IRB approved data use for the data collected. CASE CLOSED.
5	04	Coatesville	H	04/07/2011	RCO Inquiry seeking reporting guidance on 13 subjects consents by Next of Kin in Alzheimer's Disease protocol.	Remedial actions: Revise SOP; no re-consent required; data can be used. CASE CLOSED.
6	09	Lexington	H	04/11/2011	RCO ICD audit of PTSD and concussion study found no CPRS flag (35/35);late entry CPRS consent notes (14/35); POC not IRB approved (2); Current Scope missing for POC (9/35); Incorrect version of ICD signed (5/35).	Remedial actions: Affiliate IRB to complete full Board review, not by IRB Chair on 12/20/11. Note: IRB responsibilities transitioning from affiliate to VA nu 1/1/12. Remedial actions complete. CASE CLOSED.
7	21	San Francisco VAMC	H	06/16/2011	RCO audit of a study involving imaging in the evaluation of vascular disease progression found that one subject did not have a signed HIPAA authorization form.	Remedial Actions: Obtain HIPAA from the participant; provide education to all members of research community. CASE CLOSED.
8	09	Lexington	H	06/21/2011	RCO Triennial Regulatory Audit found in heart disease study expired scopes of practice; missing training; no Cooperative Technological Administration Agreements (CTAA); Missing CoI forms; missing admin forms, documentation of approvals; missing CPRS flags and notes. Exclusion criteria not met.	Remedial actions: pending. Affiliate review 12/20/11. Note: IRB responsibilities transitioning from affiliate to VA by 1/1/2012. Remedial actions completed. CASE CLOSED
9	01	VA Boston Healthcare System	H	06/21/2011	RCO Audit found 10 out of 30 HIPAA Authorizations not signed in a spiritual care end-of-life study.	Remedial Actions: PI to obtain missing HIPAA Authorizations within 30 days. CASE CLOSED.
10	01	VA Boston Healthcare System	H	06/25/2011	RCO Audit found 20/20 participants in a lipid medication adherence study did not use IRB approved and stamped IC. Two HIPAA not dated. One HIPAA different date than witness.	Remedial Actions: Education provided (mock informed consent process); reconsent underway.
11	22	VA Greater Los Angeles HS	H	06/27/2011	RCO audit of a study of population differences in immune response for hemophilia found collection and transfer of identifiable human blood samples without IRB approval. Samples also collected from children without obtaining a CRADO waiver. Potential Conflict of Interest issues are being investigated	Remedial actions: Multiple facility audits and investigations pending and in progress; interim actions have included suspension of the protocol and suspension of the investigator's research privileges. CASE CLOSED.
12	01	VA Boston Healthcare System	S	07/15/2011	RCO audit found that research was being conducted on two animal protocols without the required SRS approval. The species involved were rodents.	Remedial actions: lapses in SRS reviews determined to be reportable; Lapses unlikely to result in harm. CASE CLOSED

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
13	12 NE	Hines	H	07/18/2011	RCO Audit of Parkinson's Disease retinal study found ICD obtained by person not on study without training, missing CPRS documentation, HIPAA Authorizations missing for all (4) subjects.	Remedial Actions: Re-consent and obtain missing HIPAA Authorizations for 4 participants. CASE CLOSED
14	01	VA Boston Healthcare System	H	07/22/2011	RCO audit of a Weight management study found expired ICD and HIPAA documents; missing HIPAA Authorization signature; erroneous dates of signature; missing dates of signature for ICD and HIPAA.	Remedial Actions: Mock informed consent process performed; reconsenting attempts continuing; procedure to report future such incidents. CASE CLOSED.
15	22	VA San Diego HS	H	07/26/2011	RCO audit of blast injury effects found 10 cases where subjects signed an ICD, but did not sign the associated HIPAA authorization.	Remedial actions: Obtain the missing HIPAA authorizations; IRB determined that data obtained from subjects without HIPAA authorization could not be used for research purposes; IRB accepted the PI plan to prevent a recurrence. CASE CLOSED.
16	22	VA San Diego HS	H	07/26/2011	RCO audit of OEF/OIF couples reintegration studies identified 12 of 89 subjects did not sign a HIPAA authorization for one study & 1 of 124 subjects did not sign a HIPAA authorization for the 2nd study.	Remedial actions: The IRB (and R&DC) accepted the PI plan to prevent a recurrence; no permitted use (disclosure) of data without effective HIPAA authorization. CASE CLOSED.
17	05	DC VAMC	H	08/01/2011	RCO regulatory audit found that research was conducted during lapse of IRB approval. Four subjects consented during lapse. Study involved evaluation of myeloma progress risk in African Americans.	Remedial actions: Consult with IRB tracking software contractor to determine and correct the glitch in the system. CASE CLOSED.
18	22	VA San Diego HS	H	08/02/2011	RCO audit of 3 behavioral intervention studies by one PI (1)angry veterans, (2,3) drug dependent subjects, no HIPAA authorization for multiple subjects.	Remedial actions: IRB and R&DC have reviewed and accepted the PI's plans to obtain compliant HIPAA authorizations and a plan to prevent a recurrence; no disclosure permitted without effective authorization. CASE CLOSED.
19	04	VA Pittsburgh HCS	H	08/12/2011	RCO Audit of medication adherence study found non-VA investigator accessing PHI without WOC appointment. Enrollment and other ongoing research activities suspended.	Remedial actions: PI meet with IRB Chair for training; PI to obtain WOC and VA credentialing; protocol modification; hire dedicated research coordinator; report cause of serious non-compliance to IRB. Actions have been completed. CASE CLOSED.
20	04	Philadelphia	H	08/21/2011	RCO ICD Audit found five subjects in an alcohol and cocaine study with no witness signature; 3 subjects with no documentation in CPRS. Additional audits found subject assessments completed prior to IRB approval; unauthorized person calling subjects, 10 subjects no witness signature.	Remedial Actions: Regulatory audit completed; training completed; oversight and review by senior study staff; external review of all ICDs within 24 h of consent; IRB review of all ICDs; all ICDs reviewed with Veteran at follow-up visit. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
21	16	Oklahoma City	H	08/23/2011	RCO Audit of hyperthyroidism study found enrolled children and collected cord blood without CRADO waiver; Used non-VA ICD for 24 of 55 participants; Unauthorized staff obtained consent; other consent deficiencies; lost ICD and HIPAA authorizations	Remedial actions: - obtain VA and OUHSC HIPAA authorizations from each subject - suspended study enrollment - self reported pediatric research to ORD - PI to report multiple informed consent process & documentation deviations to IRB -RCO will conduct a complete regulatory audit of study. CASE Closed
22	05	DC VAMC	H	08/25/2011	RCO ICD Audit revealed 3 subjects were consented by an individual without authorization to consent; one of the three subjects was also consented using an outdated ICD. Study is a pilot study for Clinical Trials of upper extremity Amputee Training.	Remedial Actions: PI to reconsent the 3 subjects. CASE CLOSED.
23	09	Lexington	H	09/06/2011	RCO Informed Consent Audit found in PTSD medication non-adherence study: PI with expired WOC appt, person obtaining consent not IRB approved; delayed/missing progress notes,41/41 missing scanned ICFs in CPRS, missing flagging; missing HIPAA for 9/41 subjects; follow-up HIPAA from 2008 incomplete.	Remedial actions: RCO placed protocol on "administrative hold"; concurrence by IRB, Privacy Board, RDC Chairs. No PI response to ACOS. Affiliate IRB review on 12/20 and RDC 12/22 for study closure. CASE CLOSED
24	08	Miami	H	09/12/2011	RCO audit found protocol violation in retrospective liver and kidney chart review study that was collecting prospective data. Prospective data was not included in the IRB-approved protocol.	Remedial Actions: The IRB will require an amendment to include data that was not in the original proposal and approved protocol and to extend the years of retrospective data to be collected. Amendment received and approved by the IRB. OHRP reporting completed for serious noncompliance. CASE CLOSED.
25	22	VA Greater Los Angeles HS	H	09/16/2011	RCO audit found that an investigator had subjects enrolled in one study sign ICD for another study for the sole purpose of reimbursing the subjects for participation in the first study.	Remedial actions: Letter of apology to subjects; for-cause RCO audit. CASE CLOSED.
26	16	Central Arkansas VHS	H	09/27/2011	RCO Audit found PI of surgical decision making study failed to submit continuing review or closure request despite numerous reminders and prior counseling	Remedial Actions: PI's 3 studies were suspended or terminated and research privileges were revoked. CAVHS IRB had required several contingencies be satisfied before studies could resume, but the PI has not responded to the IRB Chair and Administrator's attempts to arrange a meeting. CASE CLOSED.
27	03	VA New York Harbor HCS	H	09/27/2011	RCO Audit found 16 subjects with no signed HIPAA Authorizations in a study of periprocedural glycemic control in coronary angiography patients.	Remedial Actions: IRB and PO reviewed. HIPAA Authorizations were found and the RCO Audit report was corrected. The report of non-compliance was in error. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
28	16	Central Arkansas VHS	H	10/03/2011	RCO audit found that a limited data set in a post-operative gastro-intestinal study was transmitted to a non-VA entity (study sponsor) without authorization, no DUA was in place.	Remedial Actions: Terminated protocol; Sequestered data, destroyed samples; Self reported to OHRP & FDA PI's research privileges suspended. CASE CLOSED.
29	11	VA Illiana Healthcare System	H	10/04/2011	RCO informed consent audit identified that IRB did not document approval of informed consent waivers appropriately for three studies.	Facility in process of program closure by end of December, 2011. Program closed January 24, 2011. CASE CLOSED.
30	09	Lexington	H	10/05/2011	RCO regulatory audit of PTSD study found improper approval of research personnel by AO/R; no CRADA or Clinical Trials agreement with affiliate; no current approved PI; ACOS/R placed study on admin hold.	Remedial actions: Study closure; other actions pending. IRB review 12/20/11 for study closure. RDC 12/22/11. CASE CLOSED.
31	22	VA San Diego HS	H	10/07/2011	RCO Audit (closure audit) of a colonoscopy study found that 18 of 63 ICDs were not available for review; none of the 45 ICDs viewed contained IRB stamp; and none of the HIPAA authorizations had been obtained. In addition, not all required RCO consent audits had been completed by the RCO.	Remedial Actions: IRB retroactively (post study closure) waived requirement for informed consent and HIPPA authorization for all study participants. CASE CLOSED.
32	05	DC VAMC	H	10/12/2011	RCO Regulatory audit found that research related to the effects of volunteering on the volunteer was initiated without the PI completing required human subjects and info security training.	Remedial actions: Research service changed their documentation of training process. CASE CLOSED.
33	08	Tampa	H	10/18/2011	RCO audit found a PI's failure to report one or more unanticipated SAEs or problems involving risks to subjects or others in an Oncology Registry of Chronic Myelogenous Leukemia (CML) protocol.	Remedial actions: The R&DC tasked the RCO with monitoring all SAEs reported and actions from the IRB. Report to OHRP completed. CASE CLOSED.
34	04	VA Pittsburgh HCS	H	10/19/2011	RCO audit of a foot ulcer study found 1)participation by the research coordinator in the conduct of an active protocol without required credentialing; 2)failure by investigator to report three SAE within the required timeline.	Remedial Actions: PI to meet with IRB to discuss findings; review other protocols to ensure method not used and if used submit UPR; modify protocol to state consent obtained prior to audio or video taping; if method not used amend protocol to remove reference to the method. CASE CLOSED
35	11	VA Illiana Healthcare System	H	10/20/2011	RCO Regulatory Audit of cognition in OEF/OIF Veterans with PTSD found scopes of practice lacked review; HIPAA waivers not documented correctly; incorrect continuing review dates.	Facility in process of program closure by end of December, 2011. Program closed January 24, 2011. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
36	16	Jackson	H	10/21/2011	RCO audit found that the PI began Hepatitis B research interactions before obtaining informed consent and conducted research after IRB approval had expired	Remedial actions: Re-consent all subjects (27); Amend protocol and ICDs to reflect actual procedures; RCO and IRB admin trained PI & study staff . CASE CLOSED.
37	09	VA Tennessee Valley HCS	H	10/28/2011	RCO ICD and regulatory audit of a One Minute Preceptor Model study found 10/14 were consented using unapproved versions of the ICD; 4 ICDs were on an ICD that had never been submitted to the IRB; 6 ICDs were used prior to IRB approval.	Remedial actions: PI counseled. CASE CLOSED.
38	09	Lexington	H	10/31/2011	RCO audit found in a human, regulatory audit that; PI was no a VA employee; no CTAA in place for collaborative research with affiliate; RDC expedited/conditional approval; poor documentation of HIPAA waiver; no data safety and security approval	Remedial actions: re-review of SNC scheduled 12/20/11 and RDC 12/22. Affiliate IRB transitioning to VA IRB by 12/31/2011. CASE CLOSED
39	09	Lexington	H	10/31/2011	RCO audit found in a human, regulatory audit that; PI was not a VA employee; RDC expedited/conditional approval; poor documentation of HIPAA waiver; no data safety and security approval	Remedial actions: Pending Affiliate IRB transitioning to VA IRB 12/31/2011. Affiliate IRB review 12/20 and RDC review 12/22. Remedial actions completed. CASE CLOSED
40	16	Central Arkansas VHS	H	11/01/2011	RCO Audit found local site investigator (LSI) used an ICD version for Hepatitis C/depression study apparently not approved by the VA CIRB. VA CIRB suspended study pending completion of RAP and follow-up audits of PI and LSI study files.	Remedial actions: Study suspended; Local RCOs audit for # enrolled with wrong ICD; compare documents on LSI files with CIRB files; Reconsent applicable participants; plan to track study doc submission & dissemination to sites; submit amendment for all changes so far; Staff training. CASE CLOSED.
41	07	Tuscaloosa	H	11/04/2011	RCO Audit found in a rural health human subject study 12 ICDs improperly approved by the IRB; approval stamp missing on all but the front page of the ICDs.	Remedial actions: ICF reissued with IRB approval stamp; notes to file explaining errors; reconsent 12 subjects, and training for IRB Clerk. CASE CLOSED.
42	11	VA Illiana Healthcare System	H	11/08/2011	RCO regulatory and ICD audit found IRB programmatic non-compliance in a rotating shift sleep pattern study. The IRB reviewed and approved incorrect/inadequate PI documents instead of contingent approval. IRB failed to review scopes of practice; failed to document that all approval criteria were met.	Remedial Actions: Facility closed research program January 24, 2012. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
43	11	VA Illiana Healthcare System	H	11/08/2011	RCO Regulatory and Informed Consent Audit of cardiac antiarrhythmic monitoring study found IRB programmatic non-compliance related to approval of HIPAA Authorization or HIPAA waiver and failure to document all criteria for approval were satisfied.	Facility in process of closing research program by December, 2011. Program closed January 24, 2012. CASE CLOSED.
44	15	St Louis	H	11/09/2011	RCO audit of HSR&D human study of Hepatitis C and depression, CIRB protocol found apparent non-IRB approved ICD; apparent lack of an authorized CIRB approval letter for amendment 2 that included the amended ICD.	Remedial actions: Request local RCO regulatory audit and comparison of the approved documents on file at the site with those at the CIRB; subjects consented with the non-IRB approved ICD will be re-consented; submit amendment; additional training for staff. Remedial actions complete. Case Closed.
45	09	Memphis	H	11/21/2011	RCO Informed Consent Audit of neurological minimal risk study found no IRB approval for use of an LAR; inappropriate LAR signatures on 10/60 ICD, 8/60 HIPAA, and inclusion of 33/60 non-veterans without IRB approval	Remedial actions: Clarify determination of decision-making capabilities; PI will remove surrogate signature from ICD, will use non-veterans after IRB approval; PI may not use data for subjects with inappropriate LAR signatures. Remedial actions complete. Case closed.
46	16	Houston	H	11/22/2011	RCO audit found that a team member on a patient safety study had not completed the required human research protections/GCP training	Remedial actions: (IRB: non-serious, not continuing)PI required to review relevant section of SOP. CASE CLOSED.
47	16	Houston	P	11/22/2011	RCO audit found that a VA PI conducted a chart review study of renal failure in influenza that included pediatric patients (all age groups). Application did not state that he was reviewing charts at a non-VA site. No CRADO waiver.	Remedial actions: PI told to review SOP excerpt regarding obtaining all required approvals before beginning research; R&DC developed corrective action plan: real-time access to e-IRB (BRAIN); revised R&DC submission forms emphasizing required R&DC approval/ ACOS/R notification; updated PI manual. CASE CLOSED.
48	16	Houston	R	11/22/2011	RCO audit found that the study (chart review of anxiety in dementia) was conducted without R&DC approval.	Remedial Actions: IRB required PI to review relevant section in SOP; R&DC submitted a systematic CAP including: RSL real-time queries to BRAIN e-IRB system; RDC's own noncompliance notice; System Redesign Team implementing QI using "lean management tools". CASE CLOSED.
49	16	Houston	R	11/22/2011	RCO audit found that the PI conducted research (chart review of posttraumatic headaches) before receiving ACOS/R notification of subcommittee and R&DC approval	Remedial actions: PI to read SOP section on written approvals; R&DC to develop and implement a corrective action plan (in process), R&DC developed a VA-specific noncompliance notification template, to be used on a case-by-case basis. CASE CLOSED.
50	20	Portland VAMC	H	11/29/2011	RCO audit found that a VA Merit Review, IRB exempt study of Veterans with dual sensory loss expired in the absence of assignment to an oversight committee and annual continuing review.	Remedial Actions: Protocol was assigned to the R&DC; the portfolio was assessed to ensure no other studies expired. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
51	11	Indianapolis	H	12/02/2011	RCO audit found a family member gave surrogate informed consent in a colorectal cancer study, a process that was not defined in the approved protocol.	Remedial actions: Amended study to use LAR in ICD process; suspension lifted; PI to enroll subjects prior to sedation; data collected with LAR consent won't be used if subject refuses enrollment after waking up; RCO to perform regular consent audits of study. CASE CLOSED.
52	11	Indianapolis	H	12/02/2011	RCO audit found digitally recorded research records in a substance abuse mental illness study of homeless veterans were being destroyed following transcription.	Remedial actions: Cease destroying research records; protocol amendment to correct ICD to ensure research records are not destroyed. CASE CLOSED.
53	21	San Francisco VAMC	H	12/02/2011	RCO Audit found failure to obtain initial or continuing approval from VA R&DC, PO or ISO review, and notification from the ACOS/R in a joint arthroplasty study in HIV-positive patients.	Remedial Actions: IRB converted to an electronic protocol submission system; developed an internal database to facility management of the research portfolio that tracks all project approvals. CASE CLOSED.
54	09	Lexington	H	12/05/2011	HSR&D study. RCO audit found 70/125 ICD were not most current version; 17/125 ICD, HIPAA Authorizations, and progress notes were not scanned into CPRS; 17/51 late entry progress notes. RCO audit accomplished at CIRB direction following previous report of apparent noncompliance.	Remedial actions: CIRB determined no reconsenting was required; written verification that subject documents had been scanned in CPRS. LEX RDC to review 12/29. CASE CLOSED.
55	10	Cincinnati	H	12/07/2011	RCO ICD Audit finding of non funded study Oxygen Desaturation and Dynamic Hyperinflation in COPD, witness signatures missing in ICDs w/ witness signature lines.	Remedial Actions: PI submitted study deviation to IRB and modification request to remove witness signature from ICD; Study Coordinator hired; RCO education of medical residents prior to involvement in PI's studies. Actions completed and Case Closed.
56	21	San Francisco VAMC	H	12/08/2011	RCO audit found apparent enrollment subjects by unauthorized personnel into a non-small cell lung cancer treatment study.	Remedial Actions: Compliant informed consent obtained from the two subjects; study coordinators reviewed HRPP handbook. CASE CLOSED.
57	15	St Louis	H	12/11/2011	RCO audit found no regulatory binder on site, no training records or scope for one person obtaining informed consent, no ICD in CPRS, no flagging in CPRS,	Remedial actions: Compile local regulatory binder; produce missing training records and scopes of practice; update missing CPRS components. Remedial actions complete. Case closed.
58	08	Tampa	H	12/12/2011	RCO Audit found that the evaluative study of visual exit barriers in dementia did not obtain and document waiver of informed consent for screening and recruiting purposes.	Remedial actions: Education was provided to the PI and study coordinators on reporting requirements. The IRB made a determination of serious noncompliance. Reports to OHRP were completed. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
59	16	Central Arkansas VHS	H	12/14/2011	RCO Audit found multiple deviations upon IRB-ordered global audit of noncompliant PI's studies. In a study of nausea and vomiting in surgical patients, errors were found in entering CPRS notes, failure to follow-up as per protocol, deletion of an ICF and PI failure to provide staff oversight.	Remedial actions: PI Suspended from conducting research at facility. CASE CLOSED
60	11	Ann Arbor HCS	H	12/15/2011	RCO performed regulatory audit of 2008 non-VA RDC-approved protocol; without RDC continuing review, and the use of incarcerated prisoners as subject population without ORD approved CRADO waiver.	Remedial actions pending any RDC actions. PI will close study at VA. RDC Coordinator administratively closed this study; RDC determined this as serious noncompliance; Research Service to work with PIs to prevent re-occurrence, and RDC response appropriate. CASE CLOSED
61	16	Houston	R	12/20/2011	RCO audit found that 13 participants in a neurobiological study were consented before R&DC approval and ACOS/R notification was sent	Remedial Actions: PI to review SOP section on obtaining required approvals; R&DC requested to develop a and implement a corrective action plan. CASE CLOSED.
62	02	VA Western New York HCS	H	12/28/2011	RCO routine regulatory audit of 2 retrospective chart reviews (Hepatitis C and capsule endoscopy) found co-investigator missing research scope of practice/functional statement.	Remedial Actions: Two new processes implemented by research office. E-mail will be sent to Research Service staff to remind them of importance of specific functional statement. Continuing Review form modified. CASE CLOSED.
63	09	Memphis	H	01/05/2012	RCO informed consent/regulatory audit found 4 unsigned/undated HIPAA documents; missing ICD pages for 1 subject, HIPAA and VA Form 10-5345; 28/89 VA Form 10-5345 blank, 7/89 incomplete, invalid WOC appt/VA training for 1 member; PI disclosed PHI to unapproved personnel for study activities	Remedial actions: PI RAP accepted. IRB determined to allow PI to provide non-study personnel use of linking key for questionnaire administration and destruction of temp research record; Suspension lifted. Remedial actions complete, CASE CLOSED.
64	04	VA Pittsburgh HCS	H	01/05/2012	RCO audit found that a subject enrolled in a study on primary care in the homeless lacked the required signed ICD and signed HIPAA authorization.	Remedial Actions: IRB deliberated on the case and found that no serious or continuing non-compliance had occurred and that no additional action was needed. CASE CLOSED
65	08	Tampa	S	01/08/2012	RCO audit found SRS failure to: review all protocols involving biological, chemical, physical, and radiation hazards; comply with continuing review requirements; submit signed Annual Research Biosafety Update; to obtain R&DC approval for a procedural change.	Remedial actions: Review all projects requiring SRS annual review; PI trained on VHA Handbook requirements; report incident to RD&C. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
66	16	Houston	R	01/17/2012	RCO Audit found that PI Conducted research (enrolled 17 participants)related to surgical site infection in cancer patients prior to receiving ACOS/R notification.	Remedial Actions: IRB required PI to review relevant section in SOP; R&DC submitted a systematic CAP including: RSL real-time queries to BRAIN e-IRB system; RDC's own noncompliance notice; System Redesign Team QI using "lean management tools", RCO-led new PI training and orientation
67	05	DC VAMC	H	01/18/2012	RCO ICD audit revealed 19 subjects did not sign HIPAA authorization. This is an NIH-funded observational f/u study of subjects treated & followed in the ACCORD trial. Study involves a physical exam; questions regarding medical conditions, treatments, & hospitalizations; blood draw & urine samples.	Remedial Actions: IRB developed a checklist to assist researchers in complying with requirements; PIs and research staff are reminded of the new requirement to obtain a separate HIPAA authorization for new studies approved after Feb 2011; Obtain authorization from all participants. CASE CLOSED.
68	06	Durham	H	01/20/2012	RCO consent audit of tissue repository study found that unauthorized person consented six subjects.	Remedial actions: Reconsent not required; specimens will be kept; all staff retrained; RCO to monitor consenting process; RCO will audit all other studies for this PI (none currently open); 4 month f/u audit of this study; PI retrained on Handbooks. CASE CLOSED
69	11	Indianapolis	H	01/20/2012	RCO for-cause ICD audit found apparent human noncompliance in a diabetes study; 1/65 HIPAA authorization portion of the ICD was not signed by subject.	Remedial actions: IRB determined no action required as the subject indicated willingness to participate in the study by printing name on and dating the HIPAA authorization. Remedial actions complete. Case Closed.
70	11	Indianapolis	H	01/20/2012	RCO ICD audit found human noncompliance in 1/51 ICD for a genetics of alcoholism study in which that HIPAA authorization portion of the ICD was not dated or signed.	Remedial actions: HIPAA Authorization mailed to subject for appropriate completion. Remedial actions complete. CASE CLOSED.
71	02	VA Western New York HCS	H	01/20/2012	RCO Audit found lack of required VA Form 10-3203, Consent for Use of Picture and/or Voice for twelve subjects in a lung cancer study.	Remedial Actions: IRB determined serious non-compliance, PI will be allowed to use the data collected, enrollment suspended pending PI education with RCO and completion of PI remedial action plan. CASE CLOSED.
72	16	Central Arkansas VHS	H	01/23/2012	RCO Audit found that PI failed to obtain a certificate of confidentiality per IRB directive. Study of exposure to combat stimuli in non-combat exposed volunteers.	Remedial actions: PI required to obtain Certificate of Confidentiality and report status of application to NIH by June 2012. CASE CLOSED.
73	16	Oklahoma City	H	01/23/2012	RCO audit found that the PI failed to obtain HIPAA authorization from one participant in an acute stroke and recovery motivation study.	Remedial actions: PI reported deviation to IRB and will either obtain HIPAA authorization from participant #36 or exclude the data. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
74	22	VA Greater Los Angeles HS	H	01/23/2012	RCO Regulatory Audit found noncompliant prescreening procedures in the conduct of three studies involving Veteran and non-Veteran subjects with schizophrenia, schizoaffective disorder and/or other psychosis.	Remedial Actions: Cease noncompliant prescreening procedures; Investigate scope of noncompliance; Establish recruitment policy and a registry. Corrective actions completed. CASE CLOSED.
75	01	VA Boston Healthcare System	H	01/25/2012	RCO audit found, and facility reported, lack of credentialing for one investigator on alcohol and bone health protocol.	Remedial Actions: Credentialing initiated. No data at issue. Credentialing completed. CASE CLOSED.
76	16	Shreveport	H	01/26/2012	RCO Audit found four participants were enrolled in the Million Veteran Program (MVP) using an outdated informed consent form due to CIRB's three-week delay in communicating the approval to MVP participating facilities.	Remedial actions: This noncompliance is reported and will be followed in DSS #0013-101-H. CASE CLOSED
77	23	Iowa City	H	01/30/2012	RCO ICD audit found 7/7 ICDs in an anticoagulation study did not contain an IRB approved date stamp.	Remedial actions: IRB requests reconsent of 7 subject, If unable to reconsent due to death, data may be used. PI to submit corrective action plan to prevent reoccurrence. PI to submit other external protocol deviations found by study monitor to the IRB. CASE CLOSED
78	12	Milwaukee	H	01/30/2012	RCO ICD audit of an imaging and robot-assisted study discovered 2 subjects failed to sign a HIPAA Authorization.	Remedial actions: Consent forms and HIPAA authorizations are now filed together; create informed consent checklist requiring a separate checkmark for ICD and HIPAA authorization signatures. CASE CLOSED.
79	00	VA Central Office	H	01/30/2012	Local RCO audits found CIRB approved revised ICD for the Million Veteran Program study was not distributed to some local sites in a timely manner resulting in investigators using the previous ICD.	Remedial actions: IRB review at 2 convened meetings; ORO is working with ORD and CIRB to issue a FAQ. CASE CLOSED.
80	05	DC VAMC	H	02/01/2012	RCO ICD Audit revealed that 3 subjects did not complete HIPAA authorization. The study involves tracking eye movement while looking at moving targets on a computer screen.	Remedial Actions: IRB developed checklist to assist researchers in complying with requirements in obtaining informed consent and HIPAA authorization; PIs and research staff reminded of the new requirement to obtain a separate HIPAA authorization for new studies approved after Feb 2011. CASE CLOSED
81	16	Central Arkansas VHS	H	02/01/2012	RCO Audit found that the PI of a VA System Parent-Child Interaction Therapy study failed to scan ICDs into participants' records.	Remedial actions: PI scanned remaining ICDs into participants' records; IRB considered actions complete. CASE CLOSED
82	09	Memphis	H	02/01/2012	RCO Triennial Audit of staphylococcus retrospective chart review study found incomplete HIPAA waiver forms; subsequently determined failure of IRB reviewer to sign HIPAA and ICD waivers was administrative oversight.	Remedial actions: IRB implementing new research submissions and tracking system (IRBNet); anticipated this will prevent administrative issues. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
83	08	Tampa	H	02/01/2012	RCO audit of a clinical trial in acute coronary subjects found two serious unanticipated adverse events that were not reported to the IRB within five business days.	Remedial Actions: The IRB reviewed the two SAEs and the delay in reporting as required. The two SAEs were determined to be serious, unanticipated, and not related to the research. The failure to report the SAEs was determined to be serious and continuing. Training Completed. CASE CLOSED.
84	11	Ann Arbor HCS	H	02/03/2012	RCO Regulatory Audit found Scope of Practice forms are missing for three study staff in this data collection study of bipolar disorder treatment.	Remedial actions: Complete and submit missing scope of practice forms for three study staff. Verify scopes of practice for all study team members. Remedial actions complete. Case Closed.
85	23	Iowa City	H	02/03/2012	RCO informed consent audit found 172/172 signed informed consent documents without a signature line for the person obtaining consent on this survey versus survey/fecal test study.	Remedial actions: PI remedial actions- none. IRB identified noncompliance for IRB with RAP to reinforce awareness to affiliate Human Subject Office of the VA requirement for the Person Obtaining Consent signature line/ date block in the future. CASE CLOSED
86	22	VA San Diego HS	H	02/06/2012	RCO Audit identified failure to obtain documentation of informed consent and HIPAA Authorization for VA subjects in a study of congestive heart failure and depression.	Remedial actions: PO review of incident; Additional staff training; and data from the affected subjects removed from the dataset. Case Closed.
87	08	Miami	H	02/07/2012	RCO Audit found failure to document inclusion exclusion criteria as described in the IRB approved protocol about clinically comparing two ophthalmologic anesthesia preparations.	Remedial actions: The IRB determined it was not an issue of noncompliance, but of documentation. The R&DC agreed. Training was provided to all Research personnel on March 12, 2012. CASE CLOSED.
88	17	VA South Texas HCS	R	02/07/2012	RCO audit found that required annual (continuing) review and approval had not been obtained since August 2009 for this benchtop science-only (previously animals and benchtop science)study.	Remedial actions: Protocol history review; RAP included obtaining required approvals, planned revisions of ACUP/IACUS SOPs, training for staff, clarification of administrative processes for closing animal portion of a project. CASE CLOSED.
89	16	Central Arkansas VHS	H	02/10/2012	RCO audit found that PI of biofeedback and PTSD study failed to document reconsent in CPRS and notify IRB as directed in previous continuing review.	Remedial actions: IRB directed PI to reconsent participant; IRB Administrator will educate PI and staff on proper documentation of consent; PI instructed to scan entire ICF into CPRS
90	21	San Francisco VAMC	H	02/10/2012	RCO Audit found that 2 of 43 subjects in a peripheral artery disease study signed, but did not print their names on, HIPAA Authorization forms.	Remedial actions: IRB determined this was not serious or continuing noncompliance. CASE CLOSED.
91	21	San Francisco VAMC	H	02/13/2012	RCO Audit found noncompliance (absence of a VA-approved PI) in a clinical human research protocol.	Remedial Actions: Review documentation for accuracy and consistency with affiliate IRB records. Case closed.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
92	21	San Francisco VAMC	H	02/13/2012	RCO Audit found noncompliance in a clinical (multi-site) sponsored study - confusion regarding VA approval, inclusion of children, and distinction of VA from non-VA activity.	Remedial Actions: Revision of policy concerning RDC project approvals and ACOS/R notifications of the same; Protocol modification to document the disallowance of enrollment of children at VA. CASE CLOSED
93	10	Cleveland	H	02/22/2012	RCO Regulatory Audit found lapsed Good Clinical Practice (GCP) and Ethics training by PI. Sponsor Medtronics.	Remedial Actions: IRB determination of not serious or continuing noncompliance. PI completed appropriate training. All actions completed. Case Closed.
94	16	Houston	P	02/22/2012	RCO Audit found VA study of Hepatitis C transplant candidates was begun without R&DC approval or ACOS/R notification and CPRS data was stored on a personal USB drive and removed by a non-VA employee.	Remedial Actions: ACOS/R suspended study until VA PI appointed & CAP completed; ISO examined resident's non-VA USB drive: no PHI, ISO activated software protection on MEDVAMC system, study team retrained on Privacy/IS Awareness. CASE CLOSED.
95	07	Tuscaloosa	H	02/23/2012	RCO Audit found amendment discrepancies with Protocol, ICD and HIPAA in a study of insomnia in combat Veterans with PTSD.	Remedial Actions: HIPAA form amendment; obtain revised HIPAA from 4 subjects; Training to PI and IRB staff; and PI report deviation to IRB. CASE CLOSED.
96	04	VA Pittsburgh HCS	H	02/27/2012	RCO Audit found a newly hired staff conducted the consent process and other procedures on a VA funded protocol prior to receiving IRB approval to perform the procedures. Study examines effectiveness of system-based intervention to deliver motivational messages to sedentary and obese Veterans	Remedial Actions: IRB approved individual's addition to study protocol and administer ICF; PI developed checklist for internal use to assure newly hired staff are appropriately credentialed, trained, and obtain IRB approval. Actions complete. CASE CLOSED
97	08	Miami	H	03/01/2012	RCO regulatory audit found that the study team was not following the IRB-approved protocol. The study team used different thresholds for inclusion/exclusion criteria than what was described in the protocol for this retrospective chart review study on cognition and depression.	Remedial actions: The RCO and PI reviewed the source documentation and found 36 out of 94 met inclusion /exclusion. IRB determined serious noncompliance and reported to OHRP. The data will not be published. Training was completed. CASE CLOSED.
98	08	Miami	H	03/02/2012	RCO regulatory audit found that saliva samples were being collected on a prostate cancer study and sent to a laboratory in Germany for analysis without having approval from CRADO for International Research.	Remedial actions: Training was provided to all PIs, IRB members and study coordinators. An internal audit was conducted by the IRB Chair and no other instances of International Research without approval was found. The IRB review checklist was modified. CASE CLOSED.
99	09	Louisville	H	03/03/2012	RCO regulatory audit of chronic alcohol consumption in HIV-Infected Patients found 2/6 enrolled subjects had exclusion criteria.	Remedial actions: Subjects with exclusion criteria are to be withdrawn from study. Exclusion criteria and CPRS entry reviewed with the study coordinator. Remedial actions complete. CASE CLOSED.

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100	17	VA North Texas HCS	H	03/05/2012	RCO Audit found 29 subjects in a colonoscopic polypectomy study were enrolled using an expired ICF. The IRB determined re-consent not necessary because there were no differences between the old and new consent forms.	Remedial Actions: PI plan to notify all performance sites of changes in consent form; IRB determined re-consent not necessary; include note-to-file of circumstances in research folder; no further action required. CASE CLOSED
101	02	VA Western New York HCS	H	03/05/2012	RCO Audit found multiple findings of non-compliance with ICD requirements for 12 subjects enrolled in two studies listed below. Follow-up For Cause RCO audit revealed additional Findings with IC.	Case Closed. Remedial Actions: ACOS/R&D notified academic affiliate sponsor of for cause audit findings, PI completed CPRS documentation, both studies terminated and use of data prohibited. Data secured by facility. PI WOC appointment was revoked. Access to CPRS terminated. CASE CLOSED.
102	02	VA Western New York HCS	H	03/05/2012	RCO Audit of COPD study found that 22 subjects were enrolled on a COPD study with a version of an ICD that was missing required risk information.	Case Closed Remedial Actions: Reconsent not required and data can be used. process for IRB review checklist revised; electronic versions of ICD now required by IRB. CASE CLOSED.
103	20	VA Puget Sound HCS	H	03/06/2012	RCO audit of a heart murmur study revealed the PI did not have an approved Scope of Practice in place.	Remedial Action: The PI's name has been added to the database to ensure scope of work, training, and credentialing can be tracked in the future. CASE CLOSED
104	09	Louisville	H	03/09/2012	RCO Audit found 27 subjects in two VA Merit spinal cord injury studies signed only affiliate ICD and HIPAA authorizations, not just one study as previously reported. New report includes the noncompliance for the 2nd study.	Remedial actions: VA consents are being obtained for each study; RCO will continue to audit the consents and the consenting process. Remedial action complete. Case closed.
105	04	VA Pittsburgh HCS	H	03/12/2012	RCO Audit found that Research staff had generated reports that contained Veteran's PII and PHI without prior IRB approval; participated in conduct of protocol without approved credentialing or scope of practice.	Remedial Actions: Study suspended; PI mentored by ACOS/R&D; staff educated; policies developed hospital wide to prevent/reduce unauthorized access and disclosure of PHI for research purposes; PI notify affected subjects and obtain signed HIPAAs or obtain Waiver of HIPAA Authorization. CASE CLOSED
106	04	VA Pittsburgh HCS	I	03/12/2012	RCO Audit found transmission of unencrypted external email (sent more than 1 year ago) containing name, SSN and medical conditions of 1 Veteran.	Remedial Actions: Retraining of VA employee; resign rules of behavior; violation sent to the service line leadership. The PI assured that the PHI sent to the home email address was deleted immediately. CASE CLOSED
107	08	Tampa	H	03/13/2012	Triennial RCO audit found an SAE not reported to the IRB and one team member not credentialed through VetPro in a Phase II Myeloma clinical trial.	Remedial Actions: The PI submitted the SAE to the IRB which determined the event to be serious, anticipated and not related. Human Resources initiated VetPro verification of study personnel was completed. CASE CLOSED.

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108	04	Philadelphia	H	03/14/2012	RCO audit found deficiencies in informed consent or HIPAA authorization procedures in a study of genetic variants in glaucoma in Afro-Americans. Additional findings from further auditing; non-approved study staff and staff training.	Remedial actions: Consenting stopped; PI to submit Protocol Deviation. Study staff training. Six month Continuing Review. Modification for use of VA Voice and/or Picture Consent Forms. PI sent letter to subjects explaining use of non IRB stamped consents for IRB review. CASE CLOSED.
109	01	White River Junction	H	03/14/2012	RCO Audit found R&DC approved study of physical therapy, gait and balance prior to IRB approval due to an administrative error). No subjects were enrolled prior to IRB approval.	Case Closed. Remedial Actions: Affiliate IRB reviewed findings and determined that the findings do not constitute serious or continuing non-compliance. R&DC to exercise increased diligence in checking subcommittee approval dates prior to R&DC approval. CASE CLOSED.
110	04	VA Pittsburgh HCS	H	03/16/2012	RCO regulatory audit identified study staff of joint replacement disparity multisite study enrolled subjects using liberalized inclusion criteria without submitting modification to the originally VAPHS IRB approved protocol.	Remedial Actions: PI submit an Unanticipated Problem Report to IRB; provide update on enrolled subjects that did not meet the eligibility criteria; submit modification to protocol to accurately describe all study procedures carried out. CASE CLOSED.
111	04	VA Pittsburgh HCS	H	03/16/2012	RCO regulatory audit of Multi-Center Study for the Prevention of Episodic Migraine identified: Investigator acquired PHI through screening process not approved by IRB; Personnel not approved by IRB and without approved scope of practice accessed CPRS to obtain the PHI.	Remedial Actions: Continuing review every 6 months; 10 subjects to be enrolled at facility prior to a formal request is made to re-open enrollment at non-facility sites; RCO to conduct a formal audit after 5 subjects are enrolled. CASE CLOSED
112	21	San Francisco VAMC	H	03/19/2012	RCO audit of a human study assessing novel kidney biomarkers found the transfer of identifiable study specimens without an approved off-site waiver.	Remedial actions: Seek off-site waiver; provide additional training to staff. Case Closed.
113	23	Iowa City	H	03/20/2012	RCO audit found that 172 participants completed ICD authorization on forms not containing signature line for "person obtaining consent." PI submitted ICD with this line, but it was removed by affiliate IRB to match their policy.	Remedial Actions: Educate the Affiliate IRB and VA PI on VA requirements for signature lines; review of all remaining VA protocols revealed no other cases where this signature line was removed. Remedial actions completed. Case Closed.
114	21	VA Palo Alto HCS	H	03/21/2012	RCO ICD Audit found that three subjects were enrolled in a biopredictors of cognitive and behavioral outcomes study without signing HIPAA Authorization; also found one subject was consented by an unauthorized staff.	Remedial actions: Authorized staff member reconsented subject; other actions pending. CASE CLOSED.
115	16	New Orleans	H	03/26/2012	RCO audit found that PI failed to obtain a Certificate of Confidentiality as required by the IRB for a couple's PTSD treatment in OEF/OIF Veterans study.	Remedial actions: Obtain Certificate of Confidentiality; amend ICD before enrolling new subjects; letter informing all enrolled subjects, followed by letter informing subjects when C of C is obtained; IO reported to OHRP

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
116	11	Ann Arbor HCS	H	03/27/2012	RCO ICD audit found 1/206 ICD in a prostate cancer decision making study was missing the required signature and date of signing as well as 1/206 ICD was missing the signature of the person obtaining consent.	Remedial actions: IRB determined SNC for these two events. Reconsenting of the 2 subjects is completed. Corrective actions appropriate per the IRB. Remedial actions complete. Case Closed.
117	23	Sioux Falls	H	03/27/2012	RCO ICD audit found the IC waiver criteria for a weight management program in underserved areas were not documented in the IRB meeting minutes.	Remedial actions: IRB to re-review study and determine if waiver of HIPAA and ICD is appropriate. Remedial actions complete, CASE CLOSED.
118	03	VA New York Harbor HCS	H	03/27/2012	RCO Audit (for-cause) found in a study of respiratory protection for healthcare workers: 5 of 160 subjects did not have signed HIPAA Authorization; ACOS letter of R&DC approval issued before all required reviews/subcommittee approvals; no documentation of dangerous good shipping training.	Remedial Actions: Staff education conducted, IRB modified internal processes to ensure improved clarity in protocol documentation, missing HIPAA Authorizations obtained, training completed. CASE CLOSED.
119	07	Tuscaloosa	H	03/28/2012	RCO ICD Audit found failure to use the most recent ICF (16% failure); the use of an unapproved/out-dated HIPAA Authorization for 32 of 43 subjects in a study of primary care quality for the homeless.	Remedial Actions: IRB review processes of posting ICDs; IRB & PO determine if HIPAA Authorizations are valid, and if not, what actions are required; and training. CASE CLOSED.
120	11	Indianapolis	H	03/29/2012	RCO audit found in a post-marketing observational study of a chronic plaque psoriasis drug study that sponsor-initiated amendment changes in the ICD were not implemented; also the Research Coordinator and several study personnel lacked IRB approval, credentials, training, and scopes of practice.	Remedial actions: PI to submit amendment with sponsor changes, updated ICD, and Summary Safeguard Statement. CASE CLOSED.
121	21	San Francisco VAMC	H	04/02/2012	RCO audit of a artero-venous fistula study discovered missing HIPAA documents for two enrolled subjects.	Remedial Action: Subjects informed and new HIPAA authorizations received; and Remedial training for study staff. Case closed.
122	12 NE	James A. Lovell Federal Health Care Center	H	04/03/2012	RCO audit found the new version of the Informed Consent Form for an obstructive sleep apnea study was never put into use after the IRB approved the amendment.	Remedial Actions: IRB requesting action plan. CASE CLOSED
123	01	VA Boston Healthcare System	H	04/03/2012	RCO audit of a behavioral health study noted documentation of Safety continuing review for 2009 was missing.	Remedial Actions: Committee and PI education provided. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
124	20	VA Puget Sound HCS	H	04/04/2012	RCO audit identified missing HIPAA authorizations in two imaging (MRI)protocols conducted by the same PI; one was missing three of five authorizations; and the other was missing five of eight authorizations. No use/disclosure has occurred for subjects enrolled into these two studies.	Remedial Actions: Staff re-education on consent process; development of a consent tool/checklist for future use; obtain HIPAA Authorizations; improved HRPP education program. CASE CLOSED.
125	09	Memphis	H	04/05/2012	RCO Triennial Audit of a thrombocytopenia study found unapproved enrollment of non-veterans, enrollment exceeds approved number, and lack of documentation of ISO/PO review.	Remedial Actions: IRB approved PI request for enrollment of non-Veterans; IRB determined PI did not exceed approved enrollment numbers. CASE CLOSED
126	06	Durham	H	04/06/2012	RCO ICD audit found that 13 subjects on a study looking at cognitive decline in healthy veterans were reconsented authorizing extended follow-up by an individual who did not have a scope of practice allowing for obtaining consent.	Remedial actions: VA Scope of Practice completed; Offsite storage confirmed; Reconsent considered duplicative and unnecessary. CASE CLOSED
127	15	VA Eastern Kansas (Leavenworth) HCS	H	04/09/2012	RCO Informed Consent Audit found 2 subjects did not complete HIPAA Authorization forms in the Million Veteran Project which studies how genes affect health.	Remedial Actions: Entry of the event into the NSOC(Ticket #73475)and local education on procedures for reporting possible non-compliance. Remedial actions complete, CASE CLOSED.
128	02	VA Western New York HCS	H	04/09/2012	RCO Audit found lack of process to conduct required annual review of scopes of practice/functional statement.	Remedial Actions: All PIs contacted to review scope of practice/functional statements, R&D SOP modified, Process Action Team charged to oversee, Continuing Review form modified, Excel spreadsheet developed for tracking. CASE CLOSED.
129	11	Indianapolis	H	04/10/2012	RCO triennial audit found in a closed, botulinum toxin study for pain management that all research documents had been destroyed, and a discrepancy between documented number of subjects enrolled and ICDs retained.	Remedial action: PI must obtain extensive human subjects research education and oversight; PI never responded to RDC remedial actions; RDC decided to not pursue further and to note PIs lack of response and admonish PI if a subsequent study is opened. Remedial actions complete, CASE CLOSED.
130	11	Ann Arbor HCS	H	04/13/2012	RCO ICD Audit found apparent, serious, continuing noncompliance in a VA-CIRB, drug-eluting stent study. RCO reviewed eight ICDs and HIPAA forms and found two subjects did not sign HIPAA. Also, ICD lacked some local site requirements. In addition, PI reporting requirements may not have been met.	Remedial Actions: HIPAA forms sent to participants for signature. No data released to Coordinating Center subsequent to the receipt of the signed HIPAA authorizations. Procedures put in place for subsequent study candidates to be presented with both forms. Remedial actions complete. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
131	04	VA Pittsburgh HCS	H	04/13/2012	RCO Audit found a Clinical Research Coordinator for a hypoxemia study used PHI contained in medical records to determine eligibility of potential research subjects without HIPAA Authorization or a waiver of HIPAA Authorization, and initiated this procedure without informed consent.	Remedial Actions: 1. Notify affected subjects that data was used in a secondary study without proper HIPAA authorization, or If #1 is impractical submit request for Waiver of HIPAA Authorization along with documentation that waiver criteria are applicable. CASE CLOSED
132	15	Columbia	H	04/18/2012	RCO ICD audit of a National Institute on Alcohol Abuse and Alcoholism funded study discovered 13/143 ICDs were executed using an incorrect, outdated version of the ICD.	Remedial actions: Education for PI and staff. Remedial actions complete. CASE CLOSED.
133	09	Memphis	S	04/18/2012	RCO audit found a protocol with a lapse of approval, lack of scopes of work for approved personnel, and a study personnel not listed in protocol.	Remedial actions: Biosafety/Biosecurity Committee review of protocol during convened meeting; review of audit findings. CASE CLOSED
134	06	Durham	H	04/20/2012	RCO audit discovered that missing form 10-9012's from previous audit of a peripheral artery disease study hadn't been corrected. IRB determined that to be not serious but continuing NC. Study closed. All forms have been scanned.	Remedial actions: All scans completed into CPRS; Study closed. CAPA submitted by PI to IRB. CASE CLOSED
135	16	Central Arkansas VHS	H	04/20/2012	RCO audit found that a screening log for a cardiology study containing Veteran participants' PHI (DOB, gender, ethnicity) was faxed to the (non-VA) study sponsor.	Remedial Actions: The sponsor's (Duke) screening log was destroyed; sponsor clarified that PHI isn't sent to fax machine, but to a password protected limited access server. IRB found non-serious, not continuing noncompliance. CASE CLOSED.
136	18	Southern Arizona VA HCS	S	04/24/2012	RCO audit found lapses in SRS annual review requirements.	Remedial actions: R&DC review; implementation of a tracking system for management of SRS review processes.
137	11	Ann Arbor HCS	H	04/27/2012	RCO Audit of 15 ICDs found that an individual, who was not authorized to obtain consent, signed one ICD as the POC. This was a cardiac rehabilitation evaluation outcomes project.	Remedial Actions: PI may not accrue new subjects until remediation plan reviewed and approved by IRB Chair; Study coordinator to be re-trained by at least two IRB staff; RCO to perform quarterly audits. Remedial actions complete, CASE CLOSED.
138	11	Indianapolis	H	04/27/2012	Triennial RCO audit for a colonoscopy screening study, sponsored by NCI, found that research was conducted at the VA without the IRB approving the VA as a performance site. Also, two study staff were listed in the current protocol who were no longer active in the study.	Remedial actions: PI to provide RCO with master log of all VA subjects enrolled; PI to submit IRB amendment adding the VA as a study site; data on VA subjects can't be used until IRB approves amendment. Remedial actions complete. CASE CLOSED.
139	03	VA New Jersey HCS	H	04/27/2012	RCO audit found that 1 subject out of 24 did not sign a HIPAA Authorization on a substance abuse study	Remedial Actions: Subject to sign HIPAA Authorization; implement checklist to prevent future reoccurrences. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
140	08	Tampa	A	05/01/2012	RCO audit found a protocol that lacked documentation of R&D approval for the addition of a staff member. A second protocol had a lapsed in SRS annual review and continuation of research activities beyond the established SRS expiration date. The protocols used rodents.	Remedial actions: R&DC deliberation; investigation of the cause for the delay in the SRS annual review; correction of research database used to track annual reviews. CASE CLOSED
141	08	Tampa	S	05/01/2012	RCO audit found two protocols with lapse in annual SRS reviews. These protocols used rodents.	Remedial actions: Correction of the database used to track annual reviews. CASE CLOSED
142	21	San Francisco VAMC	H	05/02/2012	RCO audit of a human subjects protocol (nuclear imaging test showing blood flow) identified that HIPAA authorization forms were not provided to (or signed by) 119 subjects and a VA ICD was not used for 117 subjects (subjects were enrolled on affiliate ICDs).	Remedial Actions: IRB determinations - serious but not continuing noncompliance, no data use without correction of ICD and HIPAA deficiencies; protocol amendment required. CASE CLOSED.
143	01	VA Boston Healthcare System	H	05/08/2012	RCO Audit of infectious disease study found missing HIPAA authorizations (6 subjects), Consent noted to be "verbal" for six participants.	Remedial Actions: Study suspended to enrollment pending amendment to procedures for consenting Spinal Cord Injured patients has been approved by the IRB. The data from subjects who were not consented properly will not be used. PI education conducted. CASE CLOSED
144	10	Chillicothe	H	05/09/2012	RCO consent form audit found all 15 subjects enrolled in an immunological study had not signed the HIPAA Authorization.	Remedial Actions: Obtain HIPAA Authorizations, educate study staff, and educate new PIs at facility on research procedures prior to study initiation. CASE CLOSED
145	11	Indianapolis	H	05/11/2012	RCO regulatory audit of a home-based pharmacy services study found non-Veterans enrolled without IRB approval; number of subjects in the close-out report did not match number of ICDs signed; IRB approval lapse prior to study closure.	Remedial actions: None, no noncompliance determined. CASE CLOSED.
146	11	Indianapolis	H	05/11/2012	RCO regulatory audit of a Type 2 diabetes mellitus study found potential release of identifiable data or tissues to study personnel who lack VA training; lapse in IRB approval.	Remedial actions: None, IRB determined no noncompliance occurred. CASE CLOSED.
147	19	VA Eastern Colorado HCS	H	05/11/2012	RCO audit of a cancer prevention study identified lapse in study approval.	Remedial Actions: IRB recommended repeat of CITI training, with emphasis on expiration of IRB approval. CASE CLOSED.
148	16	Houston	H	05/14/2012	RCO audit found that a team member on an anticoagulation study failed to complete required HSP and GCP training	Remedial actions: Study team completed required training modules, IRB closed case, determined non-serious, not continuing.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
149	16	Houston	P	05/14/2012	RCO Audit found 1) a study staff member never received HSP & GCP training and 2) chart review study was conducted (179 records collected)prior to R&DC approval and ACOS/R notification.	Remedial action: IRB determined noncompliance was neither serious nor continuing, reminded PI to ensure that all study staff complete training and to obtain all required approvals. CASE CLOSED.
150	16	Houston	P	05/14/2012	RCO audit found a study staff member had not completed VA HSP, GCP and "Information Security 201 for R&D Personnel	Remedial Actions: R&DC Chair sent a noncompliance notice to PI; IRB determined non-serious, not continuing, reminded PI to ensure that all study staff are trained. CASE CLOSED.
151	16	Houston	P	05/14/2012	RCO audit found that a co-investigator had not completed VA HSP&GCP training, nor had he completed "Information Security 201 for R&D Personnel."	Remedial action - IRB determined to be non-serious, not continuing, reminded PI to ensure that all study staff are trained. CASE CLOSED.
152	16	Houston	R	05/14/2012	RCO Audit found that a PI conducted research without submitting protocol to R&DC. PI had obtained IRB initial and continuing review approvals. R&DC coordinator asked PI whether she planned to submit for R&DC approval, PI never responded.	Remedial actions: PI obtained R&DC approval, IRB closed case as non-serious, not continuing. CASE CLOSED.
153	16	Oklahoma City	H	05/14/2012	RCO audit found multiple protocol violations re: informed consent and HIPAA authorization process on a bowel preparation for diabetic patients clinical trial	Remedial Actions: RCO educated study team, PI submitted deviations to IRB: non-serious, not continuing; R&DC suspended study, required documented study team HRPP retraining, CPRS notes entered on all participants; IRB reviewed progress: data use only with signed HIPAA auth; PI: 4/12, so far. CASE CLOSED.
154	16	Oklahoma City	H	05/14/2012	RCO Audit found PI failed to obtain HIPAA authorization from one research participant enrolled in a vascular study.	Remedial Actions: PI obtain HIPAA Authorization; IRB determined non-serious, not continuing, no additional actions required. CASE CLOSED.
155	16	Oklahoma City	H	05/14/2012	RCO audit of a mental health study found multiple deviations from IRB-approved informed consent and HIPAA authorization procedures.	Remedial Actions: RCO educated PI and PI reported deviation to IRB -determined SNC notified OHRP & ORD; IRB and R&DC suspended protocol; IRB determined: no data use without signed ICD or HIPAA; document study team's retraining; PI must submit a CAP before enrollment may resume. CASE CLOSED.
156	15	Columbia	R	05/16/2012	RCO for-cause audit of a nutritional epidemiologic study found possible conduct of VA research without RDC approval; conduct of international research without CRADO approval.	Remedial actions: PI educated on requirements for conducting international research and required reviews for all research approved by the VA; PI stated he would close Project 0002 and sub studies; RDC Chair will meet with PI in 6 months intervals to review research projects. Case closed.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
157	04	Coatesville	H	05/18/2012	RCO Regulatory Audit of a transitional housing programs study found that the credentials of a Co-PI had not been properly verified.	Remedial Actions: Policy review, revision and training for research office personnel. CASE CLOSED
158	16	Houston	H	05/22/2012	RCO Audit of a cardiac arrhythmia study found co-investigator did not complete required trainings on human subjects research, Good Clinical Practice and Information Security.	Remedial Actions: IRB determined non-serious, not continuing NC, reminded PI to ensure all study staff complete mandatory training.
159	16	Houston	R	05/22/2012	RCO Audit found that the PI of a gastric reflux and obesity study started research (chart review) without submitting study to the Research Service Line for R&DC review and ACOS/R notification.	Remedial Actions: None, IRB found RCO findings to be unsubstantiated. CASE CLOSED.
160	16	Houston	R	05/22/2012	RCO audit of a Hepatitis C Virus Outcomes study found that original PI submitted protocol for R&DC review and received contingent, but not final, approval; a new PI conducted research without R&DC approval or ACOS/R notification	Remedial Actions: None. IRB determined RCO findings to be unsubstantiated, decided that R&DC's contingent approval, pending IRB approval was acceptable. No ACOS/R notification was ever sent. CASE CLOSED.
161	09	Lexington	H	05/24/2012	RCO ICD audit of a PTSD study found that 21/64 ICDs were signed using the incorrect IRB-approved version.	Remedial Actions: None. CASE CLOSED.
162	01	Bedford	H	05/25/2012	RCO audit found missing HIPAA authorization for four subjects enrolled in a human protocol on women's substance abuse treatment.	Remedial Actions: IRB determinations - no use of data without HIPAA and permission to contact subjects to obtain HIPAA authorization; PI/staff refresher training re: authorization. Corrective actions completed. Case closed.
163	16	Jackson	H	05/25/2012	RCO Audit of gastric reflux and obstructive sleep apnea study found PI enrolled 27 participants using an invalid ICD, after having been trained by the RCO on IC procedures.	Remedial Actions: Re-consented and sent an explanatory letter to all 27 participants; entered CPRS consent process notes for all 27; RCO observed PI's consent discussion. CASE CLOSED.
164	16	Central Arkansas VHS	H	05/25/2012	RCO Audit of a post-deployment substance abuse study found PI failed to obtain 3 HIPAA signatures when ICD was revised and HIPAA authorization became a standalone document	Remedial actions: PI halted data collection from affected subjects until HIPAA authorizations were obtained, amended new subject enrollment folders to include HIPAA Auth. IRB will determine whether data can be used upon receipt of PI's 30-day status report. CASE CLOSED.
165	09	Louisville	H	05/25/2012	RCO ICD audit of a renal failure study found that one ICD did not contain the signature and date of the person obtaining consent.	Remedial Actions: A copy of the SOP on the ICD process was furnished to the study staff; The RCO verbally reviewed the requirements with study staff. Remedial actions complete, CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
166	08	Tampa	H	05/25/2012	RCO Audit found failure to obtain a waiver of informed consent for screening and recruiting purposes in a decision making study related to patients with prostate cancer and their relatives.	Remedial Actions: The PI submitted a report to the IRB, education was obtained from the RCO, IRB determined it to be serious noncompliance and reported it to OHRP. This was a closed study. CASE CLOSED.
167	21	VA Palo Alto HCS	H	05/25/2012	RCO audit of a neuropsychology study found that informed consent of one subject was conducted by an unauthorized individual.	Remedial Actions: IRB determined that serious noncompliance occurred and required that PI re-consent the subject. CASE CLOSED.
168	22	VA San Diego HS	H	05/25/2012	RCO audit found that 98 subjects did not sign ICDs for a protocol involving somatic symptom measurement in psychiatric inpatients.	Remedial Actions: Close study; return data and records to facility; none of the data collected to be used; formal mentoring for PI; and frequent RCO audits. CASE CLOSED
169	22	VA San Diego HS	H	05/25/2012	RCO Audit of a mood and sleep treatment study found 9/40 missing HIPAA authorization; 2 forms contained the subject's printed name, but not their signatures.	Remedial Actions: IRB permission to contact subjects for purpose of obtaining HIPAA authorization; no data use without HIPAA authorization. Case closed.
170	11	Ann Arbor HCS	H	05/29/2012	RCO Audit of a behavior outcome study found 1/30 HIPAA authorizations was not signed by subject; outdated ICD for two subjects, and undated ICDs for two other subjects.	Remedial Actions: Patients are being reconsented on appropriate ICDs and, if unreachable, data will not be used. IRB determined this not to be SNC or CNC. CASE CLOSED
171	01	VA Boston Healthcare System	H	05/29/2012	RCO ICD Audit of an Alzheimer's study found missing signature page for 1 ICD, 3 signed expired ICDs, missing research credentials for ICD obtainer, other date inconsistencies.	Remedial Actions: Reconsent 5 subjects, obtained HIPAA Authorization from 1 subject, data cannot be used for these subjects until proper consent and HIPAA are obtained; staff to perform "mock" informed consent procedure to improve processes; PI to clarify reason for date inconsistencies. CASE CLOSED.
172	01	VA Boston Healthcare System	H	05/29/2012	RCO ICD Audit of cardiovascular study found missing ICD and HIPAA (1), use of expired consent form (1), missing witness signatures (6) and other documentation problems.	Remedial Actions: Contact 9 subjects and reconsent; obtain written clarification from subjects who signed HIPAA revocation of authorization in error; PI to clarify reason for date inconsistencies. CASE CLOSED.
173	01	VA Boston Healthcare System	H	05/29/2012	RCO ICD Audit of Glaucoma study found missing HIPAA Authorization for 1 participant.	Remedial Actions: Obtained missing HIPAA authorizations from 1 subject. CASE CLOSED
174	01	VA Boston Healthcare System	H	05/29/2012	RCO ICD Audit of heart failure study found that the date of HIPAA authorization was subsequent to the screening blood draw.	Remedial Actions: Modify screening ICD regarding sending data offsite and adding data to database; have subjects who sign screening ICD also sign a HIPAA authorization (amendment submitted for additional HIPAA Authorization). CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
175	09	Memphis	H	05/30/2012	RCO Triennial Audit of an immune tolerance study found the study was approved using the inappropriate review category, that inclusion of non-veterans was not approved, and that the study lacked ISO/PO review.	Remedial Actions: RCO provided education to IRB for granting protocol exemptions. PI closed study. There was no subject enrollment. Case linked to case 0060-614-H. CASE CLOSED
176	22	VA San Diego HS	H	05/31/2012	RCO audit of a study on age differences and fear identified that one subject completed a neuropsychological questionnaire prior to being consented.	Remedial Actions: IRB determinations that noncompliance was neither serious nor continuing; data obtained without consent may be removed from the database; refresher training for study staff. Case closed.
177	22	VA San Diego HS	H	05/31/2012	RCO audit of a VA mental health services study found that 11/51 ICDs were not signed by the person obtaining informed consent.	Remedial Actions: ICD deficiencies corrected; noncompliance determined to be neither serious nor continuing; PI practice implemented to avoid a recurrence. Case closed.
178	09	Memphis	P	06/01/2012	RCO audit found failure to implement remedial actions, conduct of animal research (rats) without IACUC approval, expired IACUC protocol, lack of IBC review, missing final Radiation Safety Committee approval, lack of chemical inventory submission and review, expired safety protocol.	Remedial Actions: Audit findings to be presented to the Biosafety/Biosecurity Committee, the R&DC and the IACUC; IBC review is pending at this time. CASE CLOSED
179	11	Indianapolis	H	06/04/2012	RCO regulatory close-out audit of a retrospective outcome and satisfaction survey study discovered 59 more subjects were enrolled in the study than the 100 subjects that were approved by the IRB.	Remedial Actions: RCO provided education to the PI and the Pharmacy service on submitting IRB applications including amendments; on the regulatory audit process; and how to close a study. Remedial actions complete, CASE CLOSED.
180	01	VA Boston Healthcare System	H	06/04/2012	RCO ICD Audit of Anticoagulation Clinic study found wrong ICD used, no HIPAA Authorizations obtained and other date irregularities.	Remedial Actions: Staff education, re-consent participants, HIPAA Authorizations obtained. CASE CLOSED.
181	01	VA Boston Healthcare System	H	06/04/2012	RCO ICD Audit of PTSD study found wrong ICD used, one missing HIPAA Authorization and other date irregularities.	CASE CLOSED Remedial Actions: Education of staff, "mock" informed consent training for staff, participant reconsented and HIPAA obtained. CASE CLOSED.
182	16	Houston	R	06/05/2012	RCO audit found that a VA-paid PI conducted a low platelets retrospective chart review from 2006-2009 without obtaining R&DC review and approval. IRB approval expired and was re-approved twice before the study was submitted for R&DC review in 2009. IRB and Research Service closed study in 2011.	Remedial Actions: R&DC CAP includes: RSL real-time queries to BRAIN e-IRB system; RDC developed their own noncompliance notice; System Redesign Team QI initiative using "lean management tools", RCO-led new PI educ. CASE CLOSED.

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183	03	Northport	I	06/08/2012	NSOC reported RCO Audit found unauthorized transmission of PHI via encrypted compact disc (CD) to an affiliate study team member. The approved protocol data management plan documented that no data would be transmitted outside the VA.	Remedial Actions: PI retrieve and destroy CD; PI verify no data resides outside of VA firewall; PI and staff retake required Privacy and Information Security trainings. CASE CLOSED
184	20	Portland VAMC	H	06/11/2012	RCO audit of an auditory study that recruited inpatients found an unreported adverse event.	Remedial Actions: delinquent AE report submitted and determined to be unanticipated but not study-related, no need for convened IRB review or further action. Case closed.
185	20	Portland VAMC	H	06/11/2012	RCO audit of retrospective chart review in the data analysis phase of an artery stenting study found a discrepancy in the number of charts approved for review.	Remedial Actions: IRB determinations - noncompliance not serious or continuing; approved amendment to increase number of charts; permission to use data from (prior) unauthorized chart reviews; no further action. Case closed.
186	21	VA Northern California HCS	H	06/11/2012	RCO audit found conduct of research after protocol expiration, subject over-enrollment, and failure to obtain HIPAA Authorization from 75 Veterans in a study of the lumbar multifidus muscle.	Remedial Actions: PI must obtain valid HIPAA authorization; retake VHA Privacy Training; and receive additional training from the PO. CASE CLOSED.
187	21	VA Palo Alto HCS	H	06/11/2012	RCO ICD audit of 163 participants in an unfunded project that evaluates the characteristics of an exercise test and measures biochemical markers of myocardial ischemia found that 1 subject did not sign an ICD and 2 subjects did not sign a HIPAA Authorization.	Remedial Actions: IRB determined that serious noncompliance occurred and that the (3 subjects) data could not be used or disclosed. R&DC provided compliance counseling. CASE CLOSED
188	21	VA Palo Alto HCS	H	06/11/2012	RCO ICD audit of 4 participants in a mental health promotion study found that of the 4 consents obtained for the project, 2 were obtained by unauthorized personnel.	Remedial Actions: PI review of staff appointments and training status; improved investigator coordination; IRB determination of serious, but not continuing, noncompliance. CASE CLOSED
189	21	VA Palo Alto HCS	H	06/11/2012	RCO ICD audit of 553 participants in a survey of new participants joining Al-Anon found that 69 participants signed an outdated version of the informed consent and 89 participants signed an expired version of the informed consent.	Remedial Actions: IRB determined that continuing, but not serious, noncompliance occurred and that only minor variations existed between the approved ICD and ICD that was used. CASE CLOSED.
190	11	Ann Arbor HCS	H	06/13/2012	RCO ICD Audit of a chronic pain and substance abuse study found 20/168 subjects signed an outdated ICD. Enrollment is now complete.	Remedial Actions: PI updated processes in research clinic to ensure current ICD version used for consent of prospective subjects. IRB determined this case was not serious or continuing noncompliance. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
191	16	New Orleans	H	06/13/2012	RCO audit of a PTSD couples' therapy protocol found discrepancies between IRB minutes and correspondence re: expedited vs. full board on initial and continuing reviews; erroneous assignment of review categories; and a 3-month delay in IRB review of an SAE.	Remedial Actions: RCO educated IRB members and staff on SAE reporting timelines and procedures. CASE CLOSED.
192	15	VA Kansas City Medical Center	H	06/13/2012	RCO Audit of a study using cholinesterase inhibitors on cocaine-reinforced behavior found that: The PI did not retain a master enrollment list; 2 subjects signed old ICDs, 1 subject did not sign HIPAA, and 2 signed HIPAA revocation; and progress notes were not entered into CPRS for some subjects.	Remedial Actions: RCO to provide education. One subjects to resign HIPAA authorization and ICD; senior clinical coordinator to mentor junior coordinators; study suspended. Suspension lifted. CASE CLOSED.
193	22	VA Long Beach HS	H	06/13/2012	RCO audit found 2 subjects did not sign HIPAA Authorization documents; person obtaining informed consent did not sign 3 ICFs; and 1 witness did not sign an ICF in a human protocol involving management of antipsychotic medication associated with Obesity-2.	Remedial Actions: IRB determined serious noncompliance occurred; reconsent required; no use of data without reconsent (with HIPAA); IRB observation of consenting process; PO review. CASE CLOSED.
194	22	VA Greater Los Angeles HS	H	06/18/2012	RCO found missing HIPAA authorization for four subjects enrolled in a human protocol on studying the Dopamine D2 Receptors in Striatum of Social Drinkers. The PI did not use the date-stamped ICD to enroll subjects.	Remedial Actions: RCO must conduct a for-cause audit of all the on-site study records for this protocol; PI must obtain HIPAA authorization from subjects.
195	07	Charleston	A	06/19/2012	RCO audit identified several animal protocols which lacked documentation of annual reviews. Protocols involved rodents.	Remedial Actions: IACUC reviewed all protocols involved; IACUC Coordinator employment was terminated. CASE CLOSED.
196	01	VA Boston Healthcare System	H	06/20/2012	RCO Audit of PTSD and Substance Use Disorder study found missing ICD for one participant, expired ICD used and missing HIPAA authorization for one participant.	CASE CLOSED Remedial Actions: Study suspended to new enrollment, Staff education, Documentation of Informed Consent entered into CPRS, obtain missing HIPAA Authorization
197	08	Tampa	H	06/21/2012	RCO IC audit found the ICD and HIPAA authorization were missing for 1 of 37 subjects in a sleep apnea study. PI requested search of hard copy chart used in Gastro Suite at another VA facility. PI will submit a reportable event to affiliate IRB.	Remedial Actions: PI to reconsent the subject. Reporting to OHRP was completed. CASE CLOSED.
198	07	Columbia	H	06/22/2012	RCO audit of a PTSD study found apparent serious or continuing noncompliance. ICDs not signed for 15 subjects; incorrect ICD signed	Remedial Actions: ACOS/R requested a RCO for-cause audit; temporary suspension of recruitment and enrollment for both studies.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
199	22	VA San Diego HS	H	06/25/2012	RCO Audit finding of (one) unsigned HIPAA authorization in a septal cartilage study.	Remedial Actions: Obtain HIPAA authorization for this subject. CASE CLOSED.
200	18	Phoenix VA HCS	H	06/26/2012	RCO audit found lack of approval for enrollment of non-Veterans in a diabetes study, because of PI failure to confirm use of an IRB-required Notice of Privacy Practices.	Remedial Actions: Confirmation that study subjects were provided a Notice of Privacy Practices. CASE CLOSED
201	18	New Mexico VA HCS	S	06/27/2012	RCO audit found lapses in SRS annual review and approvals.	Remedial Actions: Review and approval projects; hire a Research Coordinator for SRS related activities. CASE CLOSED
202	16	Houston	H	06/28/2012	RCO audit of a study evaluating feasibility clinical utility, and sensitivity to change of proposed new mental health diagnostic criteria found that 134 of 197 participants were enrolled using incorrect versions of the ICD.	Remedial Actions: PI to document occurrence in each subject's research record with notation that both ICD versions contained the same information; PI to retrain study staff. CASE CLOSED.
203	17	VA Central Texas HCS	H	06/28/2012	RCO Audit found, in a high risk vascular graft surgical study, that an ICD and HIPAA authorization form were not entered into the medical record for 1 of 4 subjects (were properly obtained) enrollment and progress notes were not entered for all 4 subjects.	Remedial Actions: Provide (re)training for research staff; RCO audit CPRS study documentation at least quarterly; ensure informed consent and HIPAA authorizations are scanned into CPRS; ensure all CPRS notes are completed. CASE CLOSED
204	07	Atlanta	I	06/29/2012	RCO ICD Audit of Diabetes study found 15 missing ICDs and HIPAA Authorizations in CPRS. Copies of these documents appear to be lost - facility has original copies.	Remedial Actions: ICD and HIPAA Authorizations are now scanned and sent to the main facility via encrypted e-mail vs. by courier; CPRS audit to ensure ICDs are scanned; 15 subjects were offered credit monitoring services. CASE CLOSED
205	01	Providence	H	06/29/2012	RCO Audit found HIPAA Authorizations not collected at the time of consent for 5 subjects. Study involves endoscopies and treatment of Barrett's Esophagus (BE)subjects with Protein Pump Inhibitors.	Remedial Actions: Investigator informed not to use collected data without IRB permission and HIPAA Authorizations; personnel educated on the need of HIPAA Authorization as part of consent process; PI to request subjects sign HIPAA. CASE CLOSED
206	06	Durham	H	07/02/2012	RCO consent audit of a prospective nursing quality improvement study in insulin administration found that consent for one subject was obtained by a non-VA research staff member employed by the academic affiliate.	Remedial Actions: Reconsent of subject; Protocol amendment to change reconsent process; education of study staff. CASE CLOSED
207	16	Jackson	A	07/02/2012	RCO protocol audit found lapse in IACUC approval status in rats.	Remedial Actions: Halt all research activities on this study. CASE CLOSED.
208	01	VA Boston Healthcare System	S	07/02/2012	RCO audit found lapses in SRS annual review and approvals.	Remedial Actions: SRS review of incident; SRS Review and approval of projects using the last approval date as the date setting the one year renewal. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
209	11	Ann Arbor HCS	H	07/05/2012	RCO ICD Audit of a web-based support study for chemotherapy caregivers found that 19/30 subjects were consented with expired ICDs.	Remedial Actions: education to PI and staff on appropriate research study document management; no requirement to re-consent subjects because study now limited to data analysis and the expired ICD contained identical info as the current ICD. Remedial actions complete. CASE CLOSED.
210	16	Central Arkansas VHS	H	07/05/2012	RCO audit of a chronic kidney disease lab analysis study found the R&DC incorrectly determined to not involve human subjects. Jointly appointed VAMC/affiliate employees held the key linked to identifiers related to coded blood and tissue specimens.	Remedial actions: The facility IRB now determines whether an activity is human subjects research; RCO is doing a look-back audit of all pre-Nov. 2011 non-HSR determinations; IRB suspended study pending PI submission of application for IRB review. CASE CLOSED.
211	20	VA Puget Sound HCS	H	07/05/2012	RCO Audit of a Parkinson's disease study found documentation deficiencies with 335/335 medical records, 15 LAR-related deficiencies, and 7 occurrences of outdated ICDs used.	Remedial Actions: Staff retraining; collection of required documentation; and a consenting process and consenting tool/checklist developed for future use. CASE CLOSED.
212	12 NE	Hines	H	07/09/2012	RCO interim consent audit found 1 missing HIPAA Authorization out of 91 audited on a diabetes follow-up study.	Remedial Actions: PI will obtain HIPAA Authorization. CASE CLOSED
213	18	New Mexico VA HCS	H	07/09/2012	RCO audit found that 36 subjects in a sleep apnea study signed HIPAA authorization forms that did not contain all required elements.	Required Actions: Obtain compliant HIPAA authorization. CASE CLOSED.
214	03	Bronx	H	07/11/2012	RCO audit found five subjects were consented on IRB approved ICDs prior to the effective date. Study is a systolic blood pressure intervention trial funded by NIH.	Remedial Actions: Non-compliance reported to CIRB; PI and staff trained on proper consent procedures and research oversight; PI to reconsent subjects; RCO to follow consent of next five subjects; training to be provided to research staff coordinating CIRB studies. CASE CLOSED
215	11	Indianapolis	H	07/11/2012	RCO Audit of biomarker colorectal cancer study, sponsored by the VA, found that LARs for two subjects signed the incorrect ICD and HIPAA. The subjects were sedated at time but subsequently signed ICD and HIPAA upon regaining consciousness.	Remedial Actions: Research team will not use samples or access subject info/data until the subject provides consent; Submit amendment to remove LAR signature line from ICD; no enrolled subjects with cognitive impairment; RCO perform for-cause audit of specimens/ICDs for discrepancies. CASE CLOSED.
216	03	VA New York Harbor HCS	H	07/12/2012	RCO audit found in a colonic inflammation study that PI enrolled subjects using amended ICD documents (HIPAA and ICD as standalone documents), but failed to obtain HIPAA authorization.	Remedial Actions: Staff education; other actions pending.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
217	03	VA New York Harbor HCS	H	07/12/2012	RCO audit found one subject had signed wrong version of consent on a pilot study using telephone intervention to enhance adherence and improve quality of life in congestive heart failure patients.	Remedial Actions: Staff education; other actions pending.
218	03	VA New York Harbor HCS	H	07/12/2012	RCO audit of a study addressing major quality issues in heart failure care found 29 subjects had signed a VA ICD which did not have the IRB approval stamp.	Remedial Actions: Staff Education; other actions pending.
219	03	VA New York Harbor HCS	H	07/12/2012	RCO audit of a study using eye movement tracking as marker of neurologic integrity in neurologically impaired patients found ICDs without dated HIPAA signature, patient signatures, dated signature of person obtaining consents, and ICDS without improper documentation of informed consent by proxy	Remedial Actions: NSOC report generated; Research Coordinator educated; IRB determined PI cannot use data obtained using unapproved method and IRB representative must be present during surrogate consent process for the next 5 subjects consented.
220	08	Miami	H	07/13/2012	RCO audit found a prospective health literacy survey study with eleven documents missing either subject or person obtaining consent dates.	Remedial actions: Training with the research team. In addition, a simulation of the informed consent process revealed a lack in consent form documentation. This alerted the IRB and R&DC to create a workshop for obtaining and documenting informed consent for all research personnel. CASE CLOSED.
221	03	VA New York Harbor HCS	H	07/16/2012	RCO Audit of a retrospective analysis of cardiac imaging studies found documentation missing in meeting minutes to support IRB and RDC approvals.	Remedial Actions: Staff education; other actions pending.
222	15	VA Kansas City Medical Center	H	07/18/2012	RCO Audit found unauthorized study staff conducting informed consent process and three subjects who did not sign HIPAA waivers for this blood pressure drug trial.	Remedial Actions: Education for PI and research staff. CASE CLOSED.
223	07	Birmingham	H	07/19/2012	RCO Audit of a polyp resection study found that the ICD used to consent all 44 enrolled subjects did not contain the IRB approval stamp.	Remedial Actions: Enrollment stopped by Acting IRB Chair until FCR. CASE CLOSED.
224	15	VA Kansas City Medical Center	H	07/19/2012	ICD audit in Phase III kidney study, sponsored by Reata Company, found that two subjects were consented by someone not authorized to obtain consent. One of these subjects was subsequently enrolled and provided study drug.	Remedial Actions: The enrolled subject was reconsented by someone authorized to obtain consent; the individual who originally provided consent was added to the study so they can now provide consent. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
225	16	Houston	H	07/20/2012	RCO audit of MRSA Bundle Evaluation Chart Review Study found a resident on study team had not completed required training.	Remedial actions: IRB reminded PI of their responsibilities to ensure that all members of the study staff/ team members complete the required training modules before research protocols are initiated and that all training certificates or records are maintained in the research file. CASE CLOSED.
226	16	Houston	H	07/20/2012	RCO audit of a wound dressing randomized clinical trial found the PI enrolled 2 participants using an unapproved ICD, HIPAA authorizations were not obtained from the first 10 participants, and one study team member had not completed VA required training before engaging in VA research	Remedial Actions: Research team is asking participants to sign HIPAA forms and the IRB-approved ICD, where applicable; PI educate study staff; reconsent subjects at next visit. CASE CLOSED
227	16	Houston	I	07/20/2012	RCO Audit found that 35 signed ICDs could not be located and are believed to have been inadvertently shredded during an office move. The ICDs were scanned into each subject's CPRS record. None of scanned copies contained full or partial SSN.	Remedial Actions: 31 of 35 copies of the combined ICF were located in CPRS; IRB required a note in 4 remaining subjects' CPRS chart to document the ICF process, loss of the ICFs, and that this loss has been reported to the IRB; NSOC determined subject notification not required. CASE CLOSED
228	01	VA Boston Healthcare System	H	07/20/2012	RCO Audit of pre-operative patient education study indicated ICD irregularities. Signed, stamped version of ICD was not used and signatures were not correctly dated.	Remedial Actions: Staff education, mock informed consent training provided, plan for ensuring proper consent process submitted.
229	07	Atlanta	H	07/23/2012	RCO Audit of neurorehabilitation for traumatic brain injury study found unapproved study staff obtaining informed consent; subjects signing expired ICFs/HIPAAs; multiple ICF/HIPAAs same subject; untimely CPRS research note entries(total five subjects).	Remedial Actions: Study closed; PI training; data not used. CASE CLOSED
230	21	San Francisco VAMC	H	07/23/2012	RCO audit found that 12 subjects were enrolled into a cognitive assessment/decline study using an ICD that was not current	Remedial Actions: Re-consenting is required to correct ICD and HIPAA deficiencies. CASE CLOSED.
231	21	San Francisco VAMC	H	07/23/2012	RCO audit found that an unauthorized individual obtained consent and HIPAA authorization and a second individual did not sign a HIPAA form in an Alzheimer's progression study that involves an experimental imaging agent and genetic testing	Remedial Actions: Refresher education with no further action required. CASE CLOSED
232	21	VA Palo Alto HCS	H	07/23/2012	RCO audit found 1 participant in an advanced melanoma randomized drug therapy study did not sign the HIPAA authorization.	Remedial Actions: IRB determined serious noncompliance occurred and data could be used; PI and staff received additional training. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
233	22	VA San Diego HS	H	07/23/2012	RCO Audit found 1 instance of failure to provide documentation of Consent and HIPAA authorization in a blood pressure intervention study.	Remedial Actions: Refresher education and correction of deficiencies required (no data use without valid ICD and HIPAA); PO and R&DC concur. CASE CLOSED.
234	22	VA San Diego HS	H	07/23/2012	RCO audit found enrollment notes had not been entered into CPRS for 12 of the 42 subjects who had been enrolled during the previous nine months in a study of cariorenal biomarkers.	Remedial Actions: Refresher training for staff; double-checking the documentation by lead coordinator. CASE CLOSED
235	22	VA San Diego HS	H	07/23/2012	RCO audit found HIPAA authorizations were missing for 2 subjects in a study of altering pain experience and 9 subjects signed several weeks after enrollment. It was subsequently determined that the authorizations had been obtained but inadvertently destroyed.	Remedial Actions: Refresher training; obtain HIPAA authorizations for all 11 subjects; no use of data without first obtaining a valid HIPAA authorization. CASE CLOSED
236	22	VA San Diego HS	H	07/23/2012	RCO audit found the Person Obtaining Consent had not completed required training and did not have approved Scope of Practice that included approval for obtaining Consent in a study of isolating blood cells for in vitro research.	Remedial Actions: Refresher training; correction of deficiencies; no data use without valid ICD and HIPAA; CASE CLOSED
237	16	Houston	H	07/27/2012	RCO audit of decision-making mechanisms in cocaine users found 100% failure to use IRB-approved VA standalone HIPAA authorization and multiple uses of outdated ICD in consenting participants.	Remedial Actions: PI to reconsent subjects on stamped ICD; re-combine the separated HIPAA and ICD into one document. CASE CLOSED.
238	11	Indianapolis	H	07/27/2012	RCO audit found twenty-one subjects on this Employment in Veterans with Mental Illness study signed an ICD that did not have the IRB stamp present.	Remedial Actions: Education for PI and research staff. CASE CLOSED.
239	08	VA Caribbean HCS	H	07/27/2012	RCO audit found apparent continuing noncompliance regarding documentation of dates in informed consent documents (n=13) and HIPAA Authorizations concerning a study of pharmacogenetic-driven warfarin dosing.	Remedial Actions: The IRB requested the PI to retrain all research staff with the help of the RCO and a follow-up audit by the RCO. The PI submitted all 64 signed ICDs and HIPAA Authorizations to the R&D administrative office for scanning, as requested by the IRB. CASE CLOSED.
240	04	VA Pittsburgh HCS	H	07/27/2012	RCO regulatory audit identified that research procedure (provider survey) was conducted on 8 physicians without informed consent (ICD) or without a waiver of ICD. Study focused on determining impact of a Plain Language Prostrate Cancer Decision Aid on subject's decision making experience.	Remedial Actions: PI will not use the survey data at this time; data stored securely; specific education of PIs and IRB members on provider participation in research.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
241	22	VA San Diego HS	H	07/27/2012	RCO audit of a TBI related headache study found progress notes were missing or did not comply with VHA policy. The number of subjects was not provided.	Remedial Actions: PI refresher education regarding electronic progress notes; PI will ensure completion of all research enrollment progress notes in a timely manner. CASE CLOSED.
242	01	Manchester	H	07/30/2012	RCO audit found missing HIPAA authorization for 10 of 12 subjects enrolled in a human protocol for evaluating traumatic brain injury.	Remedial Actions: The PI contacted enrolled subjects to request HIPAA authorizations, staff received remedial training and HIPAA authorizations were added to the project checklist. CASE CLOSED.
243	01	Manchester	H	07/30/2012	RCO audit found missing HIPAA authorization for four subjects enrolled in a human protocol treating mild traumatic brain injury.	Remedial Actions: The PI sought and received HIPAA authorizations from all enrolled subjects, staff received remedial training and HIPAA authorizations were added to the project checklist. CASE CLOSED.
244	01	Manchester	H	07/30/2012	RCO audit found that an unapproved ICF was used to enroll 6 of 6 subjects and that HIPAA authorizations for all 6 subjects were missing in a human protocol using Ganaxolone to treat PTSD.	Remedial Actions: The PI contacted enrolled subjects to request HIPAA authorizations, staff received remedial training and HIPAA authorizations were added to the project checklist. CASE CLOSED.
245	05	VA Maryland HCS	A	08/01/2012	RCO audit found initiation of research prior to R&DC approval; lapses in SRS and IACUC continuing reviews and lack of training documentation for co-PI.	Remedial Actions: IACUC, SRS and R&DC review of noncompliance; submission of training documentation for co-PI. CASE CLOSED.
246	03	VA New York Harbor HCS	H	08/01/2012	RCO ICD Audit of a diabetic skin flora study found missing HIPAA Authorizations and no CPRS documentation of study participation for 73 subjects.	Remedial Actions: Staff education; other actions pending.
247	03	VA New York Harbor HCS	H	08/01/2012	RCO ICD Audit of hypertension study discovered 3 (out of 144) missing HIPAA Authorizations.	Remedial Actions: Staff education; other actions pending.
248	03	VA New York Harbor HCS	H	08/01/2012	RCO ICD Audit of variations in the use of CPRS-enabled exam room computers found that 12 non-patient participants had missing HIPAA Authorizations.	Remedial Actions: Staff education provided; other actions pending.
249	04	Philadelphia	H	08/02/2012	RCO audit discovered lack of SRS review/approval prior to IRB/R&DC approval of Randomized, Double-blind, Placebo controlled Study to Assess the Efficacy/Safety of Add On Epanova to Stain Therapy in Subjects w/ Hyper-triglyceridema/High Risk for CVD re: blood draws. Ten subjects.	Remedial Actions: SRS review and approval; assessment for any systemic issues. CASE CLOSED
250	01	VA Boston Healthcare System	S	08/02/2012	RCO audit found lapses in SRS continuing review for three IACUC protocols (species not specified).	Remedial Actions: SRS review; protocol expiration dates reported on committee action form sent directly to PI; SRS Program Coordinator sending reminders to PIs. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
251	07	Atlanta	H	08/08/2012	RCO ICD Audit of study on patients and providers perceptions of communicating adverse event (VA funded) found that a study staff member obtaining consent did not have a VA Scope of Practice or VA CITI GCP training or research credentialing (six subjects).	Remedial Actions: Review of systemic issues involved; study PI and team member training; study closed. CASE CLOSED
252	01	VA Boston Healthcare System	H	08/10/2012	RCO Audit of study of Medication Reconciliation found missing consent documents, procedures being conducted that are not described in the protocol and lack of participant consent for audio recording.	Remedial Actions: Study suspended pending follow up audit by RCO; Staff education; re-consent participants.
253	08	Tampa	H	08/13/2012	RCO audit found PI failed to obtain waivers of informed consent and HIPAA for screening/recruiting purposes in a geriatric protocol regarding wheelchair positioning.	Remedial Actions: Training was provided to the PI by the RCO. An amendment was submitted to the IRB for an ICD waiver for screening purposes and a report was sent to OHRP. CASE CLOSED.
254	22	VA Long Beach HS	H	08/13/2012	RCO audit found missing CPRS notes for 120 human subjects enrolled in a 1-day radial artery access with ultrasound study.	Remedial Actions: CPRS notes entered for all new subjects; new issues identified by ORO review of IRB minutes; further information requested to permit resolution. CASE CLOSED.
255	09	VA Tennessee Valley HCS	H	08/15/2012	RCO Triennial audit found missing scopes of practice for two staff of this closed diabetes retrospective, descriptive analysis of diabetic patients study. RCO failure to report issue to ORO in a timely manner.	Remedial Actions: Educate PI on requirement for scopes of practice. Review of ORO reporting criteria for RCO. CASE CLOSED.
256	09	VA Tennessee Valley HCS	H	08/15/2012	RCO Triennial audit found missing scopes of practice for two staff on this closed, diabetes retrospective case-controlled observational analysis study. In addition, RCO failed to report issue to ORO in a timely manner.	Remedial Actions: Education for PI to requirement for scopes of practice. RCO review of ORO reporting requirements. CASE CLOSED.
257	09	VA Tennessee Valley HCS	H	08/16/2012	RCO Triennial Audit found one missing scope of practice on this retrospective chart review of all operative cases.	Remedial Actions: Education of PI on scope of practice requirements; RCO review of VHA Handbook requirements for reporting to ORO. CASE CLOSED.
258	16	Gulf Coast HCS	H	08/17/2012	RCO audit found that the co-PI consented a subject without obtaining HIPAA authorization in a Telemental Health Chronic Pain Group study. There are no external sponsors or funding sources.	Remedial Actions: Reconsent subject and obtain authorization; AO/R provide training to key personnel on proper consenting procedures. CASE CLOSED.
259	09	Louisville	A	08/17/2012	RCO audit found 18 month lapse in protocol review (species not specified)	Remedial Actions: Research Animal Safety Subcommittee review; Full-time research coordinator to track renewals; monitoring of renewal dates by Research and Development Office tracking system. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
260	07	Tuscaloosa	H	08/21/2012	RCO ICD audit of a closed study found 1 subject in an Insomnia in Combat Veterans with PTSD study signed defective document.	Remedial Actions: IRB prohibited use of subject's data. CASE CLOSED
261	08	Tampa	S	08/30/2012	RCO audit found a protocol with unauthorized personnel.	Remedial Actions: SRS investigating issue and determining remedial actions; a new electronic tracking system implemented for tracking key personnel. CASE CLOSED.
262	04	VA Pittsburgh HCS	H	09/06/2012	RCO audit found 4 subjects were consented on an outdated version of informed consent document in a smoking cessation study of low income Veterans.	Remedial Actions: Study staff education; written plan to ensure compliance with requirements that enrolled subjects' records are flagged; study team to run weekly queries to ensure all alerts are entered; consent forms to be double checked using internal tracking database for completion. CASE CLOSED
263	18	Southern Arizona VA HCS	H	09/11/2012	RCO audit found missing scopes of practice for two research assistants during triennial audit of a closed industry sponsored investigational drug study related to gastroesophageal reflux disease.	Remedial Actions: Research Administration must ensure scopes of practice are approved for all researchers prior to study approval; policies will be modified to reflect this requirement. CASE CLOSED.
264	21	VA Palo Alto HCS	H	09/11/2012	RCO audit found missing HIPAA authorization for 18 subjects enrolled in a human diabetic protocol.	Remedial Actions: Seek HIPAA authorization from subjects; Disallow use of prior data collected without authorization. CASE CLOSED.
265	11	Indianapolis	H	09/12/2012	RCO audit of this study reviewing personal narratives of Veteran's with mental illness found two subjects were consented by a research staff member that did not have their Scope of Practice (SOP) and VA Training on file with the Research Service.	Remedial Actions: Scopes of Practice were completed and sent to the ACOS/R for signature. Training completed through VA Training system (TMS). All Scopes and required training documents placed in the Regulatory Binder. CASE CLOSED
266	02	Syracuse	H	09/12/2012	RCO audit found two subjects were enrolled in a study using outdated IRB-approved ICDs and five subjects endorsed but failed to initial an outdated version of the HIPAA authorization. The study is a Pilot Test of a Primary Care-Friendly Intervention for Insomnia and Nightmares in OEF/OIF Veterans.	Remedial Actions: Study staff education; PI to reconsent subjects; HIPAA authorizations to be obtained on revised document; information collected cannot be used until consent and HIPAA documents are re-signed. CASE CLOSED
267	02	Canandaigua	H	09/13/2012	RCO audit found PI amended IRB approved procedure (assignment of trainers to either immediate or delayed training condition) without submitting amendment to IRB for approval. Study is an evaluation of training video addressing suicidal thoughts and behavior in substance abuse treatment.	Remedial Actions: Assurance PI will make compliance with all IRB approved protocols a goal of his annual performance review; conduct monthly review of protocols with study coordinator to ensure compliance and make review available to the IRB. RCO conduct audits of all PI protocols for compliance.

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268	02	Canandaigua	H	09/13/2012	RCO audit found that an eligibility criterion for retrospective chart review study required AUDIT-C scores, but scores for 467 subject records reviewed could not be verified. The study is to evaluate Service Utilization and Suicide in Veterans treated for alcohol abuse.	Remedial Actions: Principal investigator education on records retention. CASE CLOSED
269	04	Philadelphia	H	09/17/2012	RCO Audit of scanned research documents for VA CIRB study "Measuring Cross Cultural Competence in VA Primary Care" found that an informed consent document did not have a signature for a person obtaining consent.	Remedial Actions; Signed ICD re-scanned in medical record; noncompliance reported to VA CIRB.CASE CLOSED
270	08	Tampa	S	09/17/2012	Facility self-reported initiation of a study prior to written approval from ACOS/R	Remedial Actions: None, study was closed at the time the non-compliance was discovered. CASE CLOSED.
271	16	Central Arkansas VHS	H	09/18/2012	RCO regulatory audit conducted noted no documentation in Research Administration or investigator records of SRS approval for a study of subjects with Critical Limb Ischemia and no Options for Revascularization.	Remedial Actions: Pending
272	20	VA Puget Sound HCS	H	09/24/2012	RCO consent audit found one subject signed an incorrect HIPAA form in a human protocol on alcohol dependence.	Remedial Actions: PI retrained staff to ensure use of correct HIPAA and ICDs; data from subject will not be used. CASE CLOSED.
273	21	VA Sierra Nevada HCS	H	09/24/2012	RCO audit found multiple instances of informed consent noncompliance involving all 13 ICDs within 1 human protocol on smoking cessation.	Remedial Actions: Pending.
274	05	VA Maryland HCS	H	09/26/2012	RCO regulatory audit of a Ribavirin Pharmacokinetics study of Hepatitis C Virus revealed 9 findings. Expired IRB approval; research initiated before R&DC approval; Fellow not credentialed; subject file lost & training not complete. RCO unable to review subject records due to PI delays.	Remedial Actions: Audit findings sent to IRB and R&DC; determinations and actions are pending.
275	08	Tampa	H	09/27/2012	RCO found in a study of Heart Failure Outcomes failure to obtain and document a waiver for informed consent and HIPAA Authorization for screening purposes and failure to report one serious adverse event (SAE) as required.	Remedial Actions: The PI was educated regarding the requirements for approval of waiver of ICD for screening and recruiting purposes, and the SAE reporting requirements. PI submitted the waiver to the IRB. The IRB determined the SAE to be serious, unanticipated, not related. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
276	04	VA Pittsburgh HCS	H	09/27/2012	RCO audit found PII of 117 research subjects (diabetes in Veterans with serious mental illness study) given to and stored at the Coordinating Center without proper subject consent. Study staff failed to adequately report an incident as a medical emergency.	Remedial Actions: Research Staff education by the investigator and RCO; thorough review of procedures for multisite studies by the IRB Chairs and office research staff to assure protocol and consent form adequately describe data sharing. CASE CLOSED
277	17	VA North Texas HCS	H	09/28/2012	RCO audit found a study monitor's report that noted one subject met exclusion criteria and was enrolled in a cardiology study in error.	Remedial Actions: The PI was asked to provide the RCO with copies of source documents with highlighted information on inclusion/exclusion criteria for patients considered for enrollment in high-risk studies and to submit all monitor reports to the RCO/IRB within 10 days of receipt. CASE CLOSED.
278	17	VA North Texas HCS	H	09/28/2012	RCO audit found ICD and HIPAA Authorization form for one subject in a gastrointestinal tract study had not been scanned into CPRS; in addition, HIPPA Authorization had not been signed when the subject was consented.	Remedial Actions: PI requested to develop RAP; provide plan to meet accrual goals. CASE CLOSED.
279	17	VA North Texas HCS	H	09/28/2012	RCO audit found three subjects met exclusion criteria and were enrolled in a cardiology study in error.	Remedial Actions: Study staff must re-review inclusion/exclusion criteria; PI asked to provide copies of source documents for future enrollees highlighting that inclusion criteria have been met and exclusion criteria have not been met; research program must report noncompliance to ORO. CASE CLOSED
280	04	Philadelphia	H	09/30/2012	RCO Audit at the study facility found the VAMC Coordinating Center did not request/issue Waiver of IC in a study of Diabetes Mellitus (DM) Control and Medication Adherence in Veterans with Severe Mental Illness (SMI). Linked to 0108-646-H	Remedial Actions: The Coordinating Center IRB generated a waiver of documentation of informed consent for this study via expedited process. CASE CLOSED.
281	08	Tampa	S	10/02/2012	RCO audit found a protocol with procedures which had not been approved by SRS.	Remedial Actions: Review of the SRS approval process. CASE CLOSED
282	15	Columbia	A	10/05/2012	RCO audit found a lapsed IACUC annual review for a protocol involving mice.	Remedial Actions: IACUC investigation. CASE CLOSED.
283	04	VA Pittsburgh HCS	A	10/05/2012	RCO audit found inappropriate post-operative analgesia in mice.	Remedial Actions: IACUC review; research investigator and support staff training on use of analgesics, approved procedures, post-approval compliance and documentation of post-procedure care. CASE CLOSED.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
284	23	Minneapolis	H	10/15/2012	RCO audit found 11 subjects were enrolled into a PTSD study using expired ICDS and consent for picture/voice documents; copies of these documents missing in CPRS; and no enrollment notes entered into CPRS.	Remedial Actions: IRB-approved plan to ensure use of current/approved forms; consent forms provided by PI for scanning into CPRS; enrollment notes not required as participation completed. Case closed.
285	04	Philadelphia	H	10/16/2012	RCO Regulatory Audit of dietary practices with behavioral health subjects study found IRB did not generate a Waiver of Documentation of IC for screening subjects prior to signing an informed consent (30 enrolled). Closed to enrollment, 1 active subject.	Remedial Actions: IRB granted waiver of documentation of IC. Case Closed
286	06	Salem	H	10/16/2012	RCO regulatory audit of an unfunded behavioral study looking at mood disorders associated with treatment resistant hypertension found that signed HIPAA authorization forms for two subjects were not able to be located in the subject's records.	Remedial actions: PI's provided education to the IRB requirement to obtain HIPAA authorization from study participants; Investigators counseled on good documentation practices; GCP reviewed by all staff; 3 consent procedures to be monitored; HIPAA obtained on the missing 2. CASE CLOSED
287	08	Tampa	H	10/17/2012	RCO Audit found a programmatic noncompliance regarding lack of injury language and space for sponsor with the approved Informed Consent Template.	Remedial Actions: Research Administration notified all investigators of deficiency. Research Compliance reviewed the active studies and identified 17 studies that required a change in ICD. CASE CLOSED.
288	09	Louisville	H	10/18/2012	RCO ICD audit found the study team was issued the wrong version of the ICD by the IRB office. The VA Merit project involved blood draws to study neutrophil activation. Only 1 subject signed the incorrect ICD while 38 subsequent subjects signed the correct version.	Remedial Actions: RCO reviewed the current administrative process with the RDC staff to ensure only approved ICDs are furnished to the research teams. Remedial action complete, CASE CLOSED.
289	11	Detroit	H	10/23/2012	RCO audit of 24 consents found 7 participants signed expired ICFs; 5 participants did not sign a HIPAA authorization form for this Genomic blood collection study	Remedial Actions: PI required to halt study recruitment; RCO provided education to study team; IRB requiring a remedial action plan be submitted by PI; Study amendment submitted to update ICD.
290	16	Central Arkansas VHS	H	10/23/2012	RCO ICD audit of this randomized double-blind study comparing combinations of lisinopril or placebo & losartan in subjects with diabetic nephropathy revealed that: 14 subjects were not consented during their next visit, 1 subject did not sign a HIPAA and 1 subject did not sign correct sub-study ICD	Remedial Actions: Obtain HIPAA authorization; report missed appointments & visits; correct & update CPRS; obtain consent for passive f/u subjects; obtain consent for the DNA sub-study; provide justification for the inclusion of research data collected from subjects during lapse; etc.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
291	17	VA North Texas HCS	H	10/25/2012	RCO audit found a letter of notification from the Sponsor terminating protocol at this site due to ongoing concerns of PI oversight.	Remedial Actions: PI transitioned 1 subject to commercially available medication, and implemented inclusion/exclusion verification processes for future subject enrollments; the IRB will revise its SOP for reporting of sponsor suspensions and terminations.
292	04	VA Pittsburgh HCS	H	10/25/2012	RCO regulatory audit of head, neck and lung cancers study identified that PI failed to report SAE within 5 business days of becoming aware of the SAE.	Remedial Actions: PI education on noncompliance reporting; research service to maintain separate electronic file that allows tracking of when submissions of reportable events occur and when they must be reviewed until study can reliably track and report these issues.
293	08	Tampa	H	10/26/2012	RCO Audit of a retrospective chart review study on moderate to severe TBI at a VA polytrauma rehab center collected data on a minor without a CRADO waiver.	Remedial Actions: The IRB approved an amendment to modify the inclusion age to be 18 to 85 on October 30, 2012. The data collected from the 17 year old subject will be excluded. External reports and training to the PI were completed. CASE CLOSED.
294	10	Cleveland	H	10/30/2012	RCO regulatory audit of a pharmaceutical-sponsored protocol for prevention of clostridium Difficile Infection (CDI) discovered 2/2 subjects enrolled did not have their medical records flagged in CPRS.	Remedial Actions: PI to receive training in regard to VHA Policy and local VA policy for flagging subjects; PI to receive a study Initiation Visit from the RCO. CASE CLOSED.
295	05	DC VAMC	H	10/30/2012	RCO audit found 3 subjects in a War Related Illness and Injury Study Center (WRIISC) data repository study were consented without obtaining HIPAA authorization. PI self-reported failing to obtain HIPAA authorizations from 30 participants.	Remedial Actions: Pending.
296	05	DC VAMC	H	10/30/2012	RCO audit of myeloma family study found 7 subjects were consented without obtaining HIPAA authorization.	Remedial Actions: None. NERO is following up re: PHI collected without HIPAA authorization.
297	08	Miami	H	10/30/2012	RCO Audit found a report of noncompliance regarding lack of a scope of practice in a spinal cord injury study and body mass index, that was not reviewed by the IRB.	Remedial Actions: Implement SharePoint system for credentialing portion of (e)submissions to IRB. System also includes tracking of training, education, CVs, and Scope of Practice forms. Plan for missing IRB review to consist of both emailing and hand-delivering RCO reports to IRB. CASE CLOSED
298	22	VA Long Beach HS	H	10/30/2012	RCO audit found use of unstamped ICDs with 7 of 16 subjects in a treatment study for acute or chronic blepharitis.	Remedial Actions: Data from subjects without proper consent may not be used; new PIs to be paired with senior mentor to ensure proper training. CASE CLOSED

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
299	23	Minneapolis	H	11/07/2012	RCO audit found missing ICD and HIPPA authorization for one subject enrolled in a human protocol on charting methods for depression.	Remedial Actions: noncompliance not serious or continuing; all remedial actions completed (sequestration of data collected without HIPAA authorization); case closed.
300	01	VA Connecticut HCS	H	11/07/2012	RCO Audit of a psychiatric disorder genetic study found that one subject's signed consent and HIPAA Authorization documents were missing.	Remedial Actions: Subject to re-sign documents; information pending whether IRB will allow use of data obtained without proper authorizations. CASE CLOSED
301	16	Central Arkansas VHS	H	11/09/2012	RCO audit revealed inadequate and/or missing documentation of informed consent in CPRS. Study purpose is to create registry and repository of DNA and serum to determine whether certain clinical measures can predict outcomes in Veterans with Rheumatoid Arthritis.	Remedial Actions: Scan all missing documents noted into CPRS; re-enter all informed consent process notes into CPRS as research notes; PI meet with ACOS/R every 2 weeks for progress update; RCO will audit enrollment logs
302	16	Central Arkansas VHS	H	11/09/2012	RCO audit revealed that a subject did not sign the separated HIPAA, as required by the IRB. Study is a randomized phase III trial comparing the outcomes of patients with stage III colon cancer treated with or without chemotherapy.	Remedial Actions: Subject completed HIPAA authorization and CPRS note was entered. CASE CLOSED.
303	09	VA Tennessee Valley HCS	H	11/12/2012	RCO Regulatory Audit found apparent non-compliance for this anesthesia risk quality improvement project as the IRB approved this study as expedited without waivers of informed consent or HIPAA authorization, inappropriate RDC approval, and failure of the PI to submit continuing approval forms.	Remedial Actions: IRB chairperson, IRB administrator, and RCOs to review all exempt studies to verify proper IRB determination;
304	08	Miami	H	11/13/2012	RCO audit found one research personnel participating in research without the required scope of practice in the CSP #563 trial titled: Prazosin and Combat Trauma PTSD.	Remedial Actions: The PI has completed the required local scope of practice for this individual and the form was submitted to the Research Office for review and approval.
305	16	Houston	H	11/14/2012	RCO Audit found in a non-invasive screening for high glaucoma risk male veterans study the PI exceeded the study sample size approved by the IRB by 142.	Remedial Actions: Pending.
306	20	VA Puget Sound HCS	H	11/21/2012	RCO ICD audit revealed that HIPAA authorization was not obtained for 3 out of 10 subjects who had provided samples banked in this tissue repository protocol.	IRB determinations: noncompliance not serious or continuing; corrective actions (remedial education and post-enrollment HIPAA authorizations) sufficient; case closed.
307	20	VA Puget Sound HCS	H	11/26/2012	RCO audit found 1 of 245 subjects enrolled was consented into a Parkinson's Genetic study using a draft/unapproved version of the ICD.	Required Actions: Subject was reconsented using approved ICD; procedures implemented by PI to prevent a recurrence; noncompliance neither serious or continuing; no further action required; case closed.

TABLE 7. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
308	08	Miami	S	11/30/2012	RCO audit found a lapse in Biosafety and Chemical Safety Subcommittee continuing review approvals.	Remedial Actions: Subcommittee review of all lapsed protocols; update database. CASE CLOSED.
309	11	Indianapolis	H	12/03/2012	RCO ICD audit found that 24/44 ICD signed were outdated/invalid and did not include information regarding an alcohol and drug screen on urine samples that are collected.	Remedial actions: Subjects who were consented with the invalid ICDs would have to be reconsented prior to their data being used. CASE CLOSED.
310	04	Philadelphia	H	12/05/2012	RCO ICD Audit of study on insulin therapy effects on colorectal polyps in diabetics found 3 subjects had not signed HIPAA Authorizations and research notes were not entered in CPRS.	Remedial Actions: No data use until HIPAA signatures obtained; RCO regulatory audit; other actions pending.
311	04	Philadelphia	H	12/05/2012	RCO ICD Audit of study on intimate partner violence patient needs and perspectives found unsigned HIPAA for one subject.	Remedial Actions: Obtain HIPAA signature; Submit protocol deviation to IRB; No data use until HIPAA signed.
312	21	VA Palo Alto HCS	H	12/06/2012	RCO audit of a cancer pain management study found that 1 of 3 enrolled subjects provided informed consent but did not sign a HIPAA authorization.	Remedial Actions: Subject's data withdrawn from the research study.
313	04	VA Pittsburgh HCS	H	12/06/2012	RCO regulatory audit found that PI of a Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in patients with recurrent or metastatic head and neck cancers failed to submit a report of a SAE within 3 days of becoming aware of the SAE.	Remedial Actions: PI education on timeliness of noncompliance reporting and on the newly developed electronic IRB submission database; other actions pending.
314	17	VA North Texas HCS	H	12/10/2012	RCO audit identified IND (controlled substance) storage noncompliance in a postoperative recovery study.	Remedial Actions: Pending.
315	22	VA San Diego HS	H	12/14/2012	RCO closure audit found data from 98 inpatient psychiatry subjects had been destroyed, at the instruction of the affiliate IRB, in error.	Remedial Actions: A newly formed VA IRB will accept oversight of VA studies at continuing review. CASE CLOSED.
316	09	Louisville	A	12/17/2012	RCO audit found that a study team member had a lapse in all required Collaborative Institutional Training Initiative (CITI) Training.	Remedial Actions: Reports presented at next Research Animal Studies Subcommittee (RASS) and R&DC meetings; completion of required training. CASE CLOSED.
317	01	Bedford	H	12/18/2012	RCO Audit found one HIPAA authorization form that was not signed by the subject.	Remedial Actions: Pending
318	22	VA San Diego HS	I	12/18/2012	RCO Audit of psychiatric study found that a former psychiatry resident destroyed in error 121 signed HIPAA Authorizations and 23 ICDs due to misinterpreting the affiliate IRB's instructions related to a previous noncompliance case.	Remedial Actions: The protocol is closed and the data had not been used; other actions pending.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
319	02	Canandaigua	H	12/19/2012	RCO audit identified discrepancies in the dates on "IRB Acceptance - Notification" letters signed by the IRB Chair to the study PI. Study is a survey of difficulties and treatment interests for detox patients.	Remedial Actions: Facility to contact IT to determine whether revision can be made to MIRB system to remove the automatically populated date from the signature line.
320	06	Durham	H	12/20/2012	RCO audit reported that PI of a long-term cancer observational study discovered that signatures were missing on consent forms and HIPAA.	Remedial Actions: Pending
321	16	Central Arkansas VHS	H	12/20/2012	RCO Regulatory Audit revealed apparent serious non-compliance. Subjects were not re-consented on the revised ICD, as required by the IRB. 15 subjects, who were enrolled at the time of the informed consent revision, had not been re-consented at the six month follow up visit.	Remedial Actions: Pending.
322	11	Ann Arbor HCS	H	12/21/2012	RCO Regulatory audit of this renal dietary trial found the interval between initial approval and first continuing review [420 days] violate the requirement for IRB continuing review.	Remedial Actions: Pending.
323	04	Philadelphia	H	12/21/2012	RCO ICD audit of a patient-centered intervention study (Knee Replacement)found one ICD did not have the signature of the Person Obtaining Consent and another ICD had pages 1 and 2 of the ICD missing.	Remedial Actions: Re-consent the subject missing the signature of the Person Obtaining Consent with the full version of the approved ICD; Either locate the missing pages of the ICD or re-consent the patient with the full version of the approved ICD.
324	21	VA Palo Alto HCS	H	12/21/2012	RCO audit found HIPAA authorizations were not sought from 17 subjects enrolled in blood draw study seeking biomarkers for improved diagnosis of lung nodules.	Remedial Actions: Pending.
325	04	VA Pittsburgh HCS	H	12/21/2012	RCO audit of Health Behavior Change for Hospitalized Veterans study found one subject enrolled in the study lacked the required, signed HIPAA authorization.	Remedial Actions: Pending.
326	08	Bay Pines	H	12/31/2012	RCO re-audit of a community-based housing services for homeless Veterans study found 3 ICDs not available during the first audit; 2 of these 3 subjects did not sign a HIPAA Authorization. IRB had suspended the study due to initial audit.	Remedial Actions: Study previously suspended and is now closed.
327	02	VA Western New York HCS	H	12/31/2012	RCO review of two retrospective chart reviews found that both studies initiated and completed without ISO, PO, IRB, or R&DC approvals and that the ACOS never generated the letter to initiate.	Remedial Actions: ISO and PO to review checklists for privacy and security concerns and IRB to review to make determination and decision for remedial actions

TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT

The director of each VHA research facility must lead an annual program-wide self assessment of research compliance and provide ORO with a certification of research oversight based on this self assessment in July of each year. The program requires that the facility director's certification include an action plan to remediate any deficiencies identified by the self assessment. ORO monitors implementation of these remedial actions.

Summary

- 26 = Cases Continuing from Previous Calendar Year
- 108 = New Cases in Calendar Year 2012
- 134 = Total Cases (Continuing Plus New) in Calendar Year 2012

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
1	09	Huntington	P	2010	Remedial actions: Credentialing, privileging, scope of practice; research compliance training; SOPs; MOU with affiliate for housing affiliate animals in the VA ARF. CASE CLOSED.
2	21	San Francisco VAMC	P	2010	Remedial actions: Resources and administrative support; agreements and approvals; SOPs; annual program reviews and assessments; RCO audits; PO and ISO reviews of active studies. CASE CLOSED.
3	07	Atlanta	P	2011	Remedial Actions: WOC appointments, R&DC review and evaluation of SRS, and approvals of MOU(s)and System Interconnection Agreement(s)by ISO and OI&T. Linked to 0006-508MA-P Director's Cert.2010. Linked to Case 0050-508-I. RISP to follow remaining BP Gateway item. CASE CLOSED.
4	08	Bay Pines	P	2011	Remedial Actions: Complete MOU for IBC with affiliate; R&DC to review budgetary and resource needs; conduct vulnerability assessment of research labs; review total protocols' data due to inconsistencies. CASE CLOSED.
5	04	Coatesville	P	2011	Remedial Actions: R&DC evaluation completed; training requirements completed; update MOUs and SOPs. CASE CLOSED
6	07	Columbia	P	2011	Remedial Actions: Hire IACUC Coordinator; conduct Annual Vulnerability Assessment, IACUC Annual Assessment, and SRS Annual Assessment; update SOPs; respond to query on ICD audit. CASE CLOSED.
7	16	Fayetteville	P	2011	Remedial Actions: Approve SOPs. CASE CLOSED.
8	16	Houston	P	2011	Remedial Actions: Complete scopes of practice; improve training monitoring; complete new MOU and System Interconnection Agreement; update Research Safety, Chemical Hygiene and Research Emergency Plan; inspect on-site labs, perform emergency drills; review R&DC subcommittee. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
9	11	Indianapolis	P	2011	Remedial actions: New database for credentialing, training and Scopes for WOCs; MOUs in negotiation; PI submit amendment to IRB, waiver for CRADO; updates for SOPs in process; part-time Chemical Hygiene Officer; continuing review lapse for 28 active protocols. CASE CLOSED.
10	08	Miami	A	2011	Remedial Actions: Weekly meetings between the Research Service and Engineering; repairs to the Heating Ventilation and Air Conditioning (HVAC)system.
11	16	New Orleans	P	2011	Remedial Actions: Provide summary of subcommittee evaluations and all R&DC and subcommittee minutes to MCD; revise HRPP and auditing plan SOPs. CASE CLOSED.
12	03	Northport	P	2011	Remedial Actions: Document appointment, credentialing, privileging, and scope of practice; Vetpro completion and Boarding for one animal PI. Credentialing completed. All actions completed. CASE CLOSED.
13	08	VA Caribbean HCS	P	2011	Remedial Actions: Complete training; complete scopes of practices and credentialing; update SOPs; improve continuing review monitoring; and report noncompliance items to SRO. CASE CLOSED.
14	02	Syracuse	P	2011	Remedial Actions: SOP and/or Plan for a Research Compliance Auditing Program; oversight by the facility Director of the Research Auditing Program; and all audits completion for the current reporting period. CASE CLOSED
15	08	Tampa	P	2011	Remedial Actions: Improve IRB electronic system to avoid protocol lapses; appoint a Chemical Hygiene Person; update several SOPs; add supervisor signature to scopes of practice. CASE CLOSED.
16	01	VA Boston Healthcare System	P	2011	Remedial Actions: Completion of audits required by facility's research plan. CASE CLOSED.
17	17	VA Central Texas HCS	P	2011	Remedial actions: Establish MOUs between affiliate and VA for use of the affiliate IACUC and IBC; revise Research Safety and Security Plan. CASE CLOSED.
18	01	VA Connecticut HCS	P	2011	Remedial Actions: Complete scopes of practices, mandatory training and MOU with affiliate for IBC. CASE CLOSED
19	19	VA Eastern Colorado HCS	P	2011	Remedial actions: Ensure adequate resources and administrative support; ensure sufficient VA representation on affiliate's IRBs; Ensure scopes of practice on file for 100% of research staff; Training for all staff to be completed; Update program SOPs; perform vulnerability assessment. Case closed.
20	22	VA Greater Los Angeles HS	P	2011	Remedial actions: All research personnel must have a current Scope of Practice and must complete mandatory training; required quality assurance reviews are in place and noncompliant personnel are prohibited from participation in research until the deficiency is corrected. CASE CLOSED.
21	05	VA Maryland HCS	P	2011	Remedial Actions: Complete and document training; action plan by RCO regarding auditing requirements for 2011-2012 reporting period; update scopes of practices; MOUs updated to meet VHA requirements.
22	03	VA New Jersey HCS	P	2011	Remedial Actions: Verify Facility Management Service support; complete VetPro process; FWA updated; update SOPs; CITI training completed; ISO to verify interconnections outside VA; complete semiannual chemical inventory; ISO & PO reviews at R&DC. CASE CLOSED.
23	08	VA North Florida/ South Georgia HCS	P	2011	Remedial Actions: Update and sign IBC MOU; Correct missing scopes of practice and credentialing. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
24	21	VA Northern California HCS	P	2011	Remedial Actions: Recruit permanent ACOS; perform mandatory program reviews, QA reviews; issue committee membership appointment memos; ensure scopes of practice exist for all personnel; obtain PHS and AAALAC Assurances; update all SOPs; R&DC review of budgetary and resource needs. CASE CLOSED.
25	19	VA Salt Lake City HCS	P	2011	Remedial actions: MOU for affiliate IRB services signed and effective; HRPP policies have been updated; ISO & PO reviews have now been conducted and documented for all protocols. CASE CLOSED.
26	22	VA Southern Nevada HS	P	2011	Remedial actions: AO/R, RCO position open and posted; PO/ISO do not serve on IRB/RDC; MOU for IRB in draft; SOP updates for SRS and RIPP; incomplete annual RDC review. CASE CLOSED.
27	02	Albany	H	2012	Remedial Actions: Personnel to complete refresher Human Subjects Protection and Good Clinical Practice and VA Mandatory training. CASE CLOSED
28	02	Albany	A	2012	Remedial Actions: Attending Veterinarian (AV) mentored the technician indicating that reporting any sickness or death of an animal to the AV is mandatory and directed her to the SVAMC SOP. CASE CLOSED
29	11	Ann Arbor HCS	A	2012	Remedial Actions: IACUC review; suspension of research activities; revision of policies as necessary; documentation for Scopes of Practice provided by PI. CASE CLOSED.
30	11	Ann Arbor HCS	P	2012	Remedial Actions: RDC to conduct an annual review of the IACUC and Research Safety and Security Program that contains all the required elements; Remedial actions complete, CASE CLOSED.
31	07	Atlanta	H	2012	Remedial Actions: Research Service review of systemic issues; one time process/software programming tracking failure corrected. Staff asst. retraining to track projects properly; identified protocols processed for Continuing Review.
32	07	Atlanta	A	2012	Remedial Actions: Discontinue use of animal transport courier; installation of eyewash equipment. CASE CLOSED.
33	07	Augusta	A	2012	Remedial Actions: Monitoring of HVAC in the animal facility. CASE CLOSED
34	11	Battle Creek	P	2012	Remedial Actions: The RDC should conduct an annual evaluation of the Research Safety and Security Program that includes all the requirements; Remedial actions complete, CASE CLOSED.
35	08	Bay Pines	A	2012	Remedial Actions: Maintain scopes of practice and review annually; Administrative issues related to SRS continuing review resolved; IACUC Policy Manual revised to allow chair or alternate to attend meeting with MCD; new fan installed and directional airflow problems resolved. CASE CLOSED.
36	08	Bay Pines	P	2012	Remedial Actions: Appoint new RIO; ensure Scopes of Practice for all investigators and evaluate annually; appoint new IRB member as WOC; enhance training tracking system. CASE CLOSED.
37	01	Bedford	P	2012	No Remedial Actions necessary. CASE CLOSED.
38	20	Boise VAMC	P	2012	Remedial Actions: R&DC members must complete training; conduct program reviews of RIPP; and review R&D budget. CASE CLOSED.
39	20	Boise VAMC	A	2012	Remedial Actions: Update and complete Emergency Response Plan. Complete required annual drills and vulnerability assessment. CASE CLOSED
40	07	Charleston	A	2012	Remedial Action: Facility determined none was required. ORO is requesting additional information. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
41	12	Chicago HCS	P	2012	Remedial Actions: The RDC must conduct an annual evaluation of the HRPP that includes all the VHA requirements. A summary of this report should be provided to the MCD; Remedial actions complete, CASE CLOSED.
42	10	Chillicothe	P	2012	Remedial Actions: No deficiencies identified. CASE CLOSED
43	10	Cincinnati	P	2012	Remedial Actions: RSAW to open DSS case to track SOP deficiency. CASE CLOSED
44	10	Cincinnati	A	2012	Remedial Actions: Update Animal Welfare Reporting Requirements SOP. CASE CLOSED.
45	10	Cleveland	P	2012	No remedial actions necessary. CASE CLOSED
46	04	Coatesville	P	2012	Remedial Action: Animal caretaker training. RSAW will follow. CASE CLOSED
47	04	Coatesville	A	2012	Remedial Actions: Resolve IT problems and have animal caretaker complete training. CASE CLOSED.
48	07	Columbia	A	2012	Remedial Actions: Install sensors to monitor airflow direction and pressure. CASE CLOSED.
49	07	Columbia	P	2012	Remedial Actions: Facility continues to enforce the institutional policy on training. CASE CLOSED.
50	15	Columbia	P	2012	Remedial Actions: Resources for vacant position/tracking Training and Scopes/Functional Statements; PI Handbook is being processed, waiting RDC approval; Remedial actions complete, CASE CLOSED.
51	15	Columbia	A	2012	Remedial Actions: SRS annual review process was modified; all affiliate employees (VA WOC employees) involved in VA animal research must be enrolled in the affiliate's Occupational Health and Safety Program. CASE CLOSED.
52	10	Columbus	P	2012	No remedial actions necessary. CASE CLOSED
53	10	Dayton	P	2012	No remedial actions necessary. CASE CLOSED
54	05	DC VAMC	A	2012	Remedial Actions: Scopes of practice for research personnel; ensure SRS review of protocols; hire a SRS coordinator.
55	16	Fayetteville	P	2012	Remedial Actions: Complete the MOU and update SOPs.
56	12 NE	Hines	H	2012	Remedial Actions: CRADO Waiver required for participation in a children's study.
57	16	Houston	P	2012	Remedial Actions: Follow facility's local SOP and report individuals to the R&DC and/or place their studies on an administrative hold until training completed. CASE CLOSED
58	16	Houston	A	2012	Remedial Actions: Ensure SRS approval of protocols; ensure personnel is training; complete annual reviews of IACUC protocols; ensure HVAC enhancements are completed.
59	09	Huntington	P	2012	Remedial Actions: MCD annual report summary documentation. Remedial actions complete, CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
60	11	Indianapolis	P	2012	Remedial Actions: The MWRO will follow up with facility during onsite routine review; RSAW will follow up on the IACUP items in a separate case. Remedial actions complete., CASE CLOSED.
61	11	Indianapolis	A	2012	Remedial Actions: Implement a new occupational health and safety program to encompass all personnel by fall/winter 2012. CASE CLOSED.
62	23	Iowa City	P	2012	Remedial Actions: R&DC must conduct annual reviews of research programs and associated subcommittees; summaries must be provided to the Director. CASE CLOSED.
63	16	Jackson	P	2012	Remedial Actions: Update SOPs and policies.
64	12 NE	James A. Lovell Federal Health Care Center	P	2012	No remedial actions necessary. CASE CLOSED
65	12 NE	James A. Lovell Federal Health Care Center	S	2012	Remedial Actions: SRS review to prevent lapses in continuing review.
66	09	Lexington	A	2012	Remedial Actions: SRS review; IACUC review; education and monitoring of room entry with husbandry enforcement. CASE CLOSED.
67	09	Lexington	P	2012	Remedial actions: FWA and MOU updates required; Remedial actions complete, CASE CLOSED.
68	16	Central Arkansas VHS	A	2012	Remedial Actions: Each subcommittee will appoint individuals to track training; develop new SOP to ensure timeliness of annual reviews; audit staff records to ensure correct scopes of practice are present.
69	16	Central Arkansas VHS	P	2012	Remedial Actions: Appoint all R&DC members to R&DC; ensure investigators have scopes of practice; ensure training tracking system is complete; ensure training complete.
70	12	Madison	A	2012	Remedial Actions: Training animal care staff; change of endpoint criteria; improve monitoring of diet changes and animal weights; SOP for feeding procedures updated; endpoint criteria changed. CASE CLOSED.
71	12	Madison	P	2012	Remedial Actions: Clarify "not known" response for protocols with only RDC oversight; Clarify MCD review of annual summary; animal issues followed by RSAW; Remedial actions complete, CASE CLOSED.
72	06	McGuire (Richmond)	A	2012	Remedial Actions: IACUC Review, PI and lab staff retraining; provide emergency back-up power to individually ventilated cages. CASE CLOSED.
73	09	Memphis	P	2012	Remedial actions: Requesting clarification of missing Scopes and trainings; verification of missing ORO report for Scopes. CASE CLOSED
74	09	Memphis	A	2012	Remedial Actions: Complete scopes of practice for all personnel; complete training.
75	12	Milwaukee	P	2012	Remedial Actions: The Research Safety and Animal Welfare working group will follow up on this item. Remedial actions complete, CASE CLOSED.
76	12	Milwaukee	A	2012	Remedial Actions: None required. CASE CLOSED.
77	23	Minneapolis	P	2012	Remedial Actions: Key research administration vacancies filled; SOP for reporting of serious noncompliance revised. CASE CLOSED

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
78	23	Minneapolis	S	2012	Remedial Actions: SRS to ensure initial and continuing protocols reviews are conducted at appropriate intervals; complete training requirements. CASE CLOSED.
79	18	New Mexico VA HCS	A	2012	Remedial Actions: Ensure that individuals complete all training; other actions pending.
80	16	New Orleans	P	2012	Remedial Actions: Provide MCD with copies of all R&DC and subcommittee minutes to review and sign. CASE CLOSED.
81	03	Northport	A	2012	Remedial Actions: Update Scope of Practice Documentation. CASE CLOSED.
82	16	Oklahoma City	S	2012	Remedial Actions: Police staff training; conduct multidisciplinary vulnerability assessment. CASE CLOSED.
83	08	Orlando VAMC	P	2012	Remedial Actions: On the one year anniversary of the FWA, OVAMC performed detailed evaluations of the subcommittees of the R&DC and a summary was sent to the MCD. CASE CLOSED.
84	20	Portland VAMC	P	2012	Remedial Actions: Personnel completing required training; affiliate medical school seeking AAHRPP accreditation. CASE CLOSE
85	20	Portland VAMC	A	2012	Remedial Actions: Ensure R&DC approval of all animal and/or research protocols; ensure IACUC and SRS continuing review of all protocols at appropriate intervals; document Scopes of Practice; complete training requirements. CASE CLOSED.
86	11	Saginaw	P	2012	Remedial Actions: The RDC should conduct an annual evaluation of the Research Safety and Security Program that includes all the requirements listed in VHA Handbook 1200.01; Ann Arbor RDC to review at 11/07/12 meeting; Remedial actions complete, CASE CLOSED
87	21	San Francisco VAMC	S	2012	Remedial Actions: SRS investigation; modification of procedures to minimize risks of exposure; protocol amendments; staff retraining; complete training requirements and scopes of practice; ensure provision of scientific justification where appropriate. CASE CLOSED.
88	23	Sioux Falls	P	2012	Remedial Actions: No remedial actions necessary. CASE CLOSED.
89	18	Southern Arizona VA HCS	P	2012	Remedial Actions: Drafting and approving plans, policies, SOPs; registering the IRB; and obtaining approval of the FWA amendments to organize operational IRB. CASE CLOSED.
90	18	Southern Arizona VA HCS	A	2012	Remedial Action: Facility to provide details of incident. CASE CLOSED.
91	23	St Cloud	P	2012	Remedial Actions: MOU/Affiliate IRB was revised and being reviewed for final signature. CASE CLOSED.
92	15	St Louis	S	2012	Remedial Actions: ACOS will recommend VA-salaried employees to serve on Affiliate IBC. RDC will review and nominate to the MCD. CASE CLOSED.
93	15	St Louis	P	2012	Remedial Actions: The RDC to conduct an annual evaluation of the VA CIRB and provide a summary of this to the MCD; the Research Safety and Animal Welfare (RSAW) to follow up with the salaried employee issue; Remedial Actions complete, CASE CLOSED.
94	02	Syracuse	R	2012	Remedial Actions: The R&D Service to review and verify R&DC and its subcommittee members appointment letters. CASE CLOSED

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
95	02	Syracuse	E	2012	Remedial Actions: 3 of the 5 RCEP deficient 2012 FDC audits have now been conducted; the other two are currently being audited; as of 10.31.12 all audits have been completed. CASE CLOSED
96	02	Syracuse	A	2012	Remedial Actions: None required. CASE CLOSED.
97	08	Tampa	A	2012	Remedial Actions: Develop standard operating procedures for RSSP and ACUP; complete SRS review of protocols; complete SRS annual review of protocols.
98	08	Tampa	P	2012	Remedial Actions: Revise IRB MOU; develop a system for alerting expiration of WOC appointments prior to renewal.
99	01	Togus	P	2012	Remedial Actions: R&DC must provide research oversight; must conduct reviews of programs and subcommittees (both internal and external). CASE CLOSED.
100	07	Tuscaloosa	S	2012	Remedial Actions: SRS approval of protocols; SRS continuing review. CASE CLOSED.
101	01	VA Boston Healthcare System	A	2012	Remedial Action: Ensure scopes of practices of personnel; SRS continuing review. CASE CLOSED.
102	21	VA Central California HCS	P	2012	Remedial Actions: Revise RIPP SOP; expand elements of HRPP review; conduct lab disaster drill; prepare comprehensive budget and resource report for Medical Center Director. CASE CLOSED.
103	21	VA Central California HCS	I	2012	Facility self identified non compliance with the creation of a RIPP SOP; No related policy requirement. No facility remedial action required. CASE CLOSED
104	17	VA Central Texas HCS	P	2012	Remedial Actions: Finalizing MOU; appointing VA representative to affiliate IBC; and RCO completing past due audits. CASE CLOSED.
105	17	VA Central Texas HCS	S	2012	Remedial Actions: Finalize the MOU for the IBC; appoint VA representative to IBC. CASE CLOSED.
106	01	VA Connecticut HCS	H	2012	Remedial Actions: Personnel to complete refresher Human Subjects Protection and Good Clinical Practice training
107	19	VA Eastern Colorado HCS	P	2012	Remedial Actions: Securing adequate support for R&DC Subcommittees; committee members must complete mandatory training; review of RSSP and SRS; conduct emergency response preparedness plan. CASE CLOSED.
108	19	VA Eastern Colorado HCS	S	2012	Remedial Actions: Complete review of RSSP and SRS within the next 90 days; database created to track protocol review dates and generate alerts to PI's. CASE CLOSED.
109	15	VA Eastern Kansas (Leavenworth) HCS	P	2012	Remedial Actions: None required as no deficiency identified. CASE CLOSED
110	22	VA Greater Los Angeles HS	P	2012	Remedial Actions: Complete credentialing, privileging, scope of practice requirements for personnel; PIs/staff must complete required training; obtain waiver for international research; Director must review summaries of annual R&DC review of budgetary & resource needs,& subcommittees. CASE CLOSED
111	22	VA Greater Los Angeles HS	A	2012	Remedial Actions: Ensure security upgrades to canine social housing unit are completed within specified time frame. CASE CLOSED

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
112	15	VA Kansas City Medical Center	P	2012	Remedial Actions: Request SRS and IACUC self assessment checklists and documentation used to support RDC summary presentation; Appendices 1-3, and CIRB annual review accompanied by RDC minutes supporting review and discussion of CIRB review. CASE CLOSED
113	22	VA Loma Linda HS	P	2012	Remedial Actions: The facility to provide ORO clarification for why this finding was not reported. RSAW working group may follow up with facility on IACUP deficient items. Clarification provided, deficiency did not need ORO reporting. Remedial Actions complete, CASE CLOSED.
114	05	VA Maryland HCS	A	2012	Remedial Actions: Ensure IACUC Review and approval prior to protocol initiation; SRS review; develop procedure for incorporation & review of IBC minutes. CASE CLOSED.
115	03	VA New Jersey HCS	R	2012	Remedial Actions: Verify engineering support issue, complete Scopes of Practices, credentialing and training, develop training tracking system, update CIRB MOU, update SOPs, develop ISO and PO report tracking system. CASE CLOSED
116	03	VA New Jersey HCS	A	2012	Remedial Actions: Continue monthly meeting with engineering staff, ensure scopes of practice are signed by supervising Investigators. Submit amendment request to reflect appropriate pain classification. Offer Occupational health surveillance. CASE CLOSED.
117	03	VA New York Harbor HCS	A	2012	Remedial Actions: Update on Heating, Ventilation and Air Conditioning in animal facility.
118	08	VA North Florida/ South Georgia HCS	S	2012	Remedial Actions: SRS and IACUC review with no further actions necessary. CASE CLOSED.
119	17	VA North Texas HCS	P	2012	Remedial Actions: Conduct semi-annual inventory of hazardous chemicals/agents; document inventory process; when enrolling subjects, ensure inclusion/exclusion criteria are satisfied. CASE CLOSED.
120	17	VA North Texas HCS	A	2012	Remedial Action: Ensure SRS continuing reviews are conducted at appropriate intervals. CASE CLOSED.
121	21	VA Northern California HCS	P	2012	Remedial Actions: Secure administrative services; ensure personnel have credentialing, privileging and scope of practice and training; update IRB certification and MOU with affiliate; revise R&D SOPs. CASE CLOSED.
122	21	VA Northern California HCS	S	2012	Remedial Actions: Ensure SRS initial and continuing reviews are conducted at appropriate intervals. CASE CLOSED.
123	21	VA Palo Alto HCS	P	2012	Remedial Actions: Continuing monitoring of appointments, credentialing, privileging, scope of practice, and required training; approval of MOU/System Interconnection Agreement with academic affiliate; approval of revised COI policy. CASE CLOSED.
124	21	VA Palo Alto HCS	I	2012	Remedial Actions: Revised MOU/ISA with Academic Affiliate under review with local responsible offices; then will forward MOU/SIA to the ESCCB for approval.
125	19	VA Salt Lake City HCS	P	2012	Remedial Actions: Identify research personnel to ensure training is completed; ensure all personnel have a Scope of Practice; updating FWA/VA addendum and MOU with Central IRB; establishing CRADAs for required projects; revising R&D SOPs to document recurring processes. CASE CLOSED.
126	19	VA Salt Lake City HCS	A	2012	Remedial Actions: Policy has been changed to require annual renewals for all species. CASE CLOSED.
127	21	VA Sierra Nevada HCS	P	2012	Remedial Actions: No remedial actions necessary. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 8. REMOTE REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
128	09	VA Tennessee Valley HCS	A	2012	Remedial Actions: Complete annual review of IACUC protocol; complete continuing review of SRS; ensure all training is complete.
129	09	VA Tennessee Valley HCS	P	2012	Remedial Actions: Resources (vacant positions); training updates; Facility to obtain CRADO waiver to conduct international research; Remedial Actions complete, CASE CLOSED.
130	02	VA Western New York HCS	I	2012	Remedial Actions: RIPP SOP to be updated; IRB to review and approve final version. CASE CLOSED.
131	02	VA Western New York HCS	A	2012	Remedial Actions: The Chemical Hygiene Plan, Research Security Plan, and the Research Emergency Response/Preparedness Plan were reviewed and approved; a safety drill was conducted. CASE CLOSED.
132	02	VA Western New York HCS	P	2012	Remedial Actions: Process Action Team formed to ensure appointment, credentialing and privileging for research personnel, revision of SOPs and local policies, 2011 annual reviews.
133	01	Manchester	P	2012	Remedial Actions: R&DC must provide oversight of research programs and subcommittees; conduct reviews of same; conduct reviews of budget.
134	15	Wichita	P	2012	Remedial Actions: Submit CIRB subcommittee review ; missing Appendices 1-3; communicate with KC to complete requirements. CASE CLOSED

TABLE 9. REMOTE TECHNICAL ASSISTANCE REVIEWS

ORO remote technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Remote technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Summary

- 12 = Cases Continuing from Previous Calendar Year
- 67 = New Cases – January 1 through March 31
- 30 = New Cases – April 1 through June 30
- 41 = New Cases – July 1 through September 30
- 71 = New Cases – October 1 through December 31
- 209 = New Cases in Calendar Year
- 221 = Total Cases (Continuing Plus New) in Calendar Year

Case	VISN	Facility	Focus	Date	TABLE 9. REMOTE TECHNICAL ASSISTANCE REVIEWS
1	08	VA Caribbean HCS	E	03/03/2011	ORO Remote Technical Assistant for RCEP to evaluate low volume reported on ICD audits.
2	21	San Francisco VAMC	E	04/01/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
3	01	Bedford	E	04/13/2011	ORO RCEP Remote technical assistance for new RCOs including coaching and education through first 12 months.
4	19	VA Eastern Colorado HCS	E	05/19/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
5	11	Battle Creek	E	07/05/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
6	16	Central Arkansas VHS	E	07/11/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
7	23	Sioux Falls	E	08/19/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
8	17	VA South Texas HCS	E	09/19/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
9	08	Bay Pines	E	10/20/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.

10	17	VA Central Texas HCS	E	10/24/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
11	09	Lexington	E	12/08/2011	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
12	03	VA New York Harbor HCS	E	12/19/2011	Technical assistance on accreditation status change.
13	10	Cincinnati	H	01/06/2012	Technical assistance regarding IRB determination/reporting timelines: calendar vs. business days. Response providing citation from 1058.01 re: calendar days for IRB determinations of serious or continuing noncompliance issues.
14	16	Houston	A	01/26/2012	ORO remote technical assistance for RSAW. Evaluation of Program's ability to meet the VHA requirements regarding the Heating, Ventilation and Air Conditioning (HVAC) system and corrective action plan.
15	10	Cincinnati	R	01/27/2012	Technical assistance on reporting facility noncompliance case to in ORD. VHA CO Compliance Reports ORD mailgroup provided.
16	10	Cleveland	H	01/30/2012	Technical assistance on use of one COI form and signature for two different studies. Each study should have a completed COI and signature as circumstances may vary between studies.
17	21	San Francisco VAMC	S	01/31/2012	ORO remote technical assistance for RSAW. Revision of procedures related to the acquisition, storage, use, and destruction/disposal of exempt quantities of a Select Agent.
18	20	Boise VAMC	E	02/01/2012	Technical assistance for change of RCO.
19	12	Chicago HCS	E	02/01/2012	Technical assistance for accreditation status change.
20	10	Cincinnati	E	02/01/2012	Technical assistance for FWA modification, one IRB deactivated and IRB oversight consolidated into one IRB.
21	04	Coatesville	E	02/01/2012	Technical assistance on accreditation status change.
22	10	Dayton	E	02/01/2012	Technical assistance for FWA modification.
23	11	Detroit	E	02/01/2012	Technical assistance for accreditation status change.
24	23	Iowa City	E	02/01/2012	Technical assistance for FWA modification.
25	06	Salem	E	02/01/2012	Technical assistance on accreditation status change.
26	15	St Louis	E	02/01/2012	Technical assistance for accreditation status change.
27	22	VA Southern Nevada HS	E	02/01/2012	Technical assistance for change of RCO.
28	09	VA Tennessee Valley HCS	E	02/01/2012	Technical assistance for accreditation status change.
29	04	Wilkes-Barre	E	02/01/2012	Technical assistance on accreditation status change.
30	10	Chillicothe	E	02/02/2012	Technical assistance for FWA modification, remove IRB.

31	10	Columbus	E	02/02/2012	FWA modification, IRB removed.
32	03	VA Hudson Valley HCS	E	02/02/2012	Technical assistance for FWA renewal.
33	22	VA Southern Nevada HS	E	02/03/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
34	10	Cincinnati	H	02/06/2012	Technical assistance on R&DC requirements for oversight relative to IRB review of non compliance issues. Response provided re: regulations from VHA 1058.01 and VHA 1200.01.
35	04	Coatesville	S	02/06/2012	ORO remote technical assistance for RSAW. Reviewed MOU pertaining to collection, analysis & transfer to blood samples to affiliate.
36	05	DC VAMC	E	02/06/2012	Technical assistance on accreditation status change.
37	08	Miami	E	02/06/2012	Technical assistance for FWA modification, new interim signatory.
38	23	Minneapolis	E	02/06/2012	Technical assistance for FWA modification.
39	04	Philadelphia	S	02/06/2012	ORO technical assistance for RSAW. Facility forwarded signed MOU pertaining to IACUC oversight of collaborative animal research projects.
40	08	VA Caribbean HCS	E	02/06/2012	Technical assistance for accreditation status change.
41	08	Bay Pines	S	02/07/2012	ORO remote technical assistance for RSAW. Reviewed MOU pertaining to the use of external IBC.
42	03	Northport	H	02/07/2012	Technical assistance regarding re-signing of HIPAA authorization when a newly modified ICD is issued and subjects are reconsented. need for IRB to consider whether or not modifications of ICD involve sharing of new findings/information not noted on original HIPAA.
43	23	VA Neb do not use	E	02/14/2012	Technical assistance for FWA modification.
44	12	Milwaukee	E	02/15/2012	SOP and MOU consultation and review.
45	16	Houston	E	02/22/2012	Technical assistance for FWA modification, new outpatient clinic and new acting VISN Director.
46	09	Louisville	E	02/22/2012	Technical assistance for MOU modification.
47	06	McGuire (Richmond)	E	02/22/2012	DOD Department of Navy (DON) Addendum Renewal.
48	01	Northampton	E	02/22/2012	Technical assistance on new FWA.
49	21	VA Northern California HCS	E	02/22/2012	New Department of Navy (DON) Addendum to the FWA approved.
50	04	Philadelphia	E	02/24/2012	FWA modification, new Human Protections Administrator (HPA).
51	05	DC VAMC	E	02/27/2012	ORO Remote Technical assistance for RCEP. Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office.

52	16	Jackson	E	02/28/2012	Technical assistance for FWA modification.
53	16	Central Arkansas VHS	H	02/28/2012	Referral from OIG hotline of allegation that research on weight loss and insulin action was improperly halted. Noncompliance by PI previously substantiated and remediated. No additional action required.
54	08	Tampa	E	02/28/2012	Technical assistance for FWA modification.
55	05	VA Maryland HCS	E	02/28/2012	MOU between facility and affiliate; consultation and review.
56	04	Coatesville	E	03/01/2012	Technical assistance for FWA modification, new Human Protections Administrator.
57	06	McGuire (Richmond)	E	03/01/2012	FWA renewal .
58	20	Portland VAMC	E	03/01/2012	Technical assistance for FWA modification, adding IRB of record operated by academic affiliate selected multisite research.
59	01	VA Boston Healthcare System	E	03/01/2012	Technical assistance on FWA modification, change of outpatient clinics assigned to Boston.
60	03	VA New Jersey HCS	H	03/05/2012	Technical assistance regarding consent process for usual care vs. research activities when PI and Provider are one and the same. Applicable citations from VHA 1200.05 provided on informed consent process for research related activities and usual care procedures attributable to research only.
61	04	VA Pittsburgh HCS	I	03/05/2012	Technical assistance regarding reporting requirements. A research instrument that uses a stand-alone desktop was shipped to the vendor without removing the hard drive. The desktop was used only to play sounds for hearing tests and did not record any patient data of any kind. The ISO reeducated staff that regardless of the type of instrument or computer, hard drives are not permitted to leave VA property without proper approval. The desktop did not contain PHI so ORO reporting is not required.
62	22	VA Southern Nevada HS	E	03/06/2012	Technical assistance for FWA modification to add VA Central IRB.
63	22	VA Southern Nevada HS	E	03/06/2012	MOU consultation and review.
64	18	New Mexico VA HCS	E	03/14/2012	MOU consultation and review
65	01	Northampton	P	03/14/2012	ORO Remote Techical Assistance for R&DC and HRPP. Reviewed committee formation, IRB services agreement with another VA, FWA status.
66	11	Detroit	E	03/16/2012	MOU consultation and revision
67	16	Central Arkansas VHS	E	03/16/2012	Technical assistance for FWA modification.
68	23	Minneapolis	E	03/16/2012	Technical assistance for accreditation status change.
69	16	New Orleans	E	03/16/2012	Technical assistance for accreditation status change.
70	08	Tampa	E	03/16/2012	MOU consultation and review.
71	15	VA Kansas City Medical Center	E	03/16/2012	Technical assistance for accreditation status change.

72	20	VA Puget Sound HCS	E	03/16/2012	Technical assistance for accreditation status change.
73	09	VA Tennessee Valley HCS	E	03/16/2012	DoD Addendum approved for VA/Navy collaboration
74	04	Wilkes-Barre	H	03/16/2012	ORO Remote Technical Assistance for HRPP. MOU, affiliation agreement, Data Use/Transfer Agreements, WOC appointments, Scopes of Practices, Collaborative Research Guidance, Joint Employment Agreements, use of affiliated IRBs.
75	21	San Francisco VAMC	E	03/20/2012	MOU consultation and review
76	21	VA Sierra Nevada HCS	E	03/22/2012	MOU consultation and review.
77	06	Durham	E	03/23/2012	FWA modification, new signatory official.
78	12 NE	James A. Lovell Federal Health Care Center	E	03/23/2012	Facility updated its FWA without ORO-approved addendum. Resubmit corrected FWA with VA Addendum.
79	21	San Francisco VAMC	E	03/23/2012	Technical assistance for FWA modification, addition of Clearlake VA OPC as remote site
80	06	Durham	E	04/06/2012	FWA modification, new signatory official.
81	06	Hampton	E	04/06/2012	FWA modification, change in Human Protections Administrator.
82	08	Orlando VAMC	E	04/06/2012	FWA modification to add VA Central IRB.
83	18	Phoenix VA HCS	E	04/06/2012	Technical assistance for FWA modification.
84	16	Shreveport	E	04/06/2012	FWA modification to add Community Based Outpatient Clinics
85	01	Togus	E	04/06/2012	Technical assistance on FWA modification, new signatory official.
86	01	White River Junction	E	04/06/2012	Technical assistance for FWA renewal.
87	01	White River Junction	E	04/06/2012	Technical assistance MOU consultation and review of MOU with Dartmouth.
88	23	VA Black Hills HCS	E	04/10/2012	Technical assistance for FWA renewal/
89	21	VA Central California HCS	E	04/10/2012	Technical assistance for FWA modification.
90	04	Coatesville	R	04/12/2012	Technical assistance regarding permissibility of assessing a fee to outside investigators who want data from the repository for preparation and transmission. Response provided: Guidance from 1200.05 and 1200.12, recommendation to review with CFO and General Counsel.
91	12	North Chicago-inactive	A	04/16/2012	ORO Remote Technical Assistance for RSAW. Review IACUC MOU.
92	08	VA Caribbean HCS	S	04/16/2012	ORO remote technical assistance for RSAW. Safety review of a research project conducted at an Affiliate program.

93	04	Butler	H	04/18/2012	Technical assistance concerning project initiated to be part of Annual Quality Management Assessment of patient falls. Determined to be non-research operations activity.
94	04	Coatesville	R	04/20/2012	Technical assistance on exempt research oversight by R&DC and IRB involvement in review of amendments to determine any change in exempt status. Once exempt determination made the responsibility for approval and continuing review belong to R&DC but submitted amendments can be referred to IRB to see if they change exempt status.
95	16	New Orleans	S	04/20/2012	ORO remote technical assistance for RSAW. Reviewed research protocol and supporting documents regarding categorization of recombinant deoxyribonucleic acid (rDNA).
96	08	VA Lake City	E	04/24/2012	Technical assistance for FWA modification.
97	16	Jackson	H	04/25/2012	Technical assistance presentation via video conferencing on IRB Review of Scientific Design and SAE, UPIRSO Reporting and Review. Received feedback from audience and SRO colleagues, generated lessons learned for future reference.
98	12 NE	James A. Lovell Federal Health Care Center	H	04/30/2012	Technical assistance regarding information comparative to facilities with similar size research programs related to cost analysis for maintaining their own IRB. Discussed facility cost for protected time for R&DC and IRB members; discussed costs for employing committee coordinators; provided two points of contact for facilities with similar size human research programs. case closed
99	16	Shreveport	E	05/01/2012	MOU consultation and review.
100	17	VA North Texas HCS	E	05/07/2012	Technical assistance for FWA modification.
101	07	Columbia	E	05/08/2012	ORO Remote Technical Assistance for new RCO, including coaching and educational needs assessment and resources.
102	01	Manchester	E	05/08/2012	Technical assistance on MOU for VA Manchester and academic affiliate.
103	16	Fayetteville	E	05/11/2012	Technical assistance for FWA modification.
104	16	Muskogee	E	05/11/2012	Technical assistance for FWA renewal.
105	02	Syracuse	E	05/11/2012	Technical assistance for FWA renewal.
106	04	Coatesville	H	05/17/2012	Technical assistance on OHRP reporting requirements for non compliance issues. VHA Handbook 1058.01 and OHRP reporting guidance provided.
107	15	VA Eastern Kansas HCS	E	05/22/2012	Technical assistance for FWA modification.
108	17	VA Central Texas HCS	E	05/25/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
109	02	Syracuse	H	05/30/2012	Technical assistance to ensure that the HRPP Coordinator had consulted the IRB prior to abolishing the requirement to have expiration date and IRB Chair initials on Consent Forms.
110	01	Northampton	P	06/04/2012	Technical Assistance on establishing new research program.
111	05	DC VAMC	E	06/06/2012	ORO Remote Technical assistance for RCEP. Evaluated and addressed auditing plan and progress on 2011-2012 triennial auditing requirements.

112	08	Orlando VAMC	E	06/06/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
113	16	Jackson	H	06/11/2012	AO/R and IRB requested technical presentation on expedited and exempt review procedures.
114	08	Tampa	A	06/12/2012	ORO remote technical assistance for RSAW. Review of MOU between VA and affiliate Institution pertaining to the IACUC relationship and oversight.
115	15	Wichita	E	06/14/2012	Technical assistance for FWA modification.
116	16	Fayetteville	E	06/15/2012	MOU consultation and review.
117	16	Central Arkansas VHS	H	06/15/2012	Technical assistance on effectively chairing an IRB.
118	20	Boise VAMC	E	06/20/2012	MOU consultation and review.
119	20	VA Puget Sound HCS	E	06/20/2012	Technical assistance regarding an unauthorized, non-VA institution that designated the VA Puget Sound IRB as an IRB of Record on its FWA.
120	20	Boise VAMC	E	06/22/2012	Technical assistance for FWA renewal.
121	10	Cincinnati	E	06/22/2012	Technical assistance for FWA modification.
122	17	VA Central Texas HCS	H	07/02/2012	Technical assistance regarding potential human subject research noncompliance concerning PI record retention in association with a VA NSOC report. Requested IRB to review, IRB determined that noncompliance was neither serious nor continuing.
123	04	Coatesville	H	07/11/2012	Technical assistance regarding proposed collaborative research with university regarding blood protein analysis of de-identified specimens obtained from VA subjects. Requirements of VHA Handbooks 1200.05, 1605.1 and ORD interim guidance for collaborative research reviewed with research staff.
124	04	Clarksburg	H	07/13/2012	Technical assistance regarding IRB determination of exempt vs. expedited protocols with IIHI. References from VHA 1200.05 and OHRP policy and decision charts provided.
125	02	Bath	E	07/19/2012	Technical assistance for FWA modification, new signatory official.
126	08	Miami	E	07/19/2012	Technical assistance for FWA modification, new signatory official.
127	11	Saginaw	E	07/19/2012	Technical assistance for FWA modification.
128	03	VA New Jersey HCS	E	07/19/2012	ORO Remote Technical assistance for RCEP. Discussed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office.
129	08	VA North Florida/ South Georgia HCS	E	07/19/2012	Technical assistance for FWA modification.
130	21	VA Pacific Islands HCS	E	07/20/2012	Technical assistance for FWA renewal.
131	04	Wilkes-Barre	E	07/20/2012	Technical assistance for FWA renewal.

132	20	Portland VAMC	H	07/30/2012	Technical assistance regarding NSOC report that data from one VA research subject was disclosed outside of the VA prior to obtaining HIPAA authorization. CIRB determination - noncompliance not serious or continuing; credit monitoring offered to subject; NSOC ticket closed;
133	18	Southern Arizona VA HCS	E	08/02/2012	ORO Remote Technical Assistance for RCEP. Facility starting internal IRB
134	21	VA Pacific Islands HCS	I	08/02/2012	ORO Remote Technical Assistance for RISP. Facility initiated query regarding lab error in placing PHI on specimen label instead of coded information. Subsequently determined signed HIPAA authorization was in place and incident was a protocol deviation.
135	07	Augusta	E	08/03/2012	MOU consultation and review.
136	10	Cincinnati	E	08/03/2012	Technical assistance for FWA modification.
137	01	Northampton	E	08/03/2012	Technical assistance on FWA modification with addition of VA Central IRB.
138	22	VA Greater Los Angeles HS	H	08/03/2012	Technical assistance regarding IRB review and assessment of apparent serious noncompliance identified in an NSOC report.
139	21	VA Sierra Nevada HCS	E	08/06/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
140	02	Canandaigua	H	08/10/2012	Technical assistance regarding prohibition on "recruitment only" studies in VA.
141	07	Charleston	E	08/14/2012	FWA modification, new signatory official.
142	04	Coatesville	E	08/14/2012	MOU consultation and review.
143	15	VA Eastern Kansas HCS	E	08/14/2012	MOU consultation and review.
144	18	Southern Arizona VA HCS	E	08/20/2012	R&DC SOP consultation and review
145	20	Boise VAMC	E	08/23/2012	MOU consultation and review.
146	04	Coatesville	H	08/23/2012	Technical assistance regarding proposed research involving partnership with a non affiliated academic researcher involving de-identified blood sample genetic marker analysis of blood samples taken from VAMC subjects in a detoxification facility. Teleconference conducted with RCO and IRB Chair review of guidance for collaborative studies; De-identification of specimens; MOU issues; Consent process and HIPAA issues.
147	15	VA Eastern Kansas HCS	E	08/23/2012	MOU consultation and review.
148	22	VA San Diego HS	E	08/23/2012	Review and consultation on HRPP and IRB SOPs.
149	18	Southern Arizona VA HCS	E	08/24/2012	Technical assistance for FWA modification, add new IRB
150	22	VA Greater Los Angeles HS	S	08/29/2012	ORO remote technical assistance for RSSP. Guidance on the use of VA IBC by affiliate.
151	01	Togus	E	09/04/2012	Technical assistance including MOU consultation and review for change of IRB oversight to affiliate university.

152	02	Canandaigua	H	09/11/2012	Technical assistance regarding "continuing review of studies closed for enrollment but are in data analysis and manuscript preparation phase."
153	07	Augusta	E	09/12/2012	FWA modification, Acting Director.
154	22	VA San Diego HS	E	09/12/2012	Technical assistance for FWA modification to add CBOC
155	02	Syracuse	E	09/13/2012	ORO Remote Technical Assistance for RCEP. Discussed 5 RCEP related deficiencies on 2012 FDC; four protocols did not have triennial audits; one closed protocol did not have a closure audit conducted; 3 of the deficient audits have been completed; other two are near completion.
156	18	New Mexico VA HCS	E	09/14/2012	MOU consultation and review
157	20	VA Puget Sound HCS	E	09/19/2012	ORO Remote Technical Assistance for RCEP. ICD audits were not conducted during the auditing period; explanation unsatisfactory; RCEP clarified various aspects of auditing process; RCO clarified why seven audits not conducted; RCEP announced its intent to conduct onsite technical assistance.
158	11	Indianapolis	E	09/21/2012	MOU review and consultation
159	17	VA South Texas HCS	E	09/24/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
160	12 NE	James A. Lovell Federal Health Care Center	S	09/25/2012	ORO remote technical assistance for RSAW. Consult with facility Human Resources Department regarding union representative; issue periodic requests to union leadership; provide meeting notices to union leadership; maintain documentation of actions.
161	05	DC VAMC	E	10/09/2012	ORO Remote Technical assistance for new RCOs in first year. Reviewed audit plan, interpersonal communication and dynamics with research program, and RCO office.
162	09	Lexington	E	10/12/2012	Review and consultation on IRB SOP and R&DC SOP in connection with Midwest site visit.
163	15	VA Eastern Kansas HCS	E	10/12/2012	MOU consultation and review.
164	07	Charleston	E	10/16/2012	Technical assistance on change of RCO.
165	07	Columbia	E	10/16/2012	Technical assistance for change of RCO.
166	05 SR	DC VAMC	E	10/16/2012	Technical assistance for new full-time RCO .
167	12	Hines	E	10/16/2012	Technical assistance for Change of RCO.
168	16	Central Arkansas VHS	E	10/16/2012	Technical assistance for change of RCO.
169	12	Milwaukee	E	10/16/2012	Technical assistance for Change of RCO.
170	16	New Orleans	E	10/16/2012	Technical assistance for change of RCO.
171	16	Shreveport	E	10/16/2012	Technical assistance for change of RCO.

172	23	VA Black Hills HCS	E	10/16/2012	Technical assistance for change of RCO.
173	23	VA Black Hills HCS	E	10/16/2012	Technical assistance for change of RCO.
174	17	VA Central Texas HCS	E	10/16/2012	Technical assistance for change of RCO.
175	21	VA Palo Alto HCS	E	10/16/2012	Technical assistance for change of RCO.
176	20	VA Puget Sound HCS	E	10/16/2012	Technical assistance for addition of a second RCO.
177	17	VA South Texas HCS	E	10/16/2012	Technical assistance for change of RCO.
178	15	Wichita	E	10/16/2012	Technical assistance for change of RCO.
179	23	Fargo	E	10/17/2012	Technical assistance for change of RCO.
180	23	VA Black Hills HCS	E	10/17/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
181	16	Houston	E	10/18/2012	Technical assistance for FWA modification, return of medical center director from detail.
182	23	Iowa City	E	10/18/2012	Technical assistance for FWA renewal.
183	06	McGuire (Richmond)	E	10/18/2012	FWA modification, new signatory official.
184	20	VA Puget Sound HCS	E	10/18/2012	Technical assistance for FWA modification.
185	22	VA San Diego HS	E	10/18/2012	Technical assistance for FWA modification to add new Internal IRB
186	07	Birmingham	E	10/19/2012	FWA modification, acting director.
187	16	Central Arkansas VHS	E	10/19/2012	Technical assistance for FWA modification.
188	01	Togus	E	10/19/2012	Technical assistance on FWA modification, new medical center director.
189	23	Fargo	E	10/22/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
190	12	Madison	H	10/22/2012	Technical assistance concerning recruitment efforts by PI to use VISN 12 PHI for recruitment; discovered missing HIPAA waivers and DUA-DTAs for sharing PHI. PI must submit an IRB amendment to update approved HIPAA waivers, report noncompliance for use of PHI to IRB.
191	12	Milwaukee	E	10/23/2012	Technical assistance for VISN Change of RCO.
192	03	Bronx	E	10/25/2012	FWA modification, new signatory official.
193	04	Clarksburg	E	10/25/2012	Technical assistance for FWA modification, new signatory official.

194	23	Minneapolis	E	10/25/2012	Technical assistance for FWA modification.
195	01	Northampton	E	10/25/2012	ORO RCEP Remote Technical assistance for new RCOs including coaching and education through first 12 months.
196	06	Durham	E	11/06/2012	FWA modification, change of Human Protections Administrator to John Whited
197	16	Central Arkansas VHS	E	11/06/2012	Technical assistance for change of RCO.
198	11	Detroit	E	11/07/2012	Technical assistance for RCO.
199	16	Central Arkansas VHS	E	11/07/2012	MOU Consultation and review.
200	03	Northport	M	11/09/2012	ORO Remote Technical Assistance for RCO/acting RIO. ORO reviewed the definition of research misconduct, the information needed to be contained within an allegation of research misconduct, the obligations that an Informant has when making an allegation, and the responsibilities of a RIO.
201	18	Southern Arizona VA HCS	E	11/09/2012	Technical assistance for FWA modification, add new IRB
202	21	VA Central California HCS	E	11/09/2012	Technical assistance for FWA modification.
203	19	VA Eastern Colorado HCS	H	11/09/2012	Technical assistance regarding closed NSOC report in which no data breach had occurred but concerns were raised regarding possible conduct of unauthorized VA research and unauthorized access to PHI. PO and R&DC should conduct assessments and reach determination regarding conduct of unauthorized VA research and unauthorized access to PHI.
204	15	VA Eastern Kansas HCS	E	11/09/2012	Technical assistance for FWA modification.
205	16	Oklahoma City	E	11/13/2012	MOU consultation and review.
206	11	Ann Arbor HCS	E	11/15/2012	Technical assistance for FWA modification.
207	02	VA Western New York HCS	E	11/15/2012	FWA modification , new Human Protections Administrator.
208	02	Albany	E	11/16/2012	Technical assistance for FWA renewal.
209	16	Oklahoma City	E	11/16/2012	Technical assistance for FWA modification.
210	21	San Francisco VAMC	E	11/19/2012	RCEP remote technical assistance support program for new RCOs, including coaching and educational needs assessment and resources.
211	21	San Francisco VAMC	E	11/21/2012	Technical assistance for change of RCO.
212	01	Northampton	E	11/28/2012	ORO RCEP Remote Technical assistance for new RCOs including coaching and education through first 12 months. Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office.
213	16	New Orleans	E	12/05/2012	Technical assistance for change of RCO.

214	01	Northampton	P	12/05/2012	ORO Technical assistance for multiple areas including orientation of newly hired RCO. Reviewed reporting responsibilities, key handbooks, learning resources, required processes, documentation and record keeping.
215	02	Albany	E	12/06/2012	ORO Remote technical assistance concerning RCEP resources.
216	03	VA New York Harbor HCS	A	12/13/2012	ORO remote technical assistance for ACUP. Post hurricane Sandy operations.
217	02	Albany	E	12/17/2012	Technical assistance for new RCO orientation.
218	16	Houston	E	12/17/2012	Technical assistance for change of RCO.
219	06	Salem	E	12/17/2012	Technical assistance on change of RCO.
220	12 NE	Hines	H	12/20/2012	ORO Remote Technical Assistance for HRPP. Discussed ongoing efforts to revise IRB SOP to harmonize it with VHA and Department of Navy requirements and with terms of the VA/Department of Defense (DoD) MOU.
221	16	Oklahoma City	I	12/27/2012	Technical assistance regarding simultaneous NSOC and Facility reporting the loss of a sponsor laptop. Participants at this site must be offered sponsor credit monitoring; clarified by VHA Privacy as not VA data; sponsor clarified laptop was unencrypted; valid ICF and HIPAA Authorizations in place; copies of VA data retained.

TABLE 10. REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

VA requires that unanticipated serious adverse events (SAEs) in research be reported to, and rapidly reviewed by, the responsible the Institutional Review Board (IRB). Reporting to ORO is required for unanticipated SAEs, including deaths, that the IRB judges to be caused by, or probably caused by, the research. ORO uses these reports to review local SAE management and assist facilities in improving their research programs.

Summary

- 7 = Cases Continuing from Previous Calendar Year
- 6 = New Cases – January 1 through March 31
- 5 = New Cases – April 1 through June 30
- 8 = New Cases – July 1 through September 30
- 5 = New Cases – October 1 through December 31
- 24 = New Cases in Calendar Year
- **31 = Total Cases (Continuing Plus New) in Calendar Year**

TABLE 10. REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
1	04	VA Pittsburgh HCS	10/03/2011	Facility reported suspension of drug study involving subjects with hepatocellular carcinoma due to death of a participant; subject did not meet inclusion exclusion criteria; AE relationship to study unknown. Study funded by NCI (ECOG);required agencies notified. Two other studies suspended by ECOG.	Remedial actions: IRB suspension of new enrollments. ECOG suspension of PI's two additional studies pending audit. IRB determination that the SAE regarding the death of the participant is Serious, Unexpected, and Relationship Unknown. CASE CLOSED
2	01	Providence	10/28/2011	Facility reported adverse event in a CSP prazosin treatment study of combat trauma PTSD possibly due to overdose after having skipped the study medication for 6 days.	Remedial Actions: Study drug halted; team members trained on what to do if doses are missed, Better definition of "regular dose" in protocol.
3	01	VA Connecticut HCS	11/18/2011	Subject in drug study (losartan and lisinopril) for diabetic nephropathy study hospitalized with cardiac symptoms. Subject is heavy smoker and has history of ischemic heart disease and carotid artery occlusion.	Remedial Actions: IRB will review once hospitalization records received. IRB agreed with PI determination that the AE was not related to research. CASE CLOSED
4	15	Kansas City	11/23/2011	Hospitalization of subject with primary UTI/ pneumonia, secondary Pulmonary Embolism/Deep Vein Thrombosis related to chemotherapy in open label metastatic prostate cancer study.	Remedial actions: IRB determined SAE anticipated, risk-benefit ratio acceptable without further actions. CASE CLOSED.

TABLE 10. REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
5	11	Detroit	12/01/2011	Facility reported an SAE in a NIH funded hypertension study: a subject was hospitalized due to hypotension and confusion, possibly caused by self double dosing of study drugs with anti-hypertensive effect and/or other prescribed medications following unrelated surgery.	Remedial actions: Study drugs halted; review of all medications prescribed to affected subject; evaluation of mental status prior to re-entry into the study; subject not re-enrolled; CIRB determined SAE to not be related to study medication. Case Closed.
6	15	Kansas City	12/12/2011	Patient with prolonged pancytopeniain in Phase 1 dose escalation trial of oral azacitidine for myelodysplastic syndromes found to have several bone marrow granulomas.	Remedial actions: IRB determined SAE serious, unanticipated, and not related. CASE CLOSED.
7	15	Kansas City	12/16/2011	Facility reported serious, unexpected and related problem identified by the Sponsor. Sponsor voluntary recall of study drug.	Remedial Action Plan: IRB/RDC concurred that the unexpired drug had no new or emerging safety signals. Case closed.
8	20	Portland	01/10/2012	A subject in a multiple sclerosis study fainted and fell to the floor after an intravenous line was inserted and removed.	Remedial actions: ICD changed to inform future study participants of potential risk. CASE CLOSED.
9	**09**	**Memphis**	**01/13/2012**	**Facility reported subject death in Phase I rheumatoid arthritis trial. Death certificate indicated Acute Myocardial Infarction. IRB reviewer determined SAE was possibly related to study drug.**	**Remedial action: Temporary enrollment suspension pending Sponsor evaluation; unblind treatment arm of subject (was on active drug). Suspension lifted by DMC/CSR&D after safety review. IRB determined death was neither caused by nor probably caused by the research.**
10	08	Tampa	01/24/2012	Facility reported AEs in an ORD funded study involving the use of service dogs. In 1 case a subject's family member was bitten and another, a dog died unexpectedly.	Remedial Actions: Enrollment suspension. Veterinarians and ORD to evaluate the training offered and the service dog agency. Reporting to OHRP completed. CASE CLOSED.
11	20	Portland	02/16/2012	Adverse Event Report in a lung cancer study consisting of tumor misclassification with additional round of chemotherapy.	Remedial Action: PI clarified subject did not receive an additional dose of study drug, rather, the subject, who had been previously discontinued from the study drug, received a standard of care medication.
12	19	VA Eastern Colorado HCS	03/08/2012	A subject in a cocaine dependence treatment study with longstanding mental health pathology experienced suicidal ideation and severe anxiety and self-referred to a non-VA emergency department, where a mood stabilizing agent was prescribed.	Remedial Actions: PI stopped the study medication. IRB approved a protocol amendment regarding exclusion criterion and study risks in consent. Case closed.
13	06	McGuire (Richmond)	03/16/2012	Facility reported that a normal subject in a study to test an approved cancer drug on subjects with hepatic impairment tested positive for the hepatitis C virus (HCV). The source of the infection is unknown.	Remedial actions: Root Cause Analysis completed; source of Hepatitis infection indeterminate; Corrective & Preventative Action plan in effect; Infected subject continues to be followed. CASE CLOSED
14	17	VA North Texas HCS	04/13/2012	A subject in an industry sponsored drug study for acute coronary syndrome who did not meet enrollment criteria was administered study drug, and developed hemorrhagic shock, cardiac arrest and subsequent renal failure.	Required Actions: Suspension of enrollment; Development of action plan to prevent recurrence and procedure for review of high-risk studies; IRB re-review of PI's studies completed; resolution pending PI acceptance of IRB oversight plan.

TABLE 10. REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
15	00	VHACO	04/18/2012	A participant in a community-acquired pneumonia study died after being admitted to a non-VA facility for chest pain. IRB determined the event was serious and unanticipated, but a relatedness to study was unknown.	Remedial Actions: IRB determined the death could not be reasonably considered to be related or probably related to research, but a possibility could not be ruled out. IRB determined no further actions required. CASE CLOSED.
16	**09**	**Memphis**	**04/19/2012**	**Death of a subject in a CSP inpatient study of Veterans with pneumonia. Subject was discharged with stable vital signs but died a few days later after being hospitalized for chest pain. IRB initial determination possibly related pending further information.**	**Remedial Actions: CIRB determined the event could not be reasonably considered to be caused by the research, However, the possibility of relatedness could not be ruled out absolutely; no further action was needed. CASE CLOSED**
17	16	Jackson	05/25/2012	Participant in a lung cancer treatment study experienced a grade 3 proteinuria Grades 1&2 are expected	Remedial Actions: IRB reminded study staff of unanticipated SAE reporting requirements, noting that grade 3 proteinuria had just been specified as reportable in ECOG's most recent amendment, GVSMVAMC IRB approved on 2.7.12.
18	20	VA Puget Sound HCS	05/31/2012	Subject in a study to determine if Nasal Insulin improves forgetfulness was hospitalized for evaluation of transient stroke-like symptoms.	Remedial Actions: Study drug permanently discontinued. SAE probably not study-related, no further action required. Case closed.
19	**05**	**VA Maryland HCS**	**07/09/2012**	**A research participant was found dead at home. Family member was concerned research may have contributed to the death. This is an educational study that did not involve dispensing of medication, but did involve screening patients for side effects of antipsychotic medications.**	**Remedial Actions: IRB determined that the death was not related to research; facility responded to family member's letter; IRB sent a separate letter to the participant's family. CASE CLOSED**
20	16	Central Arkansas VA HS	07/12/2012	Participant on a hepatocellular carcinoma Phase III RCT developed hepatic necrosis; IRB's preliminary determination was serious, unanticipated, and possibly related to study participation.	Remedial Actions: PI must revise ICD to add risk of hepatic necrosis and re-consent participants still receiving study drug/placebo at their next study visit.
21	01	Manchester	07/31/2012	A subject in a treatment study of cognitive symptoms in patients with mild TBI and/or PTSD may have had a miscarriage of an early pregnancy. Subsequently determined the subject was not pregnant.	Remedial Actions: The IRB determined that an SAE had not occurred and that remedial actions were not required. CASE CLOSED.
22	08	Tampa	08/19/2012	A subject enrolled in the Service Dogs for Veterans with PTSD study reported that the dog he was paired with was sick at time of pairing and has remained sick. This may increase the risk to subject.	Remedial Actions: VA has suspended additional pairings of Veterans with service dogs from this vendor. Investigation of this matter continues. IRB determined serious, related, unanticipated, increased risk to subject.
23	**15**	**Kansas City**	**08/24/2012**	**Subject was enrolled in multicenter phase IV Trial to Evaluate the Effect of Sazagliptin in Patients with Type II Diabetes. PI learned that subject died outside the VA.**	**Status: Facility made many attempts to obtain death certificate and contact next of kin. Facility exhausted all possible information gathering avenues; IRB determined that there was no indication that the death was caused by the research, and recommended no further action. CASE CLOSED**

TABLE 10. REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
24	07	Columbia	09/05/2012	A subject in study to compare the efficacy of the combination of angiotensin receptor blocker (ARB) plus an angiotensin converting enzyme inhibitor with ARB alone had been hospitalized at another non-VA facility.	Remedial Actions: IRB determined the SAE could not be reasonably considered related or probably related to research, but the possibility could not be ruled out. CASE CLOSED.
25	**12**	**VA Chicago HCS**	**09/21/2012**	**Subject enrolled in November 2011 in study to evaluate the Tryton Side Branch Stent in the treatment of de novo bifurcation lesions within native coronary circulation died in September 2012.**	**Status: IRB determined within the 5-day reporting period that the death was not related to the research. CASE CLOSED.**
26	**17**	**VA North Texas HCS**	**09/25/2012**	**Subject in study of acute coronary syndrome in violation of exclusion criterion (within 24 hours of prior anticoagulant therapy) developed profound hypotension and eventual hemorrhagic shock, which precipitated multi-organ failure and death.**	**Status: IRB determined that the subject died as a result of participation in the research although the primary event was a standard of care procedure. Study was terminated, PI's 8 other studies were suspended. Facility is conducting a protected peer review to determine if sanctions are warranted. CASE CLOSED.**
27	20	Portland VAMC	10/29/2012	Preliminary (48 hour) report to ORO of a reportable Adverse Event in a PTSD and mindful meditation study; detailed report and assessment to follow.	Status: AE determined to have been serious, unanticipated, and study related; further action (i.e., ICD revision)Pending
28	20	Portland VAMC	11/07/2012	Notification of an AE. Subject in rehabilitation study reported knee pain and swelling after completing three baseline assessments.	Status: Unanticipated problem involving risk, study-related, but not serious. No further action required. CASE CLOSED
29	**00**	**VHACO**	**11/16/2012**	**Death of a CSP #562 subject at a non-VA hospital of unknown cause. CIRB determined the SAE to be serious and unanticipated, but relatedness could not be determined. Study team to provide a presumptive cause of death and death certificate.**	**Status: Based on additional information including death certificate, IRB determined that the subject's death was un-related to research. CASE CLOSED.**
30	15	Kansas City	12/03/2012	Subject passed out for 5 minutes following IV dose of donepezil and cocaine.	Status: PI waiting results of cardiac echo and chest CT. Study placed on clinical hold by FDA due to safety concerns.
31	**15**	Kansas City	12/07/2012	**Subject was enrolled in November 2010 in multicenter phase IV Trial to Evaluate the Effect of Sazagliptin in Patients with Type II Diabetes. Subject died in non-VA hospice of Chronic Obstructive Pulmonary Disease in November 2012 while still taking study drug.**	**Status: IRB determined within 5-day reporting period that the death was not caused by the research. CASE CLOSED.**

TABLE 11. RESEARCH MISCONDUCT AND DEBARMENT REVIEWS

ORO monitors all reported cases of alleged research misconduct (i.e., fabrication, falsification, or plagiarism) that involve VA research. ORO ensures that correct procedures are used by each facility's Inquiry and Investigation Committees and provides guidance as needed. ORO determines when notification of various VA offices and federal agencies must be given and facilitates coordination. In certain cases, ORO may perform onsite technical visits to provide assistance.

* NOTE: Because of the need to follow strict federal Inquiry, Investigation, and Adjudication procedures for research misconduct, and because of the range of consequences for research misconduct and debarment, such cases may take months or years to resolve. In addition, the resolution of some cases is delayed because they are also under the jurisdiction of the VA Office of Inspector General (OIG), the Department of Health and Human Services (HHS) Office of Research Integrity, the Food and Drug Administration (FDA), and/or a university affiliate.

Summary

- 4 = Cases Continuing from Previous Calendar Year *
- 2 = New Cases – January 1 through March 31
- 2 = New Cases – April 1 through June 30
- 2 = New Cases – July 1 through September 30
- 3 = New Cases – October 1 through December 31
- 9 = New Cases in Calendar Year
- 13 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 11. RESEARCH MISCONDUCT AND DEBARMENT REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
1	03	VA New York Harbor HCS	04/13/2010	Research misconduct allegations involving fabrication and falsification.	Status: The VISN Director's adjudication of the case was completed and resulted in a finding of research misconduct; ORO's administrative review of the case is pending.
2	02	Syracuse	04/29/2010	Research misconduct allegation involving fabrication and falsification.	Status: VISN adjudication completed and resulted in a finding of research misconduct; ORO administrative review pending.
3	18	New Mexico VA HCS	04/04/2011	Research misconduct allegation involving fabrication and falsification.	Status: The Inquiry Committee determined that there was not sufficient evidence to open a formal investigation, and the MCD concurred with the Committee's determination. CASE CLOSED.
4	19	VA Eastern Colorado HCS	09/07/2011	Research misconduct allegation involving possible falsification of data.	Status: Threshold determination met; joint-Inquiry convened; Inquiry Committee determined that the facts did not warrant an Investigation and the Facility Director concurred. CASE CLOSED.

TABLE 11. RESEARCH MISCONDUCT AND DEBARMENT REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
5	02	Syracuse	03/07/2012	Research misconduct allegation involving fabrication.	Status: The RIO determined that a publication referenced in an ORI notice of a research misconduct finding against the Respondent involved VA research. ORO closed the case based on the Respondent's signing of a Voluntary Exclusion Agreement containing appropriate corrective actions. CASE CLOSED.
6	11	Detroit	03/30/2012	Research misconduct allegations involving falsification.	Status: An Investigation into the allegations is ongoing.
7	18	VA Phoenix HCS	06/11/2012	Research misconduct allegation involving falsification.	Status: ORO reviewed an allegation forwarded by the RIO and determined that it did not involve research misconduct. ORO instructed the RIO to refer the allegation to the IRB for investigation as another type of research impropriety. CASE CLOSED.
8	18	VA Phoenix HCS	06/15/2012	Research misconduct allegation involving fabrication.	Status: Threshold determination completed; Inquiry completed; Investigation pending.
9	15	Columbia	07/16/2012	Research misconduct allegation involving falsification.	Status: The Inquiry Committee determined that there was insufficient evidence to open an Investigation, and the MCD concurred with the determination. CASE CLOSED.
10	22	VA San Diego HS	08/29/2012	Research misconduct allegation involving plagiarism.	Status: ORO determined that the allegation pertained to an authorship dispute rather than plagiarism. CASE CLOSED.
11	22	VA Greater Los Angeles HS	11/07/2012	Research misconduct allegation involving fabrication and/or falsification.	Status: Inquiry convened.
12	07	Birmingham	11/09/2012	Research misconduct allegation involving falsification.	Status: Inquiry pending.
13	22	VA Greater Los Angeles HS	12/05/2012	Research misconduct allegation involving plagiarism.	Status: ORO determined that the allegation pertained to an authorship dispute rather than plagiarism. CASE CLOSED.

TABLE 12. ACRONYMS

A = Animal Care and Use Program Focus
AAALAC = Association for Assessment and Accreditation of Laboratory Animal Care International
AAHRPP = Association for Accreditation of Human Research Protection Programs
ACORP = Animal Component of Research Protocol
ACOS/R = Associate Chief of Staff for Research
ACUP = Animal Care and Use Program
AIB = Administrative Investigation Board
ANSI = American National Standards Institute
AO/R = Administrative Officer for Research
ARF = Animal Research Facility
AWA = Animal Welfare Act
AWR = Animal Welfare Regulations

BSC = Biosafety Cabinet
BSL-3 = Biosafety Level 3

CAP = Corrective Action Plan
CC = Case Closed
CIO = Chief Information Officer
CIRB = Central Institutional Review Board (ORD)
CO = ORO Central Office
COI = Conflict of Interest
CoPI = Co-Principal Investigator
COS = Chief of Staff
CPRS = VHA Computerized Patient Record System
CRADA = Cooperative Research & Development Agreement
CRADO = VHA Chief Research & Development Officer
CRC = Clinical Research Coordinator
CSP = VHA Cooperative Studies Program
CVMO = ORD Chief Veterinary Medical Officer

DMC / DSMB = Data Monitoring Committee / Data and Safety Monitoring Board
DMR = Designated Member Review
DoD = Department of Defense
DTA = Data Transfer Agreement
DUA = Data Use Agreement

E = Research Compliance Officer Education Focus
ECOG = Eastern Cooperative Oncology Group
EIL = Equipment Inventory List
ESCCB = Enterprise Security Change Control Board

FCD = Facility Center Director
FCR = Full Committee Review
FDA = Food and Drug Administration
FDC = Facility Director Certification
FIPS = Federal Information Processing Standards
FISMA = Federal Information Security Management Act
FOIA = Freedom of Information Act

GFE = Government Furnished Equipment
GFI = Ground Fault Interrupter

H = Human Research Protection Focus
HCS = Health Care System
HHS = Department of Health and Human Services
HIPAA = Health Insurance Portability & Accountability Act
HRPP = Human Research Protection Program
HSR&D = Health Services Research and Development
HVAC = Heating, Ventilation and Air Conditioning

I = Information Security Focus
IACUC = Institutional Animal Care and Use Committee
IBC = Institutional Biosafety Committee
ICD / ICF = Informed Consent Document / Form
IDE = FDA Investigational Device Exemption
III = Individually Identifiable Information
IND = FDA Investigational New Drug
IRB = Institutional Review Board
IRM = Information Resource Management
ISA/SIA = Interconnection Security Agreement
ISO = Information Security Officer

IT = Information Technology
ITOC = VA OI&T Oversight and Compliance Office

LAN = Local Area Network
LAR = Legally Authorized Representative
LSI = Local Site Investigator

M = Research Misconduct Focus
MCD = Medical Center Director
MOU = Memorandum of Understanding
MRI = Magnetic Resonance Imaging
MVP = VA Million Veteran Program Research Study

(continued on next page)

TABLE 12. ACRONYMS

(continued from previous page)

NARA = National Archives and Records Administration
NIH = National Institutes of Health
NIST = National Institute of Standards and Technology
NPC = Nonprofit Research and Education Corporation
NSOC = VA Network & Security Operations Center

OBA = NIH Office of Biotechnology Activities
OE = Other Equipment (Non-GFE)
OEF-OIF = Operation Enduring Freedom / Iraqi Freedom
OGC = Office of General Counsel
OHRP = HHS Office for Human Research Protections
OIG = Office of Inspector General
OI&T = VA Office of Information and Technology
OLAW = PHS Office of Laboratory Animal Welfare
ORD = VHA Office of Research and Development
OPC = Outpatient Clinic
ORI = HHS Office of Research Integrity
OSHP = Occupational Safety and Health Program

P = Multiple Concerns Focus
PBM = VHA Pharmacy Benefits Management
PET = Positron Emission Tomography (Scan)
PHI = Protected Health Information under HIPAA
PHS = Public Health Service
PI = Principal Investigator
PII = Personally Identifiable Information
PKI = Public Infrastructure Key
PO = Privacy Officer
POC = Person Obtaining Consent
PTSD = Post-Traumatic Stress Disorder

QA = Quality Assurance
QI = Quality Improvement

R = Research & Development Committee Program Focus
RAP = Remedial Action Plan
RCEP = Research Compliance Officer Education Program
RCO = Research Compliance Officer
RCS = Record Control Schedule
RDC / R&DC = Research & Development Committee
rDNA = Recombinant Deoxyribonucleic Acid
REAP = VHA Research Enhancement Award Program
RIA = Research Integrity Assurance
RIO = Research Integrity Officer
RIPP / RISP = Research Information Protection / Research Information Security Program
RO = ORO Regional Office
ROI = Release of Information
RPSS = Research Protocol Safety Survey
RSSP = Research Safety and Security Program

S = Research Safety Focus
SAE = Serious Adverse Event
SAT = Select Agent and Toxin
SECVA = Secretary of Veterans Affairs
SIA/ISA = Interconnection Security Agreement
SMART = Site Monitoring Auditing & Review Team
SNC = Serious Noncompliance
SOP = Standard Operating Procedure
SRS = R&DC Subcommittee on Research Safety
SSN = Social Security Number
SWOG = Southwest Oncology Group

T = BSL-3 Program Focus
TAV = Technical Assistance Visit (ORO)
TBI = Traumatic Brain Injury

UPR = Unanticipated Problem(s) involving Risk(s)
USDA = United States Department of Agriculture
USH = VA Under Secretary for Health

VA = Department of Veterans Affairs
VAMC = VA Medical Center
VASI = VA Sensitive Information
VHA = Veterans Health Administration
VHACO = VHA Central Office
VIREC = VA Information Resource Center
VISN = Veterans Integrated Service Network
VMO = Veterinary Medical Officer
VMU = Veterinary Medical Unit
VPN = Virtual Private Network

WOC = VA Appointment Without Compensation

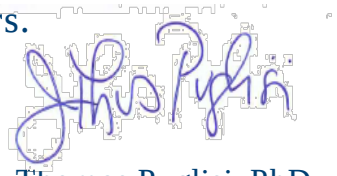
Department of Veterans Affairs
Veterans Health Administration

Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2013

This report summarizes the activities of the Veterans Health Administration Office of Research Oversight (ORO) from January 1 through December 31, 2013, and describes all suspected lapses in protecting human subjects and others in VA research as required under title 38 United States Code (38 U.S.C.) §7307(d)(4).

The report was prepared for the Committees on Veterans' Affairs of the Senate and the House of Representatives of the United States pursuant to 38 U.S.C. §7307(f).

ORO reports directly to the Under Secretary for Health in monitoring, reviewing, and investigating compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Federalwide debarment for research impropriety, and the activities of facility-level research compliance officers.



J. Thomas Puglisi, PhD
Director and Chief Officer
Office of Research Oversight

CONTENTS

A. INTRODUCTION

The Department of Veterans Affairs (VA), through the Veterans Health Administration (VHA) Office of Research Oversight (ORO), conducts one of the most comprehensive programs of research compliance oversight in the Federal Government.

Creation of ORO within VA was mandated under legislation signed by the President of the United States on December 6, 2003, as Public Law 108-170. Section 401 of this statute stipulates ORO's functions as follows:

> *(a) Requirement for Office. – (1) There is in the Veterans Health Administration an Office of Research Oversight (hereinafter in this section referred to as the 'Office'). The Office shall advise the Under Secretary for Health on matters of compliance and assurance in human subjects protections, research safety, and research impropriety and misconduct. The Office shall function independently of entities within the Veterans Health Administration with responsibility for the conduct of medical research programs. (2) The Office shall -- (A) monitor, review, and investigate matters of medical research compliance and assurance in the Department with respect to human subjects protections; and (B) monitor, review, and investigate matters relating to the protection and safety of human subjects and Department employees participating in medical research in Department programs.*

This report summarizes ORO's activities for the period from January 1 through December 31, 2013. The summary includes oversight activities carried out by ORO in advising the Under Secretary for Health (USH) on matters of regulatory compliance related to the protection of human research subjects, research safety, research laboratory security, and research misconduct, as required under title 38 United States Code (38 U.S.C.) §7307.

These activities reflect ORO's responsibilities to monitor, review, and investigate matters of regulatory compliance in each of these aspects of VA research. The report addresses suspected lapses from all causes in protecting human subjects and others in VA research as required under 38 U.S.C. §7307(d)(4).

The report also includes ORO's activities in providing oversight of laboratory animal welfare, research safety, research laboratory security, research information security and privacy, Governmentwide nonprocurement suspensions and debarments for research impropriety, facility research compliance officer (RCO) audits, and RCO education, as directed by the USH.

A total of 108 VHA facilities operated research programs in CY2013. All 108 of these facilities operated human research programs, 80 of these facilities operated laboratory research programs, and 77 of these facilities operated animal research programs.

In addition, the VHA Central Office Human Research Protection Program (HRPP) operates an Institutional Review Board (IRB) for oversight of multi-center clinical trials sponsored by VA, such as trials conducted under the VA Cooperative Studies Program (CSP).

Summaries of ORO's compliance cases have been provided in ORO's activity reports for the first, second, and third quarters of calendar year 2013 (CY2013). ORO's activities for the fourth quarter of CY2013, including case summaries, are incorporated into this report, which provides a complete listing of ORO cases for CY2013.

Because this report contains sensitive information related to open investigations, distribution of the report should be limited to those persons engaged in authorized Congressional oversight and to other required Congressional entities.

B. BACKGROUND

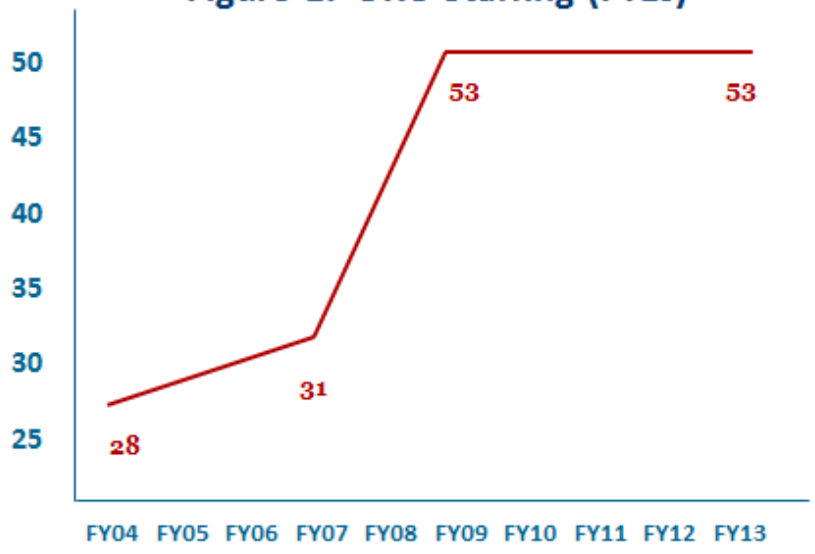
ORO Central Office (CO) develops and manages ORO's programs and provides direct oversight of the VHA Central Office Human Research Protection Program (HRPP). CO professionals also provide direct oversight of all VA research activities related to laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Governmentwide suspension and debarment for research impropriety, RCO audits, and RCO education.

ORO Regional Offices (ROs) provide direct oversight of VA research activities related to the protection of human subjects and facility research program administration and oversight. ORO's ROs are located within VA space in four geographic regions to provide prompt access and response to issues that may require onsite review and assistance. Each RO has oversight responsibility for approximately 25-30 VA research facilities:

- Midwestern RO (Edward Hines, Jr. VA Hospital, Chicago, IL)
- Northeastern RO (Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA)
- Southern RO (Veterans Integrated Service Network 7 Headquarters, Duluth, GA)
- Western RO (VA Loma Linda Health Care System, Loma Linda, CA)

A full ORO staff includes 53 individuals (28 in ORO's CO, and 25 in ORO's ROs). The Figure below illustrates the staffing levels for ORO since its creation in December 2003.

Figure 1. ORO Staffing (FTEs)



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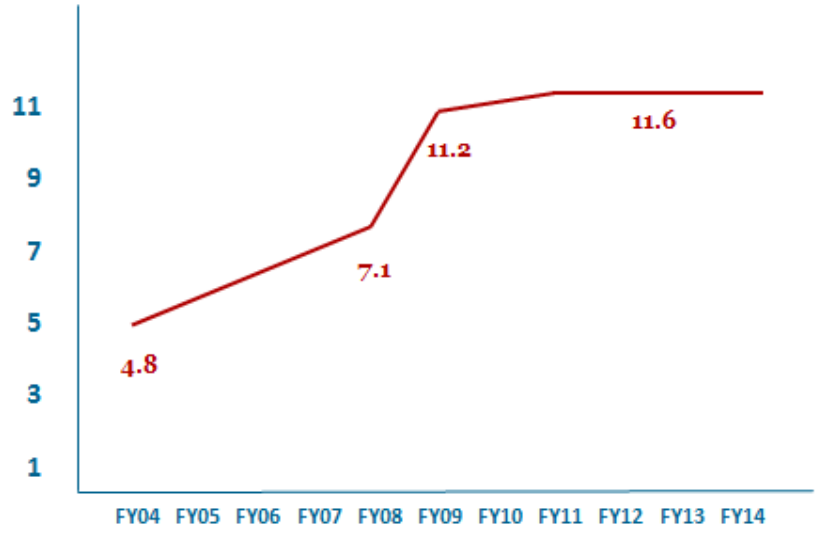
ORO's current fiscal year budget is approximately $11.6 million. The Figure below illustrates the funding provided to ORO since its creation in December 2003.

Figure 2. ORO Funding ($Millions)



ORO solicits advice and feedback from the research community through the ORO Field Advisory Committee. Committee members are encouraged to raise any and all matters of concern related to ORO's activities and to recommend strategies to enhance efficiency and effectiveness in the fulfillment of ORO's mission. The Committee convenes three times per year by video conference. Members are also invited to participate in ad hoc work groups pertinent to ORO's mission.

As previously noted, a total of 108 VHA facilities operated research programs during this reporting period. All 108 of these facilities operated human research programs, 80 of these facilities operated laboratory research programs, and 77 of these facilities operated animal research programs. In addition, the VHA Central Office HRPP operates an Institutional Review Board (IRB) for oversight of multi-center clinical trials sponsored by VA, such as trials conducted under the VA Cooperative Studies Program (CSP).

ORO fulfills its review and oversight responsibilities for regulatory compliance and assurance through three types of programs:

- Onsite research compliance reviews
- Remote compliance reviews
- Oversight of VA facilities' Federalwide Assurances (FWAs), research compliance education, and quality assurance

C. Onsite Research Compliance Reviews

ORO conducts three types of onsite compliance reviews:

- For-cause onsite reviews
- Proactive routine onsite reviews
- Proactive technical assistance onsite reviews

Most onsite reviews are announced to the facility in advance, but ORO also may conduct unannounced onsite reviews as warranted. Summaries of ORO's onsite compliance reviews are provided in the Appendix to this report. Complete reports of these reviews are available upon request.

C1. For-Cause Onsite Reviews

ORO receives reports of possible noncompliance from a variety of sources, including other VA offices, other government agencies, VA employees, Veterans, family members of Veterans, ORO's anonymous complaint line, and the media.

In cases where there may be serious, systemic concerns about a facility's research protection programs, ORO may conduct for-cause onsite compliance reviews to establish the nature and severity of the possible noncompliance, and to assess the effectiveness of the facility's research protection programs. These reviews involve in-depth evaluations of potentially serious noncompliance with the laws, regulations, and policies governing VA research.

ORO requires remedial actions to resolve any serious or continuing noncompliance that is identified. All facilities that are required to develop and execute remedial action plans are carefully monitored, and cases are held open until ORO confirms that remedial actions have been implemented satisfactorily to ensure compliance.

C2. Proactive Routine Onsite Reviews

Routine onsite reviews are systematic proactive inspections of regulatory compliance to assist VA facilities in fulfilling their responsibilities to conduct research with appropriate human subject protections, care and use of laboratory animals, research safety, research laboratory security, and research information security and privacy. Where applicable, these reviews include inspections of VA's nine Biological Safety Level Three (BSL-3) research laboratories.

The routine onsite review program involves a process of thorough onsite review, assessment, and follow-up of issues identified concerning regulatory compliance in VA research programs. Routine onsite reviews are performed on a rotating basis by teams

of two to six ORO professionals, with the size of the team proportional to the size of the VA facility's research program.

C3. Proactive Technical Assistance Onsite Reviews

ORO onsite technical assistance reviews constitute an additional proactive approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

C4. Summary: Onsite Research Compliance Reviews

Table 1 of the Appendix provides case summaries of ORO's onsite compliance reviews.

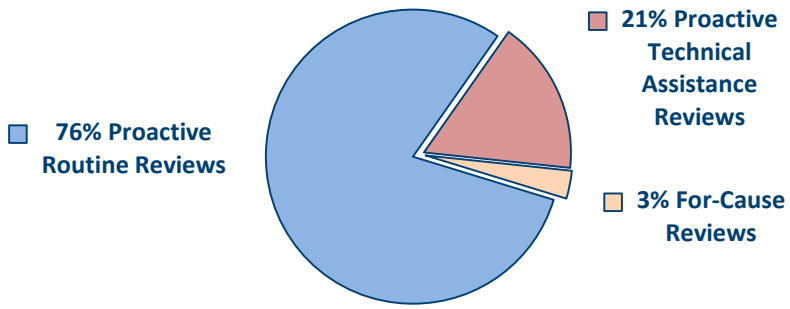
Summary: Number of Onsite Research Compliance Reviews:

- 52 = Cases Continuing from Previous Calendar Year
- 39 = New Cases – January 1 through March 31
- 43* = New Cases – April 1 through June 30
- 33 = New Cases – July 1 through September 30
- 28 = New Cases – October 1 through December 31
- 143 = Total New Cases in Calendar Year
- 195 = Total Cases (Continuing Plus New) in Calendar Year

* Includes corrected values

The Figure below illustrates ORO's onsite compliance review cases for CY2013.

Figure 3. Calendar Year Onsite Research Compliance Reviews (n=195)



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D. Remote Research Compliance Reviews

Certain compliance cases can be evaluated and managed remotely through written communications with facility leadership and facility compliance personnel. ORO conducts seven types of remote reviews to ensure compliance with VA research requirements:

- Reviews of externally identified noncompliance
- Reviews of facility self-identified noncompliance
- Reviews of Research Compliance Officer (RCO) audits
- Reviews of annual facility director certifications of research oversight
- Remote technical assistance reviews
- Reviews of unanticipated serious adverse events related to research
- Reviews of research misconduct and debarment proceedings

Each review includes monitoring by ORO to verify that remedial actions have been implemented as warranted.

D1. Remote Reviews of Externally Identified Noncompliance

ORO's remote compliance reviews include cases of apparent noncompliance that have been identified by sources external to the facility's HRPP. Such sources include, but are not limited to, apparent noncompliance identified by ORO, by other VA offices, by other government regulatory agencies, and by industry sponsors.

D2. Remote Reviews of Facility Self-Identified Noncompliance

Both ORO and the VHA Office of Research and Development (ORD) strongly encourage VA research facilities to accept responsibility and accountability for maintaining a compliant research program and fostering a culture that values adherence to the required protections for Veterans and other human research subjects, research personnel, and research animals. Building a culture of local accountability has been the focus of ORO and ORD education activities for the past several years.

VA facilities are required to report to ORO any events that might reasonably indicate serious or continuing noncompliance in research. As the focal point for fulfilling VA's research mission and a responsible steward of VA resources, each VA research facility has an obligation to serve as the primary watchdog for identifying and correcting noncompliance problems in its own research programs.

ORO works cooperatively with VA research facilities to manage their self-identified noncompliance cases by assisting them in developing appropriate remedial action plans and monitoring resolution of any deficiencies.

D3. Remote Reviews of Research Compliance Officer (RCO) Audits

Facility RCOs must conduct audits of all informed consents obtained for VA research throughout the year. Regulatory audits of all VA research projects must be conducted at least every 3 years. Facilities are required to report to ORO any apparent serious noncompliance identified in these audits.

D4. Reviews of Annual Facility Director Certifications of Research Oversight

ORO requires that the director of each VA facility conducting research lead an annual program-wide self-assessment of research compliance and provide ORO with an annual certification of research oversight based on this self-assessment. Certifications must be completed and forwarded to ORO by July 31 each year.

ORO evaluates all deficiencies identified by the facility and requires remedial actions when needed. ORO monitors the case until appropriate remedial actions have been implemented satisfactorily.

D5. Remote Technical Assistance Reviews

ORO remote technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Remote technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

D6. Remote Reviews of Unanticipated Serious Adverse Events

VA requires that unanticipated serious adverse events (SAEs) in research be reported to, and rapidly reviewed by, the responsible IRB. Reporting to ORO is required for any unanticipated deaths and other unanticipated SAEs that the IRB determines to be caused by, or probably caused by, the research. ORO uses these reports to review local SAE management and assist facilities in improving their research programs.

D7. Research Misconduct and Debarment Procedural Reviews

All Federal agencies that conduct or support research have adopted the following uniform definition of research misconduct: *fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.* VA has established precise processes for responding to allegations of misconduct involving VA research and for sanctioning with Governmentwide debarment VA investigators who commit serious improprieties in the conduct of research. The potential consequences and severity of research misconduct and Governmentwide debarment necessitate detailed procedural mechanisms for adjudication.

D8. Summary: Remote Research Compliance Reviews

Table 2 of the Appendix provides case summaries of ORO's remote compliance reviews.

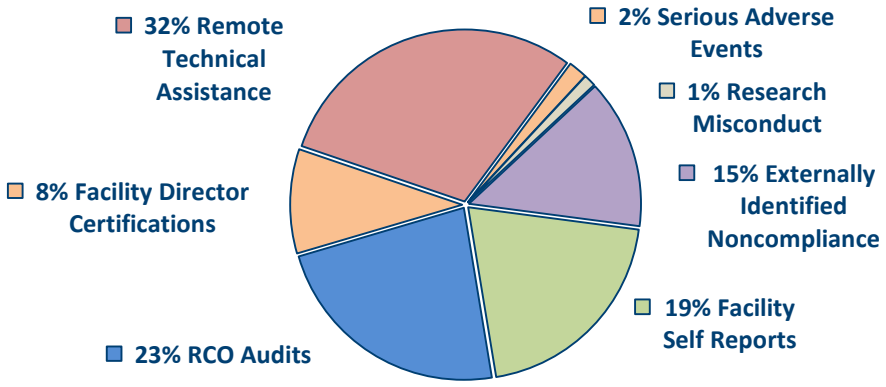
Summary: Number of Remote Research Compliance Reviews:

- 179 = Cases Continuing from Previous Calendar Year
- 222 = New Cases – January 1 through March 31
- 263* = New Cases – April 1 through June 30
- 308* = New Cases – July 1 through September 30
- 356 = New Cases – October 1 through December 31
- 1149 = Total New Cases in Calendar Year
- 1328 = Total Cases (Continuing Plus New) in Calendar Year

* Includes corrected values

The Figure below illustrates ORO's remote compliance review cases for CY2013.

Figure 4. Calendar Year Remote Research Compliance Reviews (n=1328)



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E. Research Assurance, Compliance Education, and Quality Assurance

E1. Research Assurance Program

ORO administers the VA human research assurance program. Assurances are formal agreements required by regulation and signed by VA facility directors and network directors assuring compliance with VA and other Federal requirements, including provision of adequate training and resources, for the protection of human research subjects. The Federalwide assurance (FWA) for any VA research facility requires the approval of both ORO and the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (HHS).

ORO has the authority to restrict or suspend a VA facility's FWA for failure to meet its responsibilities for protecting human subjects.

All 108 VA research facilities and the VHA Central Office HRPP hold active, approved FWAs.

Although FWAs are typically approved for 5 years, the facility must modify its FWA whenever certain changes occur (e.g., a change in the designation of an IRB or a change in responsible facility officials). ORO's participation in the approval, renewal, or modification of FWAs during this calendar year is reflected among the cases in Table 2E. ORO also tracks membership and membership changes in all IRBs used by VA research facilities to ensure regulatory compliance.

Each VA research facility that uses an IRB operated by another VA facility (19 facilities), operated by the VHA Central Office HRPP (94 facilities), or operated by the facility's academic affiliate (40 facilities) must effect a memorandum of understanding (MOU) indicating how the entities will work together to support the IRB and collaborate in the protection of human research subjects. MOUs documenting these IRB arrangements are reviewed by ORO whenever substantive modifications occur, at the time of FWA renewal, and in conjunction with ORO's onsite compliance reviews.

The MOU can also be used to document other related organizational arrangements used in human research protection programs, such as using the Research and Development Committee (R&DC) of one VA facility to oversee the research program of another VA facility. ORO regularly reviews MOUs and provides guidance to facilities on developing appropriate MOUs, as reflected among the cases in Table 2E.

E2. Research Compliance Education Program

Every VA facility conducting research is required to support at least one RCO to provide facility-level oversight of its research program. The lead RCO at each facility must report directly to the facility director, and each facility director has a responsibility to ensure the functional independence of the facility's RCO(s) relative to the Research Service.

ORO conducts an RCO education program to strengthen oversight of research at the facility level and monitors RCO activities to ensure compliance with VA requirements.

The primary function of RCOs is to conduct mandatory informed consent and regulatory compliance audits of VA research. Every VA research study must receive a 100% audit of informed consent documentation each year, as well as a full regulatory compliance audit approximately every 3 years. ORO provides audit tools for this purpose on its Web site and trains RCOs in their use.

RCOs also serve as local resources on research compliance requirements and consultants to the R&DC, IRB(s), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), and other facility research oversight committees.

ORO has developed a variety of informational materials and audit tools and conducts monthly video teleconferences for RCO education. Educational materials and audit tools are available on the ORO Web site at http://www.va.gov/oro/and the ORO Research Compliance and Technical Assistance SharePoint site, which is available to all VHA employees at http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx.

ORO regularly develops updated policy, guidance materials, and oversight tools to assist the wider VA research community in implementing optimal protections for human research subjects, laboratory animals, and research investigators. These materials are provided on the ORO Web site and SharePoint site referenced above. ORO also maintains several large ListServs for rapid distribution of guidance materials and important announcements.

ORO holds nationwide research compliance video teleconferences at 2-month intervals and contributes extensively to educational activities sponsored by ORD and national professional associations where possible.

ORO has been instrumental in convening and continues to participate vigorously in collaborative workgroups with the VHA ORD, the VHA Privacy Office, the VA Office of General Counsel, the VA Office of Information and Technology (OI&T), and the Association of American Medical Colleges (AAMC) to address common areas of concern,

including data ownership and data security issues in research with VA's university affiliates.

ORO also participates actively in several interagency workgroups, including the HHS Secretary's Advisory Committee on Human Research Protections (SACRHP), the Federal Research Integrity Workgroup, and the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight.

E3. Research Quality Assurance Program

ORO has developed a set of indicators for assessing the quality of VA research protection programs. These quality indicators have been incorporated into RCO informed consent and regulatory audits and the annual facility director certifications of research oversight.

Quality indicators for human research include documentation of informed consent, Health Insurance Portability and Accountability Act (HIPAA) authorization for use and disclosure of protected health information, IRB approval, protocol documentation, and investigator qualifications and training.

Quality indicators for animal research include Institutional Animal Care and Use Committee (IACUC) approval and investigator qualifications and training. Quality indicators for research safety include Subcommittee on Research Safety (SRS) approval.

ORO compiles the data for these indicators to identify areas for system-wide quality improvement and provides these data to each VA research facility and Veterans Integrated Service Network (VISN) for quality improvement purposes at the facility and VISN level. ORO's Annual Report of Activities includes a longitudinal summary of data for these indicators going back to CY2009.

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Department of Veterans Affairs
Veterans Health Administration

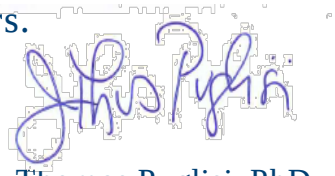
Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2013

Appendix A: Research Compliance Case Summaries
(Includes all compliance cases for 1st, 2nd, 3rd, and 4th Quarters of CY2013)

This report summarizes the activities of the Veterans Health Administration Office of Research Oversight (ORO) from January 1 through December 31, 2013, and describes all suspected lapses in protecting human subjects and others in VA research as required under title 38 United States Code (38 U.S.C.) §7307(d)(4).

The report was prepared for the Committees on Veterans' Affairs of the Senate and the House of Representatives of the United States pursuant to 38 U.S.C. §7307(f).

ORO reports directly to the Under Secretary for Health in monitoring, reviewing, and investigating compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Federalwide debarment for research impropriety, and the activities of facility-level research compliance officers.



J. Thomas Puglisi, PhD
Director and Chief Officer
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TABLE 1. ON-SITE RESEARCH COMPLIANCE REVIEWS

TABLE 1A. FOR-CAUSE ON-SITE REVIEWS

ORO for-cause onsite reviews involve in-depth evaluations of suspected serious systemic non-compliance with VA or other federal research requirements. ORO review teams typically spend 4 to 5 days at the facility examining records and interviewing key personnel involved in the issues under review. Remediation involves development by the facility of an action plan acceptable to ORO, and oversight of corrective actions by ORO until remediation is complete. NOTE: Cases under the jurisdiction of additional offices (for example, OIG or FDA) or involving physical infrastructure improvements may remain open for extended periods.

SUMMARY

- 2 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- *3 = New Cases – April 1 through June 30
- 1 = New Cases – July 1 through September 30
- 0 = New Cases – October 1 through December 31
- 4 = Total New Cases in Calendar Year
- 6 = Total Cases (Continuing Plus New) in Calendar Year

* Includes 1 case omitted from Second Quarter Report.

TABLE 1A. FOR-CAUSE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	Issue of Noncompliance	Remedial Actions
1	01	VA Boston Healthcare System	P	05/01/2012	Allegation of possible research misconduct and/or noncompliance against the LSI. ORO for-cause onsite review beginning May 1, 2012.	Remedial actions: Implement monitoring plans; ensure compliance of pharmacy practice; determine any disciplinary action needed. CASE CLOSED.
2	21	San Francisco VAMC	S	05/14/2012	Facility reported employee death; presumptive diagnosis is disseminated meningococcemia with suspect occupational exposure.	Remedial Actions: Provide prophylactic vaccination as available; revise biosafety manual; develop lab-specific SOPs; staff education and training; revise protocols with safety enhancements as needed; orientation, training and evaluation of worker competencies.

TABLE 1A. FOR-CAUSE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	Issue of Noncompliance	Remedial Actions
3	23	Iowa City	A	04/03/2013	ORO for-cause on-site review of ACUP to follow up on media reports of problem with canine research at academic affiliate.	Remedial Actions: None required. ORO has requested that the facility continue to provide updates if additional public inquiries are received. CASE CLOSED.
4	00	VA Central Office	P	04/16/2013	ORO review of allegations against the VA Office of Public Health (OPH) by a former OPH employee	Remedial Actions: Ensure approval of all manuscript authors; research data retained per federal requirements; OPH PIs empowered to fulfill all PI responsibilities; OPH leadership training. VHA to designate specific IRB for VHA Program Office research. Separate VHA administrative action.
5	01	Providence	P	06/27/2013	ORD Non-profit Program Office reported that a PI was possibly conducting genotyping on children specimens without CRADO waiver and staff conducting the work unsupervised.	Actions: ACOS/R must ensure effective system is in place to orient VA researchers with dual appointment on VHA requirements in the conduct of multisite research; consult OGC STAR team when complex multisite research activities are planned to be conducted at the VA; R&DC education on VA research.
6	23	Minneapolis	R	09/25/2013	OIG Hotline referral reported possible R&DC approval of non-VA research and the possible conduct of research by an individual lacking appropriate VA appointment and research scope of practice. This is a total knee arthroplasty study.	Remedial Actions: Facility must remediate deficiencies regarding individuals who conducted research without an appropriate appointment; multiple violations regarding informed consent and HIPAA; lack of adequate oversight of human subjects research by the PI, IRB, and R&DC; and financial COI.

TABLE 1B. PROACTIVE ROUTINE ON-SITE REVIEWS

ORO routine onsite inspections provide a proactive, systematic approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite reviews involve a two stage process of assessment and remediation. The assessment stage includes a review of compliance with current federal laws, regulations, and VA policies governing research. Remediation involves development by the facility of an action plan acceptable to ORO, and oversight of corrective actions by ORO until remediation is complete.

SUMMARY

- 49 = Cases Continuing from Previous Calendar Year
- 28 = New Cases – January 1 through March 31
- *29 = New Cases – April 1 through June 30
- 20 = New Cases – July 1 through September 30
- 22 = New Cases – October 1 through December 31
- 99 = Total New Cases in Calendar Year
- 148 = Total Cases (Continuing Plus New) in Calendar Year

* Includes 2 cases omitted from Second Quarter Report.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
1	22	VA Greater Los Angeles HS	A	06/07/2010	Remedial Actions: VMU HVAC monitoring, testing, temperature, pressure regulation, routine maintenance; security of outside canine exercise area; VMU supervision; pest control; cage standards; veterinary access to animals and records; canine husbandry; protocol adherence; SOPs; offsite oversight.
2	17	VA Central Texas HCS	S	06/28/2010	Remedial Actions: IBC MOU; annual program review; multidisciplinary vulnerability assessments; safety, security, emergency preparedness plan; safety drills; research-specific security plan; lab inspections; hazardous chemical inventories; research-specific safety training. CASE CLOSED.
3	20	Boise VAMC	A	04/11/2011	Remedial Actions: Establish procedures to review effectiveness of the ACUP annually; ensure appropriate oversight of animal research activities conducted off-site; establish SOPs for using Designated Member Review; ensure annual overheat test is conducted and reported to IACUC. CASE CLOSED.
4	20	Boise VAMC	S	04/11/2011	Remedial Actions: Ensure risk assessment results of proposals are adequately documented; adhere to MOU with collaborating VA for the establishment of shared rDNA subcommittee; ensure annual assessment security plans; R&DC annual review of SRS and RSSP; correct lab inspection findings.
5	01	VA Boston Healthcare System	A	05/09/2011	Remedial Actions: Maintain safety program consistent with VA policies and NIH guidelines; ensure protocol review process is consistent with SOPs; document official actions correctly in minutes; ensure staff completes credentialing; address VMU deficiencies. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
6	02	Syracuse	T	06/28/2011	Remedial Actions: Propagate M. tuberculosis cultures under BSL-3 containment; decontaminate Powered Air Purifying Respirator prior to removal from BSL-3 lab; install hands-free operated washing sink in D-305; install ANSI compliant eyewash in labs. CASE CLOSED.
7	01	Providence	I	08/01/2011	Remedial Actions: VASI not to be stored on non-VA OE; do not store VASI on unencrypted removable media; do not use unencrypted removable storage devices; revise HIPAA template/authorization language; document HIPAA waivers properly. CASE CLOSED.
8	03	VA New York Harbor HCS	T	09/05/2011	Remedial Actions: Modify BSL-3 ventilation system to provide sustained negative directional airflow; install ANSI-compliant eyewash. CASE CLOSED
9	07	Atlanta	S	12/13/2011	Remedial Actions: IBC review of non-exempt rDNA research; conduct and report safety, security, and emergency drills; full committee review of research involving new hazards; proper storage and labeling of chemicals; proper signage on lab entrances. CASE CLOSED.
10	08	Miami	A	01/10/2012	Remedial Actions: Conduct annual overheat test; properly review and approve offsite research; develop SOP for reporting research noncompliance; properly review protocols for alternatives; review VMU SOPs annually. CASE CLOSED.
11	08	Miami	S	01/10/2012	Remedial Actions: Conduct annual security plan drill; review all rDNA research; conduct annual vulnerability assessment; develop safety and security plan policies; make eyewash stations compliant; establish MOU with affiliate; evaluate status of WOC researchers. CASE CLOSED.
12	07	Atlanta	I	02/13/2012	Remedial Actions: Firewall management for the system interconnection; Improve process for justification of waivers of HIPAA Authorization; Improve compliance with research records retention requirements CASE CLOSED.
13	07	Birmingham	A	02/14/2012	Remedial Actions: ACOS/R must consistently issue letters to PI's to initiate research; secure laboratory areas; establish MOU for affiliate IBC oversight; revise protocol recordkeeping practices to comply with VHA policy. CASE CLOSED.
14	01	VA Boston Healthcare System	R	02/21/2012	Remedial Actions: Revised Organizational Chart, revised committee rosters, issued appointment letters and updated R&DC SOPs. CASE CLOSED.
15	18	New Mexico VA HCS	R	02/27/2012	Remedial Actions: R&DC and ACOS/R to conduct annual QA reviews and review of subcommittees and research program; R&DC not to use expedited review procedure; update R&DC roster; revise SOPs. All required actions completed. CASE CLOSED.
16	18	New Mexico VA HCS	H	02/27/2012	Significant Required Remedial Actions: Distinguish VA from non-VA research (using VA definition of research); monitor approval periods and ensure cessation of research upon expiration; discontinue use of expedited review for greater than minimal risk/substantive changes. All required actions completed, new MOU approved. CASE CLOSED.
17	19	VA Salt Lake City HCS	H	03/26/2012	Remedial Actions: Distinction of VA from non-VA human subject research; determinations of minimal risk; use of expedited review procedures; documentation for HIPAA decisions; consistency of SOPs with VHA policy; receipt, storage and dispensing of investigational drugs. CASE CLOSED.
18	08	VA North Florida/ South Georgia HCS	A	03/27/2012	Remedial Actions: Formalize a written policy for DMR subsequent to FCR protocol review; update PHS Assurance; document oversight of animal research at affiliate institution; provide emergency shower and eyewash stations in cage wash area; remediate specific VMU inspection findings. CASE CLOSED.
19	08	VA North Florida/ South Georgia HCS	S	03/27/2012	Remedial Actions: Review and document access records; Document review of multi-disciplinary vulnerability assessment; Ensure annual drills are conducted; Install emergency shower & eyewash stations; Document review of semi-annual chemical inventories; remediate specific laboratory findings. CASE CLOSED.
20	03	VA New Jersey HCS	I	05/14/2012	Remedial Actions: VASI on unencrypted CDs; VASI on non-VA audio recorder; affiliate IT equipment on appropriate EIL; incomplete documentation of waivers of HIPAA Authorization; SOPs; inaccurate de-identification of data; incomplete documentation of ISO and PO reviews; training lapses. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
21	21	VA Northern California HCS	H	06/04/2012	Required Actions: Use VA ICDs with all required elements, medical record flagging, justification for inclusion of non-Veterans, and PO/ISO review; reevaluate study risk; ensure research stops when studies expire, require training and VA appointments; maintain an IND study list; CASE CLOSED.
22	21	VA Northern California HCS	R	06/04/2012	Remedial Actions: Approve all research engaged by the facility; QA review of CRADAs; RDC must re-review MOUs; ensure all staff have appropriate VA appointments, scopes of practice, credentialing and training; maintain program records; and conduct and report the outcome of required audits. CASE CLOSE
23	16	Fayetteville	R	06/19/2012	Remedial Actions: Conduct annual evaluation of the IRB; Revise R&DC SOP to describe all recurring processes. CASE CLOSED.
24	23	VA Nebraska/ West Iowa HCS	S	06/19/2012	Remedial Actions: Establish research-specific plans; review research safety plans annually; conduct annual drills to test effectiveness research-specific plans; document semiannual chemical inventory review; ensure affiliate oversight; establish SOP for reporting; establish BSL-3 lab safety plan. CASE CLOSED.
25	02	Bath	R	07/23/2012	Remedial Actions: Update Organization Chart; conduct required annual subcommittee reviews ; conduct quality assurance reviews of publications; revise MOU or maintain administrative files for all human subject research protocols; records R&DC meeting vote counts accurately. CASE CLOSED.
26	02	Canandaigua	H	07/23/2012	Remedial Actions: Revise HIPAA Authorization template; Re-visit study performed at a detox facility using non VA ICD and HIPAA authorization; educate investigators on need of CRADO waiver to do children research; document PO and ISO reviews of active protocols CASE CLOSED
27	02	Canandaigua	R	07/23/2012	Remedial Actions: Update Organizational Chart; Update and revise MOU between Syracuse VAMC and Canandaigua VAMC; R&DC must conduct annual review of all its subcommittees; ACOS/R&D must conduct an annual quality assurance review of publications; Meeting minutes must accurately reflect vote summaries. CASE CLOSED.
28	15	VA Kansas City Medical Center	I	07/23/2012	Remedial Actions: Limit folder access; inventory IT; revise HIPAA and make consistent w/ICD; HIPAA waiver for subject recruitment; correct de-identification code; ISO review in SOP; PO review exempt studies; PO report to IRB; PO backlog; incident reporting SOP; record retention SOP. CASE CLOSED
29	07	Augusta	H	07/24/2012	Remedial Actions: Research must notify PI when approval expires; ICD must contain all required elements; POC must sign and date ICD; PIs maintain master list; IRB minutes document determinations; No data collection after Authorization revoked; Research can't manage RCO. CASE CLOSED
30	07	Augusta	R	07/24/2012	Remedial Actions: Chair not WOC; ACOS not subcommittee chair ; No expedited review; ACOS to provide written notification to PIs; R&DC complete annual reviews of subcommittees; No electronic voting; Subcommittees complete required activities; satisfy requirements annual quality reviews. CASE CLOSED
31	06	Hampton	I	08/13/2012	Remedial Actions: Ensure HIPAA authorizations or documented waivers for all research use of PHI. CASE CLOSED
32	23	Sioux Falls	A	08/21/2012	Remedial Actions: Ensure IACUC documentation and assessment of annual overheat test; remove extension cord; removed locking mechanism on emergency exit; replace threshold on exterior emergency exit door. CASE CLOSED.
33	23	Sioux Falls	S	08/21/2012	Remedial Actions: Conduct annual drills to assess research-specific security plan; SRS review of drill results; SRS review of multi-disciplinary vulnerability assessments; SRS documentation of subcommittee and programmatic activities. CASE CLOSED.
34	20	Boise VAMC	H	09/10/2012	Remedial Actions: Revise and update HRPP SOPs; ensure required representation to IRB of record; require use of photographs or video/voice recordings consent form; PO conduct required reviews.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
35	20	Boise VAMC	R	09/10/2012	Remedial Actions: Conduct annual review of subcommittees, programs, of IRB exempt research; establish and implement SOPs for all recurring and required processes; review and approve subcommittee minutes; remove ineligible voting members from the R&DC; and ensure individuals have VA appointments.
36	02	Syracuse	I	09/24/2012	Remedial Actions: Unsecured shred bins with exposed VASI; unsecured PHI in an interview room; EILs; unencrypted VASI on CDs; HIPAA Authorization template missing required element; incomplete waiver of HIPAA Authorization; ISO review; SOPs; undocumented research data repository. CASE CLOSED.
37	03	VA New York Harbor HCS	H	10/01/2012	Remedial Actions: Review and revise HRPP SOP to be consistent with VA policies; revisit IRB approval expired protocols to ensure research activities not conducted during lapse period; make draft minutes available for review within 3 weeks of the meeting; committee members complete required training; PO documentation of review. CASE CLOSED.
38	03	VA New York Harbor HCS	R	10/01/2012	Remedial Actions: Document R&DC activities in minutes; ensure approvals are granted only after all committees have approved project; ensure committee Chairs are appointed for appropriate term; conduct continuing reviews on all exempt protocols; ACOS/R&D letter to PI state research can be initiated; document annual reviews. CASE CLOSED.
39	11	Indianapolis	H	10/02/2012	Remedial Actions: Appoint VA representatives to all IRBs of record; IRB roster to identify members and alternates; HIPAA waivers to be requested and approved prior to CPRS data mining; grant Cat #4 exemptions properly; ensure compliant forms, templates, and records destruction language. CASE CLOSED
40	11	Indianapolis	R	10/02/2012	Remedial Actions: RDC must conduct continuing reviews of IRB exempt protocols; RDC must separate VA from non-VA research; RCO may not be a member of the SRS and IACUC; there must be an accurate protocol list; must update ORO of all IRB changes within 30 days. CASE CLOSED.
41	22	VA Loma Linda HS	I	10/15/2012	Remedial Actions: Waiver of HIPAA authorizations for recruitment from VA records; document all HIPAA authorization waivers; encrypt all laptops. CASE CLOSED.
42	12	Madison	A	10/23/2012	Remedial Actions: Ensure properly constituted IACUC; conduct triennial reviews at appropriate intervals; establish an MOU with affiliate; establish local SOP on reporting; IACUC review and documentation of annual overheat test; report Departures in semiannual reports. CASE CLOSED.
43	12	Madison	S	10/23/2012	Remedial Actions: Establish MOU with affiliate; conduct and document semi-annual chemical inventory; review access records weekly; review status of personnel with access to labs semi-annually; document SRS procedures consistently; establish SOP for reporting.
44	07	Atlanta	H	11/05/2012	Remedial Actions: IRB review criteria for expediting CR studies; ensure risk determination documented; IRB SOP update and revisions; apply for CRADO Waiver; revise ICD template language. All required actions completed. CASE CLOSED.
45	07	Atlanta	R	11/05/2012	Remedial Actions: Revise system and review exempt protocols; Revise SOPs; Complete annual reviews of subcommittees and quality reviews; Re-assess RCO functions. All actions completed. CASE CLOSED.
46	17	VA Central Texas HCS	I	11/05/2012	Remedial Actions: Terms for VA information on external systems; list affiliate IT equipment; correct HIPAA template, authorizations, SOPs (HIPAA waivers), 1058.01 reporting; study approval, waiver requests, privacy policy, records retention, repositories; direct ISO/PO reports; retain original records. CASE CLOSED.
47	07	Augusta	I	12/03/2012	Remedial Actions: Unencrypted VA laptop w/o waiver; Personal laptops onsite for research w/o permission; EILs; HIPAA Authorization template missing required elements; incomplete or non-existent waiver of HIPAA Authorizations; PO review; SOPs; undocumented research data repository. CASE CLOSED.
48	17	VA South Texas HCS	A	12/04/2012	Remedial Actions: Establish procedures for reporting noncompliance; ensure that deviations are scientifically justified; update whistleblower policy; ensure that all IACUC members participate in the Occupational Health Program. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
49	17	VA South Texas HCS	S	12/04/2012	Remedial Actions: review of weekly access records; establish procedures for reporting; semiannual inventory of hazardous chemicals; document the multidisciplinary vulnerability assessment; SRS membership; review the research security plan; establish an MOU for the use of the IBC
50	02	Albany	H	01/14/2013	Remedial Actions: Update HIPAA template; make determination of research activity on lapsed protocol; update IRB SOPs; complete CITI training; and update IRB appointment letters. CASE CLOSED.
51	02	Albany	R	01/14/2013	Remedial actions: develop process to ensure all committee approvals completed prior to R&DC approval; ACOS must notify PIs of continuing review approvals; complete R&DC assessments; approve subcommittee SOPs; accurately record R&DC minutes; update appointment letters. CASE CLOSED.
52	16	Gulf Coast HCS	H	01/14/2013	Remedial Actions: Revise SOP; revise consent template. CASE CLOSED.
53	16	Gulf Coast HCS	R	01/14/2013	Remedial Actions: Add MCD, ISO and PO to the appropriate committees of record in New Orleans VAMC. CASE CLOSED.
54	19	VA Salt Lake City HCS	I	01/14/2013	Remedial Actions: Obtain approvals for VASI on external information systems or remove it; obtain required HIPAA Authorizations or waivers of HIPAA Authorization for use and disclosure of PHI. CASE CLOSED.
55	21	San Francisco VAMC	H	01/14/2013	Remedial Actions: HRPP must separate VA vs. non-VA research; obtain CRADO child waiver; revise SOPs. IRB must review non-Veteran enrollment justification; prohibit cold-calling; revise ICD template; require VA 10-3203; document expedited actions. PO/ISO must provide IRB summary reports. CASE CLOSED.
56	21	San Francisco VAMC	R	01/14/2013	Remedial actions: Ensure all research is reviewed before granting approval; improve program and subcommittee reviews; establish SOPs for all recurring processes; remove ineligible R&DC members; approve final subcommittee minutes; ensure training and research scopes of practice are implemented. CASE CLOSED.
57	04	Philadelphia	A	01/15/2013	Remedial Actions: Report and document annual overheat test; update whistleblower policy; ensure properly constituted IACUC; ensure participation in the Occupational Health Program; establish procedures for reporting noncompliance. CASE CLOSED.
58	04	Philadelphia	S	01/15/2013	Remedial Actions: Establish research-specific plans; annual review of emergency response plans; review results of multidisciplinary vulnerability assessments; weekly review of access records; semi-annual review of personnel access; establish procedures for reporting. CASE CLOSED.
59	22	VA Loma Linda HS	H	01/15/2013	Remedial actions: IRB to re-review all IND studies that were inappropriately reviewed at CR; IRB must ensure the IRB meeting minutes document all members (voting and non-voting) who have attended by teleconference or videoconference; Remedial actions complete, CASE CLOSED.
60	22	VA Loma Linda HS	R	01/15/2013	Remedial Actions: Facility must ensure all voting members of the RDC are compensated full-time or permanent part-time Federal employees; the RDC must cease the practice of expedited reviews; the RDC must conduct an annual review of the VA CIRB. CASE CLOSED.
61	21	VA Pacific Islands HCS	H	02/05/2013	Remedial actions: Supplemental-remedial IRB review to distinguish VA from non-VA elements of collaborative human subject research. CASE CLOSED.
62	21	VA Pacific Islands HCS	R	02/05/2013	Remedial actions: Establish R&DC processes to distinguish VA from non-VA research, re-review collaborative research protocols, and ensure negotiated agreements are reviewed by OGC; establish SRS or seek policy waiver; and review CIRB minutes. MOU developed in collaboration with the OGC STAR group.
63	08	Miami	I	02/11/2013	Document VA data on external IT systems; approval for VASI outside VA and on mobile devices; encrypt laptops; list affiliate IT equipment; revise HIPAA template, SOP; get valid HIPAA or waiver for study; sign form 10-3203; information security plan; amend ISO and PO review; records retention. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
64	01	White River Junction	H	02/19/2013	Remedial Actions: Staff education, a coordinated review must be conducted with CPHS to reconcile all relevant SOPs, facility must ensure research is halted when IRB approval expires, update SOPs regarding determination of non-human research, modify meeting minutes. CASE CLOSED.
65	01	White River Junction	R	02/19/2013	Remedial Actions: Staff education, R&DC procedures must be reviewed and strengthened, tracking meeting attendance to ensure that quorum is maintained, minutes format, annual review of subcommittees and research programs must include all required elements, ACOS must conduct quality reviews. CASE CLOSED.
66	22	VA Southern Nevada HS	H	02/20/2013	Remedial Actions: None Required. CASE CLOSED
67	07	Charleston	H	02/26/2013	Remedial Actions: SOPs; meeting quorum; COI recusal; use of expedited review; ISO and PO review; and templates of consent and HIPAA authorization. CASE CLOSED.
68	07	Charleston	R	02/26/2013	Remedial Actions: Revising SOP; conducting business only at convened meetings; maintaining accurate active protocol list; conducting continuing review of IRB exempt protocols; and reviewing manuscripts prior to being submitted for publication. CASE CLOSED.
69	12	Chicago HCS	H	03/18/2013	Remedial actions: Facility must obtain LOU with Affiliate for compounding investigational drugs/placebos for VA research studies; Facility must ensure VA Form 10-9012 is present in health record of all subjects involved in investigational drug studies, as appropriate. CASE CLOSED.
70	12	Chicago HCS	R	03/18/2013	Remedial actions: RDC must review CIRB minutes and do an annual review; ACOS must send notifications for all research; RDC must notify ACOS of approved research in writing; system to review publications and presentations; record keeping; ACOS approval of scopes of practice. CASE CLOSED.
71	21	VA Palo Alto HCS	I	03/18/2013	Remedial Actions: MOU/ISA; System Security Plan; IT system backups; undocumented research IT systems; EILs; unencrypted VASI on CDs; ICF and HIPAA Authorization template; incomplete waiver of HIPAA Authorization; ISO and PO review roles and process; SOPs; undocumented research data repositories.
72	17	VA North Texas HCS	H	03/26/2013	Remedial Actions: PO/ISO to provide summary reports; adhere to VHA SAE policy; update local reporting policies; separate VA from affiliate research; update local research pharmacy procedures; update and educate PIs on revised administrative procedures; IRB consider review practices.
73	17	VA North Texas HCS	R	03/26/2013	Remedial Actions: Assess resource needs and advise MCD; ACOS notification to PI when research can begin; ACOS quality assurance reviews of publications, CRADAS, scopes of practice; R&DC program reviews; reviews of IRB-exempt research; compliance meeting minutes and rosters; research training.
74	07	Columbia	A	03/26/2013	Remedial Actions: Include all risk personnel in the Occupational Health and Safety Program; establish SOP for reporting noncompliance.
75	07	Columbia	S	03/26/2013	Remedial Actions: IBC review of rDNA; annual review of Safety Plan and Chemical Hygiene Plan; review of Emergency Preparedness Plan and Security Plan; annual drills; SRS review of the multidisciplinary vulnerability assessment; review of access records; MOU for offsite research; SOP for reporting.
76	16	Muskogee	H	03/26/2013	Remedial Actions: Ensure: SOP of IRB of record is available & HRPP, SOPs & MCMs, are current & consistent with VHA policies; appoint 2 VA employees as reps to the IRBs at OUHSC OR obtain waiver from CRADO; IRB must document waivers of ICD & HIPAA authorization in minutes or in IRB protocol file.
77	16	Muskogee	R	03/26/2013	Remedial Actions: R&DC ensures: annual evaluations of research programs & subcommittees are conducted; business conducted only at convened meetings, & approval letter not issued prior to review & approval by the convened R&DC; projects which are not VA research are not voted on to approval.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
78	15	Wichita	I	04/08/2013	Remedial Actions: IRB document waivers of authorization; reapply for waiver of HIPAA authorization. CASE CLOSED.
79	05	VA Maryland HCS	H	04/15/2013	Remedial actions: Revise IRB SOP on suspension termination; review training on HIPAA waiver; VA member present for VA research review; revise SOP and on train on non-Veteran research subjects; revise SOP and train on SAE, UPR, reconciling protocol, ICD, and HIPAA authorization; revise COI policy
80	05	VA Maryland HCS	R	04/15/2013	Remedial Actions: Restriction on use of expedited review; complete all subcommittee and program reviews; R&DC & IRB members complete HRP training, R&DC roster must link members and alternates; subcommittee membership must be properly constituted; SRS minutes must use prescribed format; MCD should assess RCO duties; revise SOPs.
81	06	Durham	S	04/16/2013	Remedial actions: Facility must conduct drills to test security plan; facility must revise reporting policy to fully comply with Handbook 1058.01. CASE CLOSED.
82	06	Durham	A	04/16/2013	Remedial Actions: None Required. CASE CLOSED.
83	18	Southern Arizona VA HCS	H	04/22/2013	Remedial actions: Revisions of SOPs (and associated processes) have addressed and resolved most of the Required Actions; development and execution of an MOU appears to address remaining actions, pending ORD/OGC review. CASE CLOSED.
84	18	Southern Arizona VA HCS	R	04/22/2013	Remedial actions: Seek CRADO approval for international research. CASE CLOSED.
85	07	Birmingham	H	04/23/2013	Remedial Actions: SOP; record retention in ICD; subjects dating ICDs; protocol exemption; substantive change approval; expedited review eligibility category in minutes; documentation of vote; and noncompliance determination. CASE CLOSED.
86	07	Birmingham	R	04/23/2013	Remedial Actions: SOP; R&DC Chair election; annual reviews; review of manuscripts prior to publication; review of exempt protocols; and voting via emails. CASE CLOSED.
87	05	Martinsburg VA Medical Center	I	05/06/2013	Remedial actions: Facility CIO approval of personally owned IT equipment, Background checks for study monitor direct access to VA network, revise release of data procedures for extramural research, SOPs, retention of electronic research data upon staff departure, waivers of HIPAA Authorization
88	09	Lexington	A	05/07/2013	Remedial Actions: Remediate miscellaneous animal facility deficiencies. CASE CLOSED.
89	09	Lexington	S	05/07/2013	Remedial Actions: Establish a research-specific security plan; remediate miscellaneous laboratory deficiencies. CASE CLOSED.
90	01	Togus	H	05/13/2013	Remedial actions: Ensure only an officially designated and properly convened IRB reviews and approves human subject research; Ensure human subject protocols, ICDs, and HIPAA authorizations are consistent with one another; Ensure IRB approval before subjects contact occurs; and establish SOPs.
91	01	Togus	R	05/13/2013	Remedial actions: Harmonize program documents to reflect authorized committees of record; develop and maintain updated R&DC membership listing; implement SOPs for all recurring processes to include protocol reviews; discontinue expedited review processes; and approve final subcommittee minutes.
92	01	Manchester	H	05/15/2013	Remedial Actions: Appoint representatives to each IRB of record; ensure IRB composition meets regulatory and policy requirements; develop SOPs for all required processes and agreements; comply with prohibited recruitment practices; and re-assess HIPAA authorization waivers.
93	01	Manchester	R	05/15/2013	Remedial Actions: Make resource recommendations based on evaluation of the research program; conduct QA reviews; remove ineligible R&DC members; ensure representation to affiliate IRBs; develop and implement SOPs; discontinue expedited review processes; and improve and approve meeting minutes.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
94	05	DC VAMC	H	05/20/2013	Remedial Actions: Educate on HIPAA Waivers and Authorizations, including non-Vets in VA research, and VA vs. non-VA research; re-review & approve minutes not approved by convened IRB; revise SOP for recurring processes; revise HIPAA and ICD templates; review specimens collected from dead Vets. **NOTE: OMITTED IN ERROR FROM SECOND QUARTER REPORT.**
95	05	DC VAMC	R	05/20/2013	Remedial Actions: Revise R&DC subcommittees' rosters; R&DC conduct annual evaluations of its subcommittees; reconcile appointment terms of primary and alternate members on R&DC; members complete mandatory training; R&DC suspend activity on protocols lacking subcommittee approvals; revise org chart. **NOTE: OMITTED IN ERROR FROM SECOND QUARTER REPORT.**
96	06	McGuire Veterans Affairs Medical Center	H	05/21/2013	Remedial Actions: SOP; IND delivery to pharmacy; research-related injury language in ICD; and protocol exemption. CASE CLOSED.
97	06	McGuire Veterans Affairs Medical Center	R	05/21/2013	Remedial Actions: Policy for review of manuscripts prior to publication. CASE CLOSED.
98	20	VA Puget Sound HCS	I	06/10/2013	Required Actions: Put air-gapped network terms in SSP; correct unapproved use of personal laptop; DAS OIS approval of unencrypted laptops; properly dispose VASI; account for non-VA IT; fix HIPAA authorizations; correct "prep to research", PO, reporting, and record retention policies and practices.
99	22	VA San Diego HS	H	06/10/2013	Provisional (draft) findings: delayed preparation and review of IRB minutes; insufficient information to justify waivers; IRB appointment/roster irregularities; deficiencies in IRB minutes; use of fetal tissue in VA research; inadequate RCO reporting to the IRB. CASE CLOSED.
100	22	VA San Diego HS	R	06/10/2013	Remedial Actions: R&DC must improve its own meeting minutes and approve final minutes from each of its subcommittees; ACOS/R&D must conduct QA review of all agreements in support of the research program; and the RCO must initiate all required reports of apparent serious or continuing noncompliance. CASE CLOSED.
101	12	Madison	H	06/11/2013	Remedial Actions: ISO/PO reports to IRB prior to approval; data repositories must be compliant with 1200.12; ICD template-research injury statements and access for Federal agencies; current research pharmacy files; compliant HIPAA template language; signed ICDs into CPRS; current investigator files
102	12	Madison	R	06/11/2013	Remedial Actions: Re-review protocol #2011-0843; VA research is approved by the RDC; consistent collaborative systems in place; RDC meeting minutes accurately record actions; RDC Chairperson is elected; approve VA CIRB minutes; perform annual CIRB review; update MCD/PI publications review.
103	15	St Louis	A	06/18/2013	Remedial Action: Review whistleblower policy. CASE CLOSED.
104	15	St Louis	S	06/18/2013	Remedial Actions: Review the Chemical Hygiene Plan annually; conduct annual drills; register IBC; review local policies.
105	05	Martinsburg VA Medical Center	H	06/19/2013	Remedial Actions: ISO and PO to provide summary reports to the IRB and ISO and PO must attend IRB meetings and complete human subjects protection training, revise SOPs accordingly.
106	05	Martinsburg VA Medical Center	R	06/19/2013	Remedial Actions: Update R&DC approval process; update MOU; update organizational chart and FRC reporting lines; follow presentation approval processes; and evaluate auditing program, revise SOPs accordingly.
107	09	Mountain Home	H	07/08/2013	Remedial actions pending: approval letters/minutes to include expedited category; participation of non-Veterans to be documented; MCD to be notified directly of noncompliance; amendment justifications to be required; CR application to include all requirements; remedial actions complete, CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
108	09	Mountain Home	R	07/08/2013	Remedial actions: Facility to ensure updated IRB rosters are provided to ORO; ACOS/R to ensure animal studies receive approval notifications; facility to update training requirement SOPs for consistency; R&DC to ensure annual subcommittee review is complete. CASE CLOSED.
109	06	W.G. (Bill) Hefner VA Medical Center	R	07/09/2013	Remedial Actions: R&DC conduct business with quorum; ensure SRS functioning in compliance with VHA policies. CASE CLOSED
110	12 NE	Hines	A	07/15/2013	Remedial Actions: Revise Whistleblower policy; establish a policy for reporting noncompliance to external agencies. CASE CLOSED.
111	12 NE	Hines	S	07/15/2013	Remedial Actions: Weekly review of access records; review of research specific plans; review of drills; review of annual multi-disciplinary vulnerability assessment.
112	23	VA Nebraska/West Iowa HCS	H	07/16/2013	Remedial Actions: Retain all required records (initial versions of tabled submissions returned to PIs); document eligibility categories for expedited IRB actions (i.e., in minutes and letters to PIs). CASE CLOSED.
113	23	VA Nebraska/West Iowa HCS	R	07/16/2013	Remedial Actions: R&DC must approve all subcommittee final minutes; must not use expedited review process; must conduct all required annual reviews; ACOS must document QA reviews of other agreements; clinicians must have an approved Scope of Practice; all staff must complete all required training.
114	03	Northport	H	07/22/2013	Remedial Actions: Educate IRB staff re: COI, re-review study; ensure documentation of controverted issues and resolution; IRB reviewer education of submitted study documents for consistency. CASE CLOSED.
115	03	Northport	R	07/22/2013	Remedial Actions: Review of all existing agreements; revise subcommittee composition, revise rosters; human subjects protection training by R&DC members; signatures on written notifications.
116	03	Bronx	A	08/06/2013	Remedial Actions: Revise Whistleblower Policy. CASE CLOSED.
117	03	Bronx	S	08/06/2013	Remedial Actions: Conduct an annual multidisciplinary vulnerability assessment; ensure drills to test safety and security plans; establish a research-specific security plan.
118	21	VA Sierra Nevada HCS	H	08/12/2013	Remedial actions: Revise SOPs; ensure ICDs include all required information and statements; document and communicate IRB decisions; provide list of approved studies investigational drugs to pharmacy; and update FWA.
119	21	VA Sierra Nevada HCS	R	08/12/2013	Remedial Actions: Request RAP to address deficiencies involving the review of programs/committees, MOUs, CRADAs; ACOS must conduct QA reviews; improve time to complete subcommittee minutes; maintain committee membership lists; review internal policies; review committee business practices.
120	09	Memphis	H	08/19/2013	Remedial Actions: Conduct IRB meetings with at least one non-scientific member present; review all lapsed protocols to determine if work continued during lapse and assess non-compliance; ISO/PO timely review of all protocols; update IRB roster; revise RCO audit structure; revise forms.
121	09	Memphis	R	08/19/2013	Remedial actions: R&DC must review VA CIRB meeting minutes; R&DC must do an annual review of the VA CIRB; R&DC must not allow contingent approvals; the R&DC must give the ACOS/R a written list of protocols approved; the ISO/PO must provide timely reviews.
122	01	VA Boston Healthcare System	I	08/19/2013	Remedial Actions: System Security Plan update; overly permissive logical electronic access to PHI; CD/DVD encryption; IT system backups; EILs; HIPAA Authorization missing required statements; incomplete documentation of waivers of HIPAA Authorization; SOPs; undocumented research data repositories.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
123	23	Fargo	I	09/09/2013	Remedial Actions: Ensure use of e-mail encryption; remove VASI from affiliate systems; revise HIPAA authorizations and Waiver of HIPAA authorization; revise SOPs; require the use of standalone HIPAA authorization; ensure ISO/PO reviews are submitted to IRB; ensure mandatory trainings are complete.
124	23	Sioux Falls	I	09/09/2013	Remedial actions: Document VASI on OE in VA agreement; remove VASI from shared drive; sanitize palm pilots; encrypt laptop; secure passwords; logs for IT closets; list OE in inventory; revise HIPAA template and study authorizations; revise SOPs; revise HIPAA waivers; ensure ISO/PO reviews
125	16	Jackson	H	09/24/2013	Remedial Actions: SOP; HIPAA authorization for exempt protocols; ICD on treatment for injury; documentation for consent waiver; IND log, separate storage, and label for specific studies; HIPAA waiver while requesting written ICD; and miss info in ICD on specimens for future research.
126	16	Jackson	R	09/24/2013	Remedial Actions: SOP and policies; organizational chart; chair election; annual review of VA CIRB; and review of publications.
127	10	Dayton	I	10/07/2013	Remedial Actions: Systemic absences of documentation for waivers of HIPAA Authorization approvals; ISO and PO review process; IRB SOPs on waivers of HIPAA Authorization; RCS; unapproved use of personal IT equipment for VA use; electronic folder permissions with PHI open to all staff.
128	15	VA Kansas City Medical Center	A	10/15/2013	Remedial Actions: Establish MOU with affiliate for shared oversight of animal research; ensure presentation of semi-annual IACUC self-assessments to MCD includes all required participants.
129	15	VA Kansas City Medical Center	S	10/15/2013	Remedial Actions: Ensure conduct of annual drills; ensure weekly review and documentation of access records.
130	02	Syracuse	H	10/21/2013	Remedial Actions: Revise HIPAA and Informed Consent Document templates; document processes are in place for reviewing and reporting of non-compliances; provide justification for inclusion of non-Veterans in VA research; conduct evaluations of facility's outreach program.
131	02	Syracuse	R	10/21/2013	Remedial Actions: Update CIRB MOU; conduct adequate annual quality assurance reviews; ensure use of VA e-mail for conducting VA business; ensure approvals from all subcommittees are in place prior to R&DC approval; protocols/amendment approved by electronic voting must be reviewed
132	10	Cleveland	R	10/22/2013	Remedial Actions: Final- Develop procedure for publication review; submit all RCO audit reports to the RDC; update all appointment letters; refine ACOS annual QA reviews; ensure RDC conducts annual review of exempt protocol.
133	16	Oklahoma City	H	10/22/2013	Remedial Actions: SOPs; event reporting; PO and ISO review summaries to IRB; alternate member assignments, presence of VA representative at convened meetings; timely meeting minutes; expedited review procedures; VA appointment letters.
134	16	Oklahoma City	R	10/22/2013	Remedial Actions: Update SOPs; update organizational chart; review publications; R&DC review of exempt protocols; recusal recording.
135	21	VA Central California HCS	H	10/28/2013	Remedial Actions: revise policies to ensure IRB approval letters include required documentation of the eligibility categories for expedited actions. Corrective action completed. Case Closed.
136	21	VA Central California HCS	R	10/28/2013	Remedial Actions: Request RAP to address deficiencies involving the review of SRS business practices; review laboratory practices; harmonize "in lieu of" subcommittee documentation; maintain committee membership lists; and maintain written procedures for all recurring processes.
137	04	VA Pittsburgh HCS	I	11/04/2013	Due to travel restrictions, this site visit was postponed. CASE CLOSED
138	15	Columbia	H	11/19/2013	Remedial actions: revise HIPAA authorization template; inform ORO within 30 days of IRB membership changes.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
139	15	Columbia	R	11/19/2013	Remedial actions: The R&DC must approve complete, unreacted sets of final HSIRB meeting minutes; the R&DC must establish a process to receive written notification of projects approvals from the subcommittees signed by a voting member.
140	17	VA Central Texas HCS	H	11/19/2013	Remedial Actions: Implement procedures to ensure minutes are completed and approved in a timely manner; correct procedural deficiencies in research pharmacies; establish processes to correct administrative procedural deficiencies (exemptions, waivers, and modifications).
141	17	VA Central Texas HCS	R	11/19/2013	Remedial Actions: RDC must ensure it only approves VA research; RDC must maintain SOPs for all recurring processes; RDC meeting minutes must document activities of convened meetings; and Scopes of Practice must be in place for all research staff.
142	03	Bronx	H	12/02/2013	Remedial Actions: Separate VA and non-VA in collaborative studies; conduct IRB business only with quorum; ensure non-affiliated member obtain WOC; update IRB SOP; ensure all human research is reviewed by VA IRB.
143	03	Bronx	R	12/02/2013	Remedial Actions: R&DC to perform annual evaluations of all subcommittees and programs; ACOS/R conduct adequate annual QA reviews; update R&DC SOPs; R&DC committee members complete all required training.
144	22	VA Long Beach HS	A	12/09/2013	Remedial Actions: Ensure participation of the VMO/VMC in MCD meetings; update whistleblower policy.
145	22	VA Long Beach HS	S	12/09/2013	Remedial Actions: Ensure consistency of chemical labeling; verify appropriate signage on microwave equipment.
146	08	VA North Florida/ South Georgia HCS	H	12/10/2013	Remedial Actions: Pending
147	08	VA North Florida/South Georgia HCS	R	12/10/2013	Remedial Actions: Pending
148	10	Cleveland	H	12/22/2013	Remedial actions: correct use of Category #4 exemptions; follow local SOP for expired protocols; correct injury statement in ICD template; ensure Pharmacy receives all required study documents; correct member designations on IRB roster.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS

ORO onsite technical assistance reviews constitute an additional proactive approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Summary

- 1 = Case Continuing from Previous Calendar Year
- 11 = New Cases – January 1 through March 31
- *11 = New Cases – April 1 through June 30
- 12 = New Cases – July 1 through September 30
- 6 = New Cases – October 1 through December 31
- 40 = Total New Cases in Calendar Year
- 41 = Total Cases (Continuing Plus New) in Calendar Year

* Includes 1 case omitted from Second Quarter Report.

Case	VISN	Facility	Focus	Date of Review	TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
1	22	VA Greater Los Angeles HS	A	06/15/2011	Follow-up to review and provide guidance on remedial actions from previous on-site review. New compliant animal unit HVAC system reliant upon yet-to-be installed facility-wide upgrades.
2	03	VA New York Harbor HCS	H	01/14/2013	Technical Assistance: Key issues addressed were improved IRB processes incl. initial reviews, content of IRB minutes, IRB review of substantive modifications, noncompliance reporting; improved protocol continuing review process; IRB exempt protocol determinations. CASE CLOSED
3	03	VA New York Harbor HCS	R	01/28/2013	Technical Assistance: Key issues addressed, Exempt protocol determinations; subcommittee meeting minutes review; determinations on use of identifiers in human subjects research; R&DC SOP revisions. CASE CLOSED
4	17	VA North Texas HCS	E	01/28/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
5	03	VA New York Harbor HCS	H	02/04/2013	Technical Assistance: Key issues addressed were improved IRB processes incl. expedited initial review; expedited continuing reviews; IRB review of substantive modifications; record management of amendments and IRB minutes for timely IRB review. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
6	21	VA Northern California HCS	E	02/05/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
7	06	Salem	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
8	06	Asheville	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
9	06	Durham	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
10	06	W.G. (Bill) Hefner	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
11	19	VA Eastern Colorado HCS	E	03/05/2013	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
12	20	VA Puget Sound HCS	E	03/26/2013	Technical assistance: To review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED
13	03	VA New York Harbor HCS	H	04/01/2013	Key issues addressed: management of expedited items on IRB agenda; pre-review of protocol submissions for completed paperwork; review of IRB meeting minutes to ensure complete documentation of actions; mentorship of IRB Chair. ORO observation of next IRB mtg. CASE CLOSED.
14	10	Dayton	H	04/24/2013	Technical Assistance: no remedial actions required. CASE CLOSED.
15	22	VA Greater Los Angeles HS	E	04/24/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
16	10	Cincinnati	H	04/25/2013	Technical Assistance: The ISO and PO were not completing their reviews and providing the IRB with a summary of their findings prior to the IRB review and approval; the RDC was not approving research with a committee vote once all RDC subcommittees had approved the research. CASE CLOSED.
17	02	Albany	R	05/06/2013	Key Issues: WOC processing, Research SharePoint, interdepartmental communications, Research Administrative staffing, data tracking systems, statistical software. CASE CLOSED.
18	03	VA New York Harbor HCS	H	05/06/2013	Key Issues: Management of Continuing Review submissions on IRB agenda; Management of Primary Review of protocol submissions; review of IRB meeting minutes; IRB review of substantive modifications; IRB review of collaborative studies; NERO observation of next IRB mtg. CASE CLOSED

Case	VISN	Facility	Focus	Date of Review	TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
19	01	Providence	E	05/13/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
20	03	VA New York Harbor HCS	H	06/03/2013	Key issues addressed: Management of Amendments and Continuing Review submissions on the IRB agenda; multiple revisions to the IRB agenda; procedures for conducting expedited continuing reviews; study recruitment plans and regulatory requirements; NERO observation of next IRB mtg. CASE CLOSED.
21	01	VA Boston HCS	H	06/14/2013	Remedial Actions: None - technical assistance on informed consent. CASE CLOSED.
22	01	Togus	E	06/18/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
23	17	VA Central Texas HCS	H	06/25/2013	Technical Assistance: Guidance provided regarding identification and management of collaborative research; separation of VA from non-VA research; role of R&DC and IRB; and record retention requirements. CASE CLOSED. NOTE: OMITTED IN ERROR FROM SECOND QUARTER REPORT.
24	03	VA New York Harbor HCS	H	07/01/2013	Technical Assistance: Topics covered included pre-review of protocol submissions for completed paperwork and other admin support of processes; review of IRB meeting minutes to ensure complete documentation of actions; mentorship of IRB Chair. NERO observation of next IRB mtg. CASE CLOSED
25	05	DC VAMC	H	07/08/2013	Key issues addressed: undocumented motions and votes on action items -many were "acknowledged;" types of HIPAA waivers (recruitment only, full authorization) were not specified; key documents were not provided to IRB members before the meeting. NERO will observe next IRB mtg. CASE CLOSED.
26	01	Northampton	I	07/31/2013	Technical Assistance: To review RIPP-related policies and procedures for the research program. CASE CLOSED.
27	01	Northampton	E	08/01/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED

28	05	DC VAMC	H	08/05/2013	Topics discussed: Alterations of informed consent, agenda management and distribution of all materials required to inform evaluation of 38 CFR 16.111 criteria, substantive review of potential or perceived COI. CASE CLOSED.
29	15	VA Kansas City Medical Center	E	08/20/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
30	15	VA Eastern Kansas (Leavenworth) HCS	E	08/22/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
31	03	VA New York Harbor HCS	H	09/09/2013	Recommendations: Improved management and tracking of administrative file documents; tracking of subject enrollment; IRB review of data repository requirements, process for de-identification of data, telephone recruitment procedures, and documentation of justifications for waivers of HIPAA and IC. CASE CLOSED.
32	05	DC VAMC	H	09/09/2013	IRB exempted a protocol without a description of the educational model being used & controversy about possible vulnerable participants. NERO recommended revisiting this determination. CASE CLOSED.
33	08	Miami	E	09/11/2013	Technical Assistance: Review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office, and progress towards audit goals. CASE CLOSED
34	03	VA New York Harbor HCS	M	09/23/2013	Technical Assistance: The Federal Policy on Research Misconduct; VHA Handbook 1058.02 ("Research Misconduct"); and applicable sections of VA Handbook 0700 ("Administrative Investigations"). CASE CLOSED.
35	05	DC VAMC	H	09/30/2013	Technical Assistance: consulted with MCD; addition/removal of agenda items; RCO, ISO, and PO non-receipt of IRB agendas or reviewer packets; and R&DC to evaluate contingencies on study #01630. CASE CLOSED.
36	05	DC VAMC	H	11/18/2013	Observations: IRB is unaware of their duties in re: review of noncompliance and SAEs per 1058.01; collaborative research is partially or not addressed at all; info security and privacy issues are often missed on protocol review. CASE CLOSED.

37	09	Huntington	E	11/19/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
38	02	Albany	E	12/04/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
39	05	DC VAMC	H	12/09/2013	Technical Assistance: IRB reviewed 2 VA studies without VA rep present; member complained about last minute initial review; IRB difficulty determining serious noncompliance; question re contractor statement of work text re: data destruction. CASE CLOSED
40	08	Orlando VAMC	I	12/17/2013	Technical Assistance: RISP to review information security and privacy policies and procedures for the research program.
41	05	DC VAMC	H	01/06/2014	Technical Assistance: Observed IRB meeting; pending.

TABLE 2. REMOTE RESEARCH COMPLIANCE REVIEWS

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Certain compliance cases can be evaluated and managed remotely through written communications with facility leadership and facility compliance personnel. Among these reviews are remote reviews of apparent noncompliance that have been identified by sources external to the facility's HRPP. Such sources include, but are not limited to, apparent noncompliance identified by ORO, by other VA offices, by government regulatory agencies, and by industry sponsors. Table 5 summarizes ORO's remote reviews of apparent noncompliance identified by such external sources. NOTE: Cases under the jurisdiction of additional offices (for example, OIG or FDA) or involving physical infrastructure improvements may remain open for extended periods.

Summary

- 43 = Cases Continuing from Previous Calendar Year
- 37 = New Cases – January 1 through March 31
- *36 = New Cases – April 1 through June 30
- 32 = New Cases – July 1 through September 30
- **55 = New Cases – October 1 through December 31
- 160 = Total New Cases in Calendar Year
- 203 = Total Cases (Continuing Plus New) in Calendar Year

* Includes 1 case misclassified in Second Quarter Report.
** Includes 2 cases misclassified in Third Quarter Report.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	07 MA	Atlanta	I	06/16/2010	A physician's assistant recorded patient data on a personal laptop for unknown purposes; then left the VA. Data return was requested. Destruction of the information could not be confirmed.	Remedial Actions: OIG criminal investigation; results pending.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
2	20	VA Puget Sound HCS	I	11/21/2011	NSOC reported vulnerability in what was thought to be a secure email system between the VA, an affiliate research institution and possibly 25 other sites related to bone marrow transplant studies. Research protocols permit transmission by fax not via email/list serv. AIB determined no breach of VASI	Remedial Actions: Affiliate immediately inactivated the listserv; AIB completed; transmit VASI by email only with encryption; improve information security/privacy training for research staff; increase RCO staff; enhance PO/ISO audits; evaluate new MOU with affiliate. CASE CLOSED
3	12	Madison	H	06/05/2012	Affiliate IRB and Eastern Cooperative Oncology Group reported enrollment of ineligible VA subjects and missed study labs for four participants enrolled in this multiple myeloma trial.	Remedial Actions: Study is now closed at the VA; remaining PI's studies restricted to 6 month continuing review and must have co-PI added; PI to receive additional human subjects training; studies to receive quarterly audits; participants notified of closure. Remedial action completed. CASE CLOSED.
4	23	Minneapolis	H	07/17/2012	Facility reported suspension of PI privileges to conduct research at VA facility. PI was not compliant in record keeping and carrying out basic protocol and ICD processes in a brain cognition study.	Remedial Actions: PI research privileges suspended then reinstated; New IRB application completed; Processes established for regulatory documentation and creation and maintenance of master subject list; Quarterly RCO audits for one year in all PI's studies; Remedial actions complete, CASE CLOSED.
5	01	VA Boston Healthcare System	H	07/24/2012	NSOC reported that during a research media encounter, a TBI/PTSD researcher permitted a photograph to be taken of a brain scan where the procedure date was visible in the image. Subject did not consent for release of PHI.	Remedial Actions: Staff education, VA Form 5345 provided to staff with education about it is required use if PHI is to be released; subject returned to the VA (had been out of country) and signed necessary forms. CASE CLOSED.
6	02	VA Western New York HCS	I	08/16/2012	NSOC reported two medical students were collecting data containing PHI for two projects on a personal laptop and transmitting the spreadsheet via a personal email account. It was subsequently determined the research had not been approved by the IRB; HRPP case 0060-528-H opened by NERO.	Remedial Actions: ISO scanned laptop and removed all data; education to medical students on use and security of VA data; one of PI's 2 active studies was terminated; other was suspended and may re-open with new PI. PI initially terminated; after training individual was allowed to function as sub-investigator. CASE CLOSED.
7	16	Shreveport	H	08/23/2012	Facility reported that a subject took 40 extra doses of the study medication Polyphenol E (Green Tea) in a prostate cancer study. Subsequent liver function studies were within normal limits. Enrollment of an ineligible subject also occurred.	Remedial Actions: Patient education on taking medication; ICDs signed on day obtained; patients screened in real time only; patient must bring study medications to first visit; pen must be used in medical record; reason for withdrawal must be noted. CASE CLOSED.
8	18	Phoenix VA HCS	I	09/07/2012	NSOC reported a previously unaccounted for sponsor laptop was missing. It was subsequently returned by a former NPC employee. A forensic analysis determined no PHI was found on the laptop.	Remedial Actions: A loan agreement between sponsor and NPC will be executed; sponsor-owned equipment will be inventoried; education to current staff. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
9	02	Syracuse	H	09/20/2012	Sponsor audit found five investigational drug (cetuximab) vials could not be accounted for on a Phase III Lung Cancer trial. Other findings include logs did not reflect the correct number of vials, dose of each treatment and investigational drug refrigerator not adequately labeled.	Remedial Actions: Drug vials located and disposed as per local policy; appropriate labeling of investigational drug refrigerator; log update to reflect vial inventory and dose for each treatment date; review other protocols dispensing drugs; audit all studies approved to dispense drugs. CASE CLOSED
10	11	Indianapolis	H	09/20/2012	Affiliate clinical trials monitoring committee found expired ICDs were used in an affiliate cancer biomarker study; 21 subjects did not sign or date the ICDs correctly; and 3 staff obtaining consent were not on the protocol.	Remedial Actions: PI voluntarily suspended enrollment until amendment is approved by IRB to update staff list; a Project Manager will provide oversight at all future outside events. CASE CLOSED.
11	03	VA New York Harbor HCS	H	10/19/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. No SAEs reported for VA subjects.	Remedial Actions: One patient was active at this site. He has been contacted and study medication stopped. CASE CLOSED.
12	23	VA Nebraska Omaha	H	10/23/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. No SAEs reported for VA subjects.	Remedial Actions: Discontinue the study medication, provide subjects follow-up information and conduct clinical follow-up of former subjects. CASE CLOSED.
13	12	Chicago HCS	I	11/07/2012	NSOC reported that a former research employee has data containing PHI stored offsite and the former researcher affiliate site is reluctant to release the data (electronic and hard copy) back to the VA.	Remedial Actions: Since VA still owns the data, all hard copy and electronic data were returned securely to the VA and stored with appropriate access controls. CASE CLOSED.
14	16	Central Arkansas VHS (Little Rock)	H	11/09/2012	Sponsor notified facility that CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy-VA Nephron-D) due to high potassium levels and acute changes in kidney function with combination treatment of losartan .	Remedial Actions: Notify all subjects; discontinue study drug; schedule return visits for subjects; IRB to review. CASE CLOSED.
15	19	VA Eastern Colorado HCS	H	11/09/2012	WRO inquiry, following NSOC report, confirmed the conduct of an unapproved retrospective chart review study; approximately 18 Veterans' medical records were accessed and de-identified data was abstracted, analyzed and published without IRB or R&DC approval.	Remedial Actions: Training provided to PI and fellow; development of in-service training; review of publication by ACOS. All actions completed. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
16	18	Southern Arizona VA HCS	I	11/13/2012	NSOC reported a non-GFE unencrypted laptop containing 73 research subjects PHI (names, SSNs, contact/health information) was stolen from a research monitor employed by the sponsor. A valid ICD and HIPAA Authorization was signed by each subject authorizing the sponsor as recipient of the PHI.	Remedial Actions: All subjects notified and offered 1 year credit monitoring; VHA Privacy Office determined data on the stolen laptop was not VA PHI. CASE CLOSED
17	09	Memphis	H	11/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial actions: Study team to stop study drug and transition subjects to standard of care. Remedial actions complete, CASE CLOSED.
18	17	VA North Texas HCS	H	11/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks. CASE CLOSED.
19	23	Minneapolis	H	11/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks. CASE CLOSED.
20	04	VA Pittsburgh HCS	H	11/15/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Study participants contacted and instructed on what drugs to stop taking; arrange exit visit; evaluate for safety and transfer participants to standard clinical care as soon as possible; send notification of study termination to participants; documentation in CPRS CASE CLOSED
21	06	McGuire Veterans Affairs Medical Center	H	11/15/2012	DMC for CSP study notified facility that two-drug study treatment in a diabetic nephropathy study was stopped by sponsor for safety concerns. In addition, the combination therapy failed to demonstrate efficacy in lowering risk of kidney disease progression.	Remedial Actions: Participants notified by phone and certified letter; Instructed to discontinue study medication; Returned to facility for exit study visit. All final visits completed, all study drug withdrawn. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
22	12 NE	Hines	H	11/16/2012	Sponsor terminated CSP #565 study due to safety concerns including acute kidney injury and hyperkalemia. (Study was to assess the effect of combination of an angiotensin converting enzyme inhibitor and an angiotensin receptor blocker on progression of kidney disease in patients with diabetes and proteinuria.)	Remedial Actions: Study staff to notify participants; study closed out . CASE CLOSED.
23	08	Tampa	H	11/23/2012	Facility reported that CSP is terminating the Nephron-D study CSP 565 due to safety concerns.	Remedial Actions: Study Treatments have be terminated. Most participants had their exit visit as recommended by CSP. CASE CLOSED.
24	11	Indianapolis	H	11/29/2012	Facility reported the CSP DMC recommended termination of a VA sponsored diabetes study due to risk associated with study drug. Facility had 35 subjects enrolled.	Remedial Actions: Study team to stop study drug and transition subjects to standard of care. CASE CLOSED.
25	21	San Francisco VAMC	I	11/29/2012	NSOC reported that data on an encrypted NPC laptop with no direct backup copy was rendered inaccessible due to system failure. Investigation revealed the laptop contained only non-sensitive basic science molecular assay data and draft manuscripts.	Remedial Actions: The laptop was sent to an internal VA forensics team for data recovery; data can be re-created from source; IT staff will ensure data is backed-up prior to laptop upgrades. CASE CLOSED
26	15	VA Kansas City Medical Center	H	11/30/2012	CSP Coordinating Center notified facility of the DMC's recommendation to close CSP Study 565 (treatment of diabetic nephropathy) due to subject safety concerns.	Remedial actions: Subjects to be taken off study drug; subjects to complete study exit visit; CASE CLOSED.
27	10	Cleveland	H	12/03/2012	DMC notified facility of termination of CSP 565 diabetic nephropathy study because of subject safety issue.	Remedial actions: Subjects to be taken off study drug and moved to standard of care treatment; Subjects to attend a study exit visit. CASE CLOSED.
28	15	VA Kansas City Medical Center	H	12/03/2012	Pharmaceutical sponsor notified facility of termination due to safety concerns of investigational drug study involving diabetic patients with Stage 4 chronic kidney disease.	Remedial Actions: Sponsor termination of study; subject notification to stop study drug and complete exit procedures. CASE CLOSED.
29	23	VA Nebraska/ West Iowa HCS	I	12/03/2012	NSOC reported a research employee mailed two Veteran's records to a sponsor without properly redacting information. It was subsequently determined only one Veteran's record was un-redacted.	Remedial Actions: Sponsor opened packet and de-identified the disclosed medical record; facility PO reviewed the HIPAA Authorization and ICD and determined sponsor was authorized to receive disclosed PHI. CASE CLOSED.
30	07	Charleston	H	12/05/2012	Facility reported that CSP is terminating the Nephron-D study (Diabetic Kidney Disease) due to safety concerns.	Remedial Actions: Study Treatments will be terminated as soon as feasible. All participants will be transferred to standard clinical care within 6 weeks. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
31	07	Columbia	H	12/05/2012	Facility reported that CSP is terminating the Nephron-D study (Diabetic Kidney Disease) due to safety concerns.	Remedial Actions: Study Treatments will be terminated as soon as feasible. All participants will be transferred to standard clinical care within 6 weeks; amendment submitted to convert study to passive follow-up. CASE CLOSED.
32	15	St Louis	H	12/05/2012	DMC recommended termination of a CSP diabetic nephropathy study because of a subject safety concern.	Remedial Actions: Subjects to terminate study drug; subjects to attend a study exit visit; Remedial actions complete, CASE CLOSED.
33	22	VA Loma Linda HS	H	12/07/2012	DMC reported subject safety issue related to one of the investigational agents in a CSP diabetic kidney disease study.	Remedial Actions: Subjects to be taken off study drug; subjects to complete a study exit visit. CASE CLOSED.
34	10	Cincinnati	H	12/11/2012	Pharmaceutical sponsor notified facility of DMC's termination due to safety concerns of an investigational drug study involving diabetic patients with Stage 4 chronic kidney disease.	Remedial Actions: Sponsor requested termination of study, stop subject enrollment and use of investigational drug; study close out pending; SAE reporting policies updated and distributed to research stakeholders; remedial actions complete. CASE CLOSED.
35	08	VA Caribbean HCS (San Juan)	H	12/13/2012	Facility Reported the early termination of CSP study (treatment of diabetic kidney disease) due to lack of efficacy and increase risk of acute serious adverse events.	Remedial Actions: Ensure that the PI followed all sponsor recommendations in a timely manner. All active participants completed the exit visit. CASE CLOSED.
36	20	Portland VAMC	H	12/13/2012	CSP Coordinator notified facility of early Termination of a VA CSP study (#565, treatment of diabetic nephropathy) due to safety concerns.	Remedial Actions: IRB approved the close-out procedures, allowing early termination of CSP #565. CASE CLOSED.
37	23	Iowa City	H	12/13/2012	Industry sponsor notified facility of an urgent safety concern in a Bardoxolone Methyl project (BEACON) examining the occurrence of renal events in patients with kidney disease and type 2 diabetes. Unclear how many SAEs involved VA subjects.	Remedial Actions: Subjects notified to stop taking study medication; post-treatment visits; study termination. CASE CLOSED.
38	23	Iowa City	H	12/14/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks. CASE CLOSED.
39	20	VA Puget Sound HCS	I	12/17/2012	NSOC reported research packet including medical information was sent to the incorrect Veteran; further information pending.	Remedial Actions: Veteran will be sent a notification letter; Research staff reminded to verify addresses and the contents of all research packets prior to mailing. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
40	01	VA Boston Healthcare System	I	12/18/2012	NSOC reported an unauthorized individual attempted (with refusals) to connect "hundreds of times" to the Million Veteran Program production server. It also appears the individual somehow changed the local security policy to allow him to act as part of the operating system.	Remedial Actions: It was subsequently determined incident was not attempts at unauthorized access; instead was part of server back-up process. There was no inappropriate access to the server and all back-ups are appropriately secured. CASE CLOSED.
41	01	VA Boston Healthcare System	I	12/18/2012	NSOC reported permissions on a research server were not limited to appropriate personnel; one file on this server contained passwords.	Remedial Actions: The share permissions have been corrected and the service account passwords have been changed. CASE CLOSED.
42	22	VA Greater Los Angeles HS	I	12/18/2012	NSOC reported four VA research consent forms containing PHI for a CSP CIRB study sent via UPS were received and signed for by research administration staff; however the package was subsequently lost and could not be located.	Follow-up report: Facility reported that the expected package was never sent. There was not a missing package at any time; was simply a miscommunication. No violation occurred. NSOC and facility closed ticket. CASE CLOSED
43	23	VA Nebraska/ West Iowa HCS	H	12/18/2012	CSP halted Protocol 565 (Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) due to high potassium levels and acute changes in kidney function with combination treatment of losartan and lisinopril.	Remedial Actions: Stop study treatments; evaluate subjects for safety and transfer from study medication to standard clinical care; complete all study exit visits within 6 weeks. CASE CLOSED.
44	04	Philadelphia	I	01/07/2013	NSOC reported unauthorized physical access of a VA researcher's office. Items were moved/rearranged; locked drawers were opened with keys that had been hidden. Per facility report, card-swipe access records found only housekeepers had entered the area. Documents were counted; none are missing.	Remedial Actions: Facility requires advance notice when Housekeeping needs access; PHI stored in locked filing cabinets; area accessible only to small number of staff; Housekeeping remain current on VA HIPAA Privacy and Security training. CASE CLOSED.
45	21	VA Palo Alto HCS	H	01/07/2013	Sponsor requested voluntary and temporary hold on patient enrollment following notification of (non-local) unanticipated adverse events involving an implanted (stent) device.	Remedial Actions: voluntary suspension of enrollment; IRB-approved letter to study subjects, informing of the device-related event(s) and directing discussion of risks and options with the PI; did not separate AEs from VAPAHCS subjects. CASE CLOSED.
46	08	Tampa	I	01/09/2013	NSOC reported transmission of 9 separate internal unencrypted messages containing PHI and PII related to 10 Veteran research participants.	Remedial Actions: All unencrypted messages deleted from sender and recipient's email boxes; PO provided training to the sender; sender's PKI certificates re-imported; ISO to re-check the sender's computer; HIPAA notification letters not required. CASE CLOSED.
47	20	Portland VAMC	I	01/09/2013	NSOC reported transmission of an internal unencrypted email containing PII.	Remedial Actions: No data breach has occurred. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
48	06	Salem	H	01/11/2013	Sponsor of an investigational lipid-lowering drug study reported to facility an SAE event outside the VA which local VA PI feels impacts the potential safety of local VA subjects. No local subjects ever enrolled. Study closed. CASE CLOSED	Remedial Actions: Study closed by the IRB, no local subject participation. CASE CLOSED.
49	08	Miami	I	01/11/2013	NSOC reported that an unlocked filing cabinet containing research PHI was brought to the loading dock and was left unsecured for two days. The filing cabinet contained research protocol information and a logbook including patient full name, date of birth, full SSN for 75 subjects.	Remedial Actions: Credit monitoring services were offered to 26 patients and next-of-kin HIPAA notifications for the 49 deceased subjects; staff training; Research Service added to facility employee clearance list; all PIs reminded of information security requirements. CASE CLOSED.
50	16	Houston	I	01/11/2013	NSOC reported an independent evaluator for an approved VA research protocol reported that their car was broken into and a backpack was stolen. The back pack contained two uncompleted study assessment packets containing the names and home telephone numbers for two non-Veteran study participants.	Remedial Actions: Backpack was found by a citizen and returned to the owner with all documents still in the backpack; determined no PHI left facility since names and phone numbers publicly available; RCO provided Information Security education. CASE CLOSED.
51	23	Iowa City	I	01/11/2013	NSOC reported research participant A reported receiving research participant information for four other research participants in the mail on a research study. The information included the names, social security numbers and testing information.	Remedial Actions: All subjects promptly returned study materials; the four Veterans were offered credit protection services; Research team mail process change two staff to verify letter's contents prior to sealing and mailing. CASE CLOSED.
52	01	VA Connecticut HCS	I	01/16/2013	NSOC reported research nurse brought home an audio recorder containing 59 patient voice interviews in order to upload them for transcription. Twenty of the files were placed on her home desktop computer.	Remedial Actions: Copies of the audio files were securely transferred to a folder on the VA network; voice recorder stored in a VA locked cabinet; audio files on the non-VA computer were securely overwritten with the assistance of the facility ISO. CASE CLOSED.
53	06	Durham	I	01/16/2013	NSOC reported transmission of internal unencrypted email containing PHI on 227 research subjects. No data breach occurred.	Remedial Actions: The message was deleted by both employees; both employees have PKI and understand the importance of encrypting messages with III; identifiers removed from database; spreadsheet password-protected. CASE CLOSED
54	12	Milwaukee	I	01/16/2013	NSOC reported an incorrect name was written on a Million Veteran Program consent form and given to a Veteran who saw the other Veteran's name. The Veteran returned the incorrect ICD to the facility and stated he had not noticed the error. Credit monitoring and/or HIPAA notification not required.	Remedial Actions: Subject re-consented with explanatory note-to-file; coordinators to double-check all ICDs to ensure correct Veteran's name; Veterans to verify their identity prior to signing ICD. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
55	00	VA Central Office	H	01/22/2013	CIRB reported that ICDs and HIPAA Authorizations in a CSP study of genetics in schizophrenia and bipolar illness were unsecured "for an extended period of time" after housekeeping waxed the floor of the research office during the holiday season.	Remedial Actions: Document review revealed no loss of documents; no one else had access to the unsecured area. Housekeeping staff received Privacy and Security training; key control procedures were improved. PHI is now stored in locked filing cabinets. CASE CLOSED.
56	19	VA Salt Lake City HCS	H	01/23/2013	RISP reported lack of informed consent or waivers of informed consent from all Veteran participants (decisionally-impaired) in a caregiver study and referred to WRO for follow-up.	Remedial actions: Waivers of the requirements for HIPAA authorization and documentation of informed consent. CASE CLOSED.
57	00	VA Central Office	H	01/29/2013	CIRB reported a facility participating in a CSP study of genetics in schizophrenia and bipolar failed to maintain appropriate documentation of informed consent for one participant and failure to report the noncompliance in a timely manner both to the IRB and to the Local Site Investigator.	Remedial Actions: Study coordinator given additional training on informed consent requirements. There was no harm to the subject. CASE CLOSED.
58	17	VA South Texas HCS	I	01/30/2013	ORO RIPP team received a Veteran's complaint that his request to withdraw from the MVP study was not responded to in a timely manner. Return of original ICD/HIPAA Authorization requested, assurance blood sample is destroyed and medical records not accessed. Veteran threatening legal action.	Remedial Actions: RIPP acknowledged receipt to Veteran, offered reassurance; coordinating center confirmed receipt of withdrawal request; ORO advised facility of RCS requirement; PI explained to Veteran reason original records couldn't be returned; no facility noncompliance. CASE CLOSED
59	06	McGuire Veterans Affairs Medical Center	H	02/04/2013	Sponsor visit for cardiac imaging study discovered that ECG, labs, and exam done prior to consent.	Remedial Actions: Subject re-consented; Safeguards now in place to monitor and confirm consent is obtained prior to tests/procedures of any kind. CASE CLOSED
60	12 NE	Hines	I	02/04/2013	NSOC reported a PI moved study documentation to her office at the University affiliate. Study information was subsequently returned in its entirety to facility and stored in a secure location.	Remedial Actions: PI education on proper handling of research records; facility established on-site secure storage space for research records. CASE CLOSED.
61	20	Portland VAMC	I	02/07/2013	NSOC reported storage of VASI on non-GFE and potential unauthorized disclosure to the affiliate of two Veteran's PHI; also failure to create a medical record for participants.	Remedial Actions: Two Veterans will be offered credit protection services; data access approval for affiliate staff; amendment to obtain IRB approval for data storage on non-GFE; create medical records; all backup files at the affiliate deleted; PI will not request storage of VA data at affiliate; Hard copy data retained. CASE CLOSED
62	03	VA New York Harbor HCS	I	02/11/2013	NSOC reported a camera/video recorder used for a study was stolen. One research subject was identifiable only by face and date; no other III was included.	Remedial Actions: Participant was notified by phone and a notification letter; when possible, lock recording media separately from the recording device. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
63	00	VA Central Office	H	02/12/2013	Participating facility notified CIRB of failure to maintain appropriate documentation of informed consent for one participant in a CSP mental health genetics study and failure to report the noncompliance in a timely manner as required. Facility attempted without success to re-consent the subject.	Remedial Actions: Subject was administratively withdrawn from the study; LSI developed a plan to review status of all enrolled participants no less than monthly with the study team. VA Central IRB accepted the response. CASE CLOSED.
64	01	VA Boston Healthcare System	H	02/13/2013	Anonymous complaint from veteran who alleged that opt-out "consent" was used for a study of "Life Goals Psychotherapy for Depression and Cardiometabolic Risk in Primary Care Mental Health Integration."	Remedial Actions: The complaint was not substantiated. CASE CLOSED.
65	00	VA Central Office	H	02/14/2013	VA CIRB suspended enrollment in a CSP pneumonia treatment study at one facility due to lack of required documentation and study oversight by the LSI.	Remedial Actions: The LSI submitted progress, protocol deviation, and SAE reports. An RCO audit was completed. The PI clarified eligibility requirements for the study. The VA Central IRB found there was no serious noncompliance and lifted enrollment suspension. CASE CLOSED.
66	04	Erie	P	02/14/2013	For Cause Remote Review of alleged unauthorized research conducted at Erie VAMC retrospective review of results for 100 patients with Endoscopic Single Portal Carpal Tunnel Release procedure using FDA approved, marketed device.	Remedial Actions: Notification sent to MCD Erie VAMC requesting a review of the activities and a description of the results of the review in an Issues Brief. Surgeon counseled regarding research activity vs. QA/QI review of surgical intervention; publication not authorized by MCD. CASE CLOSED.
67	20	Portland VAMC	I	02/27/2013	NSOC reported four missing original informed consent forms containing PHI (full names, consent dates, last 4 SSN, name of study) for three Veterans enrolled in a study of non-small cell lung cancer. Three forms were found; the other was thought to be a re-consent that remains missing.	Remedial Actions: Unable to determine whether a re-consent actually occurred; participant is currently in long-term follow-up; IRB determined that additional re-consent was not necessary. CASE CLOSED
68	21	VA Palo Alto HCS	H	02/27/2013	Sponsor notified facility of an Unanticipated Adverse Device Effect (device unfolding) in a Core Valve study used to treat severe aortic stenosis (extreme risk study).	Remedial Actions: Local site investigator and 3 co-investigators underwent formal training to minimize the potential incidence of in-folding and how to effectively deal with in-folding should it occur; no protocol or ICD changes needed. CASE CLOSED
69	07	Augusta	H	03/04/2013	Reported by RISP that potential human research noncompliance was found in 3 exempt retrospective review protocols. The protocols should have had a HIPAA authorization or waiver of HIPAA authorization.	Remedial Actions: IRB to respond to compliance report; education for IRB on exempt determinations and granting and documenting HIPAA authorization waivers. CASE CLOSED.
70	18	Phoenix VA HCS	I	03/12/2013	NSOC reported transmission of an internal unencrypted email containing PHI. Root cause analysis determined unintentional transmission.	Remedial Actions: Sender recalled the message; retrieval is complete; email remained within VA-protected environment. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
71	16	Central Arkansas VHS (Little Rock)	I	03/14/2013	NSOC reported a WOC Research Employee used a non-VA issued USB drive to store a limited data set containing dates directly related to research participants. The WOC thought the information was de-identified, but because the information included dates it was considered a limited data set for research.	R Remedial Actions: For-cause RCO audit found no additional information security issues; RCO confirmed that all data have been returned to the VA and stored properly; specific research staff member education. CASE CLOSED.
72	23	VA Nebraska/ West Iowa HCS	I	03/18/2013	NSOC reported 119 research specimen tubes that included PHI (one initial and last 4 SSN) instead of a study code were sent to a collaborator not listed on the HIPAA Authorization.	Remedial Actions: The tubes were sent back to VA Researchers and were relabeled without partial identifiers; PI will ensure that labeled specimens do not include PHI. CASE CLOSED.
73	00	VA Central Office	I	03/19/2013	NSOC reported transmission of internal unencrypted email from a facility participating in a CSP study to the CIRB. The email contained 83 names/ phone numbers and was posted to the CIRB shared drive.	Remedial Actions: No data breach; this portion of the study documents removed from the shared drive; study coordinator will re-upload correct document without names. CASE CLOSED.
74	06	Durham	H	03/26/2013	DMC for a VA Merit Study looking at a study drug for PTSD notified this facility that an unanticipated SAE occurred at another site and the DMC was suspending the study at all sites until this could be evaluated. No affected study subjects at this particular facility.	Remedial Actions: Sponsor has halted enrollment indefinitely until safety issues resolved. CASE CLOSED.
75	06	Durham	I	03/26/2013	NSOC reported transmission of an unencrypted email to an affiliate. The email contained names and SSNs of two non-Veteran research participants. The email was sent for participant reimbursement purposes.	Remedial Actions: Research coordinator notified the participants of the mistake; study team educated on differences between VA and affiliate email policies; study team educated on the IRB-approved mechanism for in-person transfer of written reimbursement correspondence. CASE CLOSED
76	16	Shreveport	H	03/26/2013	NSOC reported Consent and HIPAA Authorizations were not dated and/or had incorrect dates. Informed IRB. No data breech.	Remedial Actions: 2 staff members will review documents for dates, signatures and other possible mistakes prior to subjects leaving the premises. CASE CLOSED.
77	00	VA Central Office	H	03/27/2013	A complaint received on the ORO complaint line stated that two subjects had been started on study procedures before signing consent to enroll in CSP 571 (Stents in Vein Graft Angioplasty) and that one had suffered an adverse event and the other should have been excluded from enrollment in the study.	Remedial Actions: Study suspended; study staff retrained; VA Central IRB determined participant's rights were violated; participants were informed & given opportunity to re-consent or withdraw from study; enrollment reopened. CASE CLOSED
78	05	DC VAMC	H	03/27/2013	ORO CO forwarded a phone complaint on CSP 571, a stent comparison trial (DIVA study). The complaint involved failure to properly obtain consent. Further information pending.	Remedial Actions: Study suspended; study staff retrained; VA Central IRB determined participant's rights were violated; participants were informed & given opportunity to re-consent or withdraw from study; enrollment reopened. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
79	21	San Francisco VAMC	I	03/27/2013	NSOC reported findings from a 2010 VA Audit: original ICD and HIPAA Authorization for one Veteran could not be located, as well as an original HIPAA Authorization for an additional Veteran. Copies had been scanned into the medical record and it is suspected the originals were inadvertently shredded.	Remedial Actions: Letters to 2 Veterans offering credit protection services; consent process and documentation training was provided to study team members. CASE CLOSED.
80	06	Durham	I	03/28/2013	NSOC reported unauthorized disclosure of one participant's PHI (SSN) to a non-VA research company coordinating the trial. SSN was to be redacted before mailing as not included on HIPAA Authorization.	Remedial Actions: The research company redacted the SSN and notified the VA of the error; reduce distractions during package preparation; 2nd research staff to review documents prior to shipping to ensure PHI redacted properly. CASE CLOSED.
81	07	Birmingham	H	04/01/2013	ORO received an inquiry from the FDA asking why the results from a study on behavioral treatment of overactive bladder in men have not been entered in www.clinicaltrials.gov as required.	Remedial Actions: PI updated *ClinicalTrials.gov* through ORD HSR&D auto reminder site; a reminder in personal calendar. CASE CLOSED.
82	03	Bronx	H	04/02/2013	FDA asked ORO to follow up on VA Cholesterol lowering study for which results had not been reported in *ClinicalTrials.gov.*	PI sent results to *ClinicalTrials.gov,* which acknowledged receipt. CASE CLOSED.
83	04	Philadelphia	H	04/02/2013	FDA inquiry re: submission of results in CT.gov for clinical trial on effects of Seroquel on sleep. (VA funded)	Remedial Actions: PI informed of submission requirements; PI issued new account and temp password to *ClinicalTrials.gov*; PI uploaded data, including SAE/AE records and continues to edit data. Actions taken satisfy immediate requirements. CASE CLOSED
84	00	VA Central Office	R	04/03/2013	The FDA reported to ORO that one VA facility conducting a VA Cooperative Study clinical trial of treatment of schizophrenia appeared to be overdue to submit study results to the *ClinicalTrials.gov* database.	Remedial Actions: CSP is determining software modifications to access and post all required data points, this will require major programming; as interim measure, CSP posted 5 study publications in the website's study results section and responded to comments from *ClinicalTrials.gov* quality assurance personnel.
85	16	Central Arkansas VHS (Little Rock)	H	04/04/2013	Minimal risk retrospective record review looking at Military Sexual Trauma Exposure and Heart Rate Variability Outcomes in Female Veterans. PI transported identifiable data outside VA without permission and accessed data outside what was approved by IRB.	Remedial Actions: Ensure all identifiable data is stored on the VA Research Service Network drive; Confirm no identifiable information remains on the co-Investigator's private computer; regulatory audit with response to audit within 7 calendar days; education with IRB administrator. CASE CLOSED.
86	06	Durham	I	04/05/2013	NSOC reported a Clinical Research Nurse accidently sent an internal unencrypted email containing the names and study ID numbers of 10 VA patients to another VA employee. The recipient of the email is the research study programmer and is authorized to view this information.	Remedial actions: Email was immediately deleted from both the recipient and the sender mailboxes; it was confirmed that the email remained within VA. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
87	06	Durham	I	04/05/2013	NSOC reported a VA researcher accidentally sent an unencrypted email containing the name and SSN of a VA patient enrolled in a research study. The email was sent to VA email addresses only and all recipients were part of the study team and were authorized to view that information.	Remedial Actions: Employee recalled the message and also requested that the recipients delete it from their Inbox and Deleted items folders; User was counseled by the ISO and is aware of the requirement to use PKI; confirmation received that email remained within VA. CASE CLOSED.
88	00	VA Central Office	H	04/15/2013	The VA Central IRB suspended enrollment at one site in a study of treatment for severe pneumonia because of possible continuing noncompliance consisting of late event reporting, missing protocol data, overall lack of attention to detail by the local study team.	Remedial Actions: All protocol deviations were resubmitted to the VA Central IRB for review with all required information completed. None were found to involve serious or continuing noncompliance, and the enrollment suspension was lifted. Study staff received training. CASE CLOSED.
89	00	VA Central Office	H	04/15/2013	The VA Central IRB made a determination of serious noncompliance due to enrollment of a subject taking an exclusionary drug in a study of a treatment for depression. There was no harm to study participants.	Remedial Actions: Education was provided to all study personnel, utilization of an exclusionary medications checklist was instituted in screening participants. CASE CLOSED.
90	08	Tampa	H	04/16/2013	NSOC reported 47 study participants enrolled in a Functional Status study without a proper HIPAA authorization.	Remedial Actions: The PI submitted a HIPAA authorization to the IRB for review, HIPAA will be obtained or data will not be used. The local SharePoint site was updated with clear instructions. CASE CLOSED.
91	10	Dayton	H	04/16/2013	RCO audit found apparent noncompliance with storage of study drug outside the Research Pharmacy for a kidney dialysis study. Subsequent RCO audit of pharmacy found same issue for a diabetes/kidney disease study conducted by same PI.	Remedial Actions: Research pharmacy to dispense both drugs; Study drugs no longer will be stored outside of research pharmacy; PI to receive education on VHA and local requirements regarding study drugs; All facility PIs to receive email reminder of study drug requirements. CASE CLOSED.
92	18	New Mexico VA HCS	I	04/18/2013	NSOC reported that a VA-issued encrypted laptop was stolen from a VA Contractor who apparently worked for CSP. The laptop contained no PHI but did contain CSP research-related documents.	Remedial Actions: Laptop was mistakenly left at airport security and retained by state police until recovery by the contractor. CASE CLOSED
93	09	Memphis	I	04/19/2013	NSOC reported that Ex-employee A found some old disks, flash drives and folders on her personal computer containing research files with VA patient first initial of last name plus the last 4 of the SSN, admission dates, discharge dates and some dates of death for approximately 172 Veterans.	Ex-employee returned storage devices to the VA; OIT scrubbed non-original data from devices; applicable devices containing original data were returned to study PI; other actions pending.
94	05	DC VAMC	I	04/22/2013	NSOC reported improper mailings of blank "release of information" forms for 3 Veterans out of 738 total medical record consent requests.	Remedial Actions: Quality control validation of mailings increased from the current 5% level to 100%. All three Veterans have returned the incorrect forms and have signed/returned the correct consent forms. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
95	08	Orlando VAMC	H	04/22/2013	NSOC Report reported a list of names and SSNs was generated prior to IRB approval of the protocol. Preparatory to Research policy violation.	Remedial Actions: Discussion of the issue with the Principal Investigator, written notification and training to all investigators, members of OVAMC research interest group and research staff, training via OVAMC newsletter. CASE CLOSED.
96	06	McGuire Veterans Affairs Medical Center	I	04/25/2013	NSOC reported one missing research file is missing. The information at risk contains patient's name, full SSN, date of birth and PHI.	Remedial Actions: Search for file unsuccessful to date of last facility report; credit protection services will be offered to patient. CASE CLOSED
97	23	Minneapolis	R	04/25/2013	OIG Hotline referral reported possible R&DC approval of non-VA research and the possible conduct of research by an individual lacking appropriate VA appointment and research scope of practice. Investigation expanded to include multiple investigators apparently lacking VA appointments for research.	Remedial actions: ORO determined that an onsite review was warranted. See Table 1, Item 6. CASE CLOSED.
98	17	VA South Texas HCS	H	04/29/2013	VA Central IRB notified facility that a Community Acquired Pneumonia study was suspended for potential safety reasons based on the review of 18 reports of protocol deviations or violations submitted to the VA CIRB.	Remedial Actions: Development of a RAP to include adding study staff and implementing personal oversight of study data collection and reporting. CASE CLOSED
99	16	Houston	I	05/01/2013	NSOC reported two missing consent forms. The consent forms contained the Veteran's full name but the PI was unable to provide information whether full or partial SSNs were included on the forms.	Remedial Actions: One Veteran will receive a letter offering credit protection services and one Next-of-Kin notification letter will be sent; staff will continue to look for forms. CASE CLOSED
100	16	Houston	I	05/01/2013	NSOC reported that medication bottles (same type and dosage) for two different research participants were inadvertently given to Veteran A. PHI disclosed was full name and medication type and dosage. Veteran A was apparently unaware that the 2nd bottle contained another subject's medication.	Remedial Actions: Veteran returned medication bottles to clinic; One Veteran was sent a HIPAA notification letter; additional Pharmacy Technician hired; PI re-educated on reporting privacy incidents; IRB reaffirmed verification process for study drug labels to PI. CASE CLOSED
101	20	Portland VAMC	I	05/01/2013	NSOC reported ICD hard copies for two study subjects records cannot be located in the study files. The consents had previously been scanned into the Veterans' medical records.	Remedial Actions: Hard copies of the two consents were subsequently located; subject notification not required since documents were found; research staff received refresher training as the incident was not reported according to required timeframes. CASE CLOSED
102	18	Phoenix VA HCS	H	05/14/2013	Inquiry in response to VANSOC report involving apparent noncompliance in human subject research	Remedial Actions: Privacy ticket closed. IRB accepted PI's corrective actions; PI to obtain valid HIPAA authorizations; PI to retrain fellows and study staff. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
103	01	VA Connecticut HCS	I	05/16/2013	NSOC reported transmission of an unencrypted email containing the PHI (full SSN, exam dates, etc) of 40 VA patients to affiliate account. PHI collected/recorded during preparatory to research activities.	Remedial Actions: Email has been deleted from affiliate account; researcher received written counseling; R&DC review incident and concurred with remedial actions. CASE CLOSED
104	01	Bedford	I	05/22/2013	NSOC reported Veteran A received study medication for Veteran B who is enrolled in the same study. Information inadvertently disclosed was Veteran's B's full name, address and his participation in this alcohol dependence/PTSD treatment study.	Remedial Actions: Veteran B was sent a HIPAA notification letter; IRB approved a protocol amendment that revised study medication procedures to reduce risk of medication delivery misdirection and inadvertent disclosure of PHI. CASE CLOSED
105	22	VA Greater Los Angeles HS	I	05/22/2013	NSOC reported transmission of an external unencrypted email from a co-investigator's personal email account to the study coordinating center at another VA. PHI included last and first name, last 4 SSN and research study name (24 participants).	Remedial Actions: Mandatory staff education regarding data security storage and transmission; non-use of personal email for sensitive research issues; installation of encryption. CASE CLOSED
106	05	DC VAMC	H	05/28/2013	NIOSH found that a subject's BP was measured after spirometry rather than before where an elevated value would have excluded participant. Spirometry testing was attempted 24 times (3 sessions of 8 attempts) contrary to protocol (1 session) in this Army Chemical Corps Vietnam-Era Veteran's Health Study.	Remedial Actions: Revised protocol to emphasize testing order, clarify spirometry contraindication, plan to develop emergency SOP; all technicians were retrained. CASE CLOSED. NOTE: Mistakenly classified as facility self-reported in Second Quarter Report.
107	18	Phoenix VA HCS	I	05/28/2013	*NSOC reported photocopies of two ICDs sent Dec 2012 for CPRS scanning in another building are missing. PHI included full name, full SSN and participation in the research* study.	Remedial Actions: One Veteran was offered credit monitoring services; the second Veteran's ICD was located. CASE CLOSED
108	00	VA Central Office	I	06/03/2013	A Research Analyst contacted the Privacy Officer to report a research participant's HIPAA Authorization and Informed Consent Document had been missing since May 1, 2013. The participant's full name and the title of the study are included on the forms.	Remedial Action: The Veteran was sent a notification letter but did not respond and was withdrawn from the study. CASE CLOSED.
109	11	Ann Arbor HCS	I	06/03/2013	NSOC reported transmission of internal unencrypted email containing full names and last 4 SSN of 108 patients.	Remedial Actions: Sender instructed to recall message, delete copies from all email boxes; educated on proper use of email encryption. CASE CLOSED.
110	05	VA Maryland HCS	I	06/04/2013	NSOC reported a MVP research participant's ICD and HIPAA Authorization are missing. The participant's full name and study title are included on the forms.	Remedial Actions: Veteran will be sent a notification letter; participant must re-consent or be withdrawn from the study and notified of the withdrawal. If withdrawn, blood sample will be removed from the database. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
111	06	Durham	I	06/04/2013	NSOC reported staff disclosed a Veteran's name and research study name by phone to a Veteran with the same last name (mistaken identity over the phone). Staff then collected phone number and home address plus research survey responses from a non-consented person.	Remedial Actions: Veteran was sent HIPAA notification letter; staff will verify identity by asking last 4 SSN during phone conversations; Information obtained from incorrect Veteran was removed from the database. CASE CLOSED
112	17	VA Central Texas HCS	H	06/18/2013	External monitor identified and facility reported a protocol exclusion criteria deviation in a first-line treatment study for chronic lymphocytic leukemia.	Remedial Actions: Enrollment error corrected, refresher education for PI and staff. CASE CLOSED.
113	20	Portland VAMC	I	06/19/2013	NSOC reported that an original signed ICF containing name and full SSN cannot be located. A research progress note was created in CPRS and a copy of the document was retained. The original was sent to the Research Service for scanning. The document was not recorded as being received for scanning.	Remedial Actions: Research staff now sign a tracking sheet when dropping off or picking up ICFs from Research Assurance Officer; credit protection services not required. CASE CLOSED
114	18	Phoenix VA HCS	I	06/27/2013	NSOC reported a physician sent an insecure text message containing one Veteran's PHI (first/last name and last 4 SSN) to a research coordinator's personal cell phone.	Remedial Actions: Text message was retrieved, reviewed and deleted; education provided to physician; all staff to be provided education to prevent future occurrences. CASE CLOSED.
115	04	Wilkes-Barre	H	06/28/2013	ORO CO learned that facility added an IRB to their FWA without submitting through ORO. CO reporting this finding to NERO who will manage the case.	Remedial Actions: Removed Wright Center IRB from FWA, revised and submitted new FWA through ORO to OHRP. CASE CLOSED.
116	06	Durham	I	06/28/2013	NSOC reported that a VA research assistant sent an unencrypted email to 3 VA employees that included the name and phone number of 3 potential research participants.	Remedial Actions: The email was recalled by the user and deleted by the recipients; email transmission education was provided to study staff; the research assistant obtained PKI certificates and was educated on their use. CASE CLOSED
117	20	VA Puget Sound HCS	I	07/03/2013	NSOC reported internal unencrypted email containing initials and last 4 SSN for one study subject.	Remedial Actions: Employee reminded of appropriate email protocol and use of PKI. CASE CLOSED
118	06	Durham	I	07/05/2013	NSOC reported a VA researcher accessed the VA server from his affiliate computer and downloaded PII, including full SSN and date of death, of 200 Veterans. The PII was emailed to the PI's affiliate email account. The email and PII were deleted from the affiliate computers.	Remedial Actions: Email and spreadsheet permanently deleted from affiliate computer system; research information protection training was provided to the entire study team; plan developed for future trainings. CASE CLOSED
119	02	Albany	I	07/10/2013	NSOC reported two workstations are missing; facility stated computer were used for bench and animal research and did not contain PHI; one computer had been turned into IT.	Remedial Actions: No PHI on computers. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
120	09	Memphis	I	07/10/2013	NSOC reported that research personnel inadvertently faxed eight signed ICDs and HIPAA authorizations to a wrong number at a business location instead of to the study coordinating center. PHI consisted of names only.	Remedial Actions: The business subsequently stated the fax had not been received; HIPAA and Privacy retraining for study staff; training on proper fax procedures. CASE CLOSED
121	01	VA Boston Healthcare System	I	07/11/2013	NSOC reported that access permissions for large databases had been set without the proper requests, approvals, and authentication through IRM or OI&T. Investigations concluded there was no exposure of PII/PHI and no inappropriate access.	Remedial Actions: The databases are being taken off the server and moved to a different server; persons with inappropriate access are being removed from the applicable server. CASE CLOSED
122	06	Durham	I	07/17/2013	NSOC reported that a research assistant discovered during internal inspections that an informed consent document was missing for one subject in a nutrition study. A scanned copy is present in CPRS; however, a full search was conducted without locating the original hard copy document.	Remedial Actions: Credit protection services offered; research assistant to daily verify ICF logging of prior day; retraining of research assistants on protocol ICF management for the protocol. CASE CLOSED
123	20	Portland VAMC	I	07/18/2013	NSOC reported that a researcher with a WOC appointment has stored without authorization a Veteran's PHI on the desktop PC in the affiliate office. PHI consists of full name, partial SSN, age, gender, and a brief hearing loss note. IRB has approved ICD and HIPAA Authorization waivers for this study.	Remedial Actions: VA PHI and VISTA images were transferred back to VA by encrypted message and saved to secure research folder on VA network; VA PHI and VISTA images were removed from affiliate desktop computer; PO verified no identifiers were contained within the VISTA images. CASE CLOSED
124	20	Portland VAMC	I	07/26/2013	NSOC reported that VA Research Study Coordinator was unable to locate a hardcopy study folder for a Veteran enrolled in a Central VA IRB study. The missing hard copy file contains the Veteran's full name, full SSN, home address, phone number and appointment dates. Original ICFs is in VA possession.	Remedial Actions: Credit Protection Services offered. CASE CLOSED
125	00	VA Central Office	I	07/26/2013	NSOC reported that MVP research personnel inadvertently faxed eight signed ICDs and HIPAA authorizations to a wrong number at a business location rather than to the study coordinating center as intended.	Remedial Actions: Upon contact, the business indicated there was no record the documents were received. NSOC determined there was no data breach. Study staff received training on mandatory reporting requirements. CASE CLOSED.
126	00	VA Central Office	I	07/29/2013	NSOC reported a physician at one CSP study site sent unencrypted protected health information from his cellular telephone to the study coordinator's cellular telephone (colorectal cancer screening study).	Remedial Actions: Text message was retrieved, reviewed and deleted from sender's and recipient's cell phones; education provided to physician and staff on mandatory VA privacy policies. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
127	00	VA Central Office	I	07/30/2013	Facility reported a study coordinator was unable to locate a hard copy study folder for one Veteran enrolled in a CSP hypertension study at one local study site. The missing folder contains extensive personally protected information.	Remedial Actions: Credit protection services offered to the Veteran. VA Central IRB determined no further actions are required. CASE CLOSED
128	00	VA Central Office	H	08/05/2013	A participating site in the Million Veterans Program may have collected blood specimens prior to obtaining written informed consent to participate in the study in as many as 1,000 Veterans.	Remedial Actions: Enrollment suspended at the site, site personnel deactivated in the recruitment/enrollment application, site visit being scheduled, training provided to local study team, and notification letter sent to potentially affected participants.
129	00	VA Central Office	H	08/06/2013	An audit of a Cooperative Studies Program colon cancer screening study at one site found that data collection began prior to receipt of written informed consent for approximately 120 study participants.	Remedial Action: Administrative hold placed on study by the VA Central IRB while LSI and study staff received training on consent procedures; consenting processes changed. CASE CLOSED.
130	01	Providence	P	08/08/2013	RCEP Technical Assistance to RCO identified that the RCO was detailed to serve as Administrative Officer for Surgery Department. Change in status not reported to ORO.	Remedial Actions: Assurance from facility Director that going forward any changes in status of RCO will be reported to ORO as per VHA Handbook 1058.01. CASE CLOSED
131	23	VA Nebraska/ West Iowa HCS	I	08/14/2013	Allegation from National Surgery Office that a PI had on on-going basis transmitted VASI to an affiliate colleague with VA WOC appointment, and that the VASI was stored on unencrypted, non-VA information systems without the required approvals.	No remedial actions required. Received clarification that no VASI is stored on non-VA equipment. CASE CLOSED.
132	04	Philadelphia	I	08/20/2013	NSOC reported a research program manager identified that a folder containing a subject's ICF, HIPAA Authorization, a voucher and a checklist is missing. PII includes name and last 4 SSN.	Remedial Actions: Subject was informed of the missing folder; subject agreed to continue participation; scanned copy of the ICD and HIPAA Authorization are contained in subject's medical record. CASE CLOSED
133	05	VA Maryland HCS	P	08/20/2013	OIG hotline referral with several allegations related to HRPP, Info Security, and misconduct in the facility's GRECC - facility response is due to OIG 10.08.13	Affiliate IRB suspended 8 studies due to concerns about conduct and sequelae of procedures used in metabolic studies, and possible coercion of participants. Awaiting facility's full investigation report to OIG.
134	00	VA Central Office	H	08/21/2013	VA Central IRB reported that a Veteran enrolled in a study of stents used in saphenous vein graft angioplasty was admitted to a non-VA hospital with symptomatic bradycardia.	Remedial Actions: None required. It was determined that the adverse event was not related to the research. CASE CLOSED.
135	18	Phoenix VA HCS	I	08/29/2013	NSOC reported that an informed consent form and HIPAA Authorization are missing for one subject enrolled in a CSP study (Million Veteran Program).	Remedial Actions: Subject signed another ICD and HIPAA Authorization and will be sent a HIPAA notification letter; research activities moved to a single more secure room with goal of improving communication among phlebotomy personnel. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
136	16	Shreveport	H	08/29/2013	Facility reported receipt of a DSMB report recommending the AleCardio trial be stopped for lack of efficacy combined with safety signals resulting in an overall unfavorable benefit risk ratio. Two subjects are on the study at this site. Neither subject has demonstrated any adverse events.	Remedial Actions: Subjects will be scheduled for end of treatment visits, including treatment options; f/u visits will be scheduled. CASE CLOSED.
137	22	VA San Diego HS	H	08/30/2013	Unanticipated problem involving research-related and (at least, potentially) serious risks to participants or others - a medication error (a study subject received twice the FDA approved dose of Citalopram/placebo for 6 weeks). No adverse outcomes were identified.	Remedial Actions: Research Pharmacy Technician to review the dispensing procedure for every study involving investigational drugs with the covering Pharmacist, before the Pharmacist approves the prescription. CASE CLOSED.
138	06	McGuire Veterans Affairs Medical Center	H	09/05/2013	Sponsor notified all sites to stop all dosing of a Crohn's Disease study drug. No AE's reported locally.	Remedial Actions: Only local subject taken off study drug; end-of-study visit completed; awaiting sponsor notification to close studies. CASE CLOSED
139	10	Cleveland	I	09/06/2013	NSOC reported that a VA Research Compliance Officer sent an unencrypted email containing the last names of two patients to a VA Principal Investigator (PI). The PI reported the incident to the Privacy Officer.	Remedial Actions: Employee provided personalized training and handouts. CASE CLOSED
140	00	VA Central Office	I	09/09/2013	NSOC reported that the informed consent document and HIPAA authorization of one participant at a local study site of a VA multicenter study were lost.	Remedial Actions: Re-consent obtained, subject to receive a HIPAA letter of notification, and refresher training provided to study staff.
141	05	DC VAMC	I	09/11/2013	NSOC reported an outside provider faxed a Veteran's medical records to an incorrect fax number and without the appropriate fax cover sheet. The Veteran is a research participant and the recipient was a VA contractor (a global research and strategy organization).	Remedial Actions: Requests for records will instruct provider to include cover sheet with faxes; contractor advised to not read faxes not addressed to them and return to sender. CASE CLOSED
142	00	VA Central Office	H	09/11/2013	A routine SMART Audit found that a blood sample was drawn from one subject without prior informed consent at one study site of a multicenter study of treatment of community-acquired pneumonia.	Remedial Actions: Blood sample destroyed; protocol deviation reported and reviewed, staff education completed. CASE CLOSED.
143	00	VA Central Office	H	09/16/2013	The Acting CSP Director notified ORO that a participant in a multicenter study of treatment for depression committed suicide.	Remedial Actions: The VA Central IRB determined that this incident was unanticipated & serious, but not related to the research. The Veteran had multiple previous suicide attempts, alcohol & substance abuse, and comorbid medical conditions that all contributed to this unfortunate event. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
144	00	VA Central Office	H	09/17/2013	A participant in a multi-center study of treatment of depression had a seizure at his workplace and fell, injuring his back. Seizures are not unanticipated in this study.	Remedial Actions: The patient's back injury was treated conservatively with pain medications alone and healed without complications. CASE CLOSED
145	09	Mountain Home	I	09/19/2013	NSOC reported unauthorized removal of original research patient records by a clinical trials coordinator. While offsite, the records were reported never out of employee control and were stored in a locked).	Remedial Actions: All data has been returned to the facility and secured; RCO provided education to coordinator re transport of VASI; lockable cabinet provided in secured clinical space for research record storage. CASE CLOSED.
146	00	VA Central Office	H	09/19/2013	RCO Audit of a low-vision intervention trial determined that two study staff at one study site did not have Scopes of Practice for the duration of a multicenter study of interventions to improve functioning with low vision.	Remedial Actions: LSI immediately submitted scopes of practice for the two study personnel for review and approval by the ACOS/R&D. The VA Central IRB did not require any further corrective action. CASE CLOSED
147	02	Syracuse	H	09/24/2013	SMART Audit team found on a randomized controlled double-blinded trial in hospitalized Veterans with severe community acquired pneumonia that blood draws were performed without informed consent on one subject.	Remedial Actions: Unauthorized blood samples destroyed; rechecked all sections of consent; confirmed accuracy of consent by the PI; maintaining logbook to track patient authorization for sample collection. CASE CLOSED
148	06	Durham	I	09/26/2013	NSOC reported that research staff used a mail merge from their master list and mailed research participants reminder letters to the correct address with incorrect names.	Remedial Actions: PO confirmed all 35 research participants received notification letters; creation of QI checklist; Research staff will manually verify subset of names, addresses prior to mailing; provide ample time for staff to recheck their work; research-wide new staff orientation. CASE CLOSED.
149	15	VA Kansas City Medical Center	I	10/02/2013	NSOC reported a VA researcher with dual appointment was approved to take tissue samples from a VA study to the university hospital for analysis. The samples and data were coded; unknown if truly de-identified. The researcher was then emailing the results unencrypted to his VA email account.	Remedial Actions: PO, ISO, and RCO reviewed the data in question and determined it met de-identification standards; no other actions required. CASE CLOSED
150	16	Central Arkansas VHS (Little Rock)	H	10/03/2013	Facility reported notification from the sponsor that treatment Arm A in this high-risk melanoma study is suspended due to a greater number of grade 5 serious adverse events than expected. The local facility does not have any subjects enrolled in Arm A.	Remedial Actions: PI to close Arm A; provide IRB with revised protocol, ICD and other related documents concerning the closure of Study Arm A.
151	19	VA Salt Lake City HCS	I	10/08/2013	NSOC reported that a research investigator emailed a spreadsheet outside VA to their coordinator for analysis. The spreadsheet contained research participant full names and dates of birth.	Remedial actions: Remedial Actions: PI and Coordinator fully removed unencrypted email with PHI from their mailboxes; reminder sent to research staff involved in incident about requirements to encrypt PHI; staff reminded about reporting requirements. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
152	01	VA Connecticut HCS	I	10/09/2013	NSOC reported that a VA Connecticut laptop was used to inappropriately access a VA Boston Healthcare System MAVERIC research server. The person to whom the laptop is assigned is not involved in research and was unaware of the event.	Remedial Actions: MAVERIC Server Admin changed passwords; all sensitive data moved to a different server; OIG investigation closed. CASE CLOSED
153	06	Durham	I	10/09/2013	NSOC reported a Veteran who was not a research participant but had the same name as a research participant in a PTSD study was contacted and provided with PHI of the study subject.	Remedial Actions: Veteran sent credit protection letter; PI received additional privacy training; PI modified recruitment strategy to focus directly on recent OEF/OIF, & PTSD clinic visits to obtain current addresses and not exclusively on the VISN MIRECC research registry addresses. CASE CLOSED
154	15	St Louis	I	10/09/2013	NSOC reported research protocols and other information were stored on a server without the proper permissions. PHI included one file with names and last four of 100 patients.	Remedial Actions: OIT staff has correctly permissioned the folders; other actions pending.
155	05	DC VAMC	I	10/10/2013	NSOC reported that a research document sent through US postal service mail and received at the facility was entered into the VA IQ correspondence tracking system. PHI included the Veteran's name, address, and surgery information.	Remedial Actions: Office of Executive Correspondence informed to forward research documents to the PI and not enter into the tracking system; contractor to request medical providers to send records by courier service. CASE CLOSED
156	00	VA Central Office	H	10/11/2013	A participant taking an exclusionary medication was enrolled in a multicenter study of treatment for depression at one study site. There was no apparent harm to the subject.	Remedial Actions: Study staff education, review of exclusionary medications, confirmation of the exact method to evaluate use of exclusionary medications before & during study participation, verification that no other participant was taking exclusionary medications. CASE CLOSED.
157	05	VA Maryland HCS	I	10/15/2013	Facility reported an affiliate audit identified the loss of research folders containing two participants' signed informed consent forms, HIPAA authorizations, and, possibly, information obtained during screening procedures in a study conducted at the affiliate.	Remedial Actions: PI submitted a corrective action plan to prevent future confidentiality breaches; offer credit monitoring to affected subjects. CASE CLOSED
158	22	VA Long Beach HS	H	10/16/2013	PI report of failure to obtain HIPAA authorization for one subject enrolled in a wound healing outcomes study.	Remedial Actions: Pending
159	00	VA Central Office	I	10/22/2013	The research coordinator for a study site of the Million Veteran Program found that a Veteran's original informed consent document and HIPAA authorization were missing from the study file. No data breach occurred.	Remedial Actions: The research coordinator submitted a protocol deviation report to the VA Central IRB; the patient signed a new ICD and HIPAA authorization; education on reporting requirements provided to study staff, IRB, and R&DC. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
160	09	VA Tennessee Valley HCS	I	10/23/2013	NSOC reported original ICD and HIPAA Authorization are missing for one subject enrolled in the MVP study (CSP). The missing documents contain the subject's name and study ID.	Remedial Actions: Subject was notified and has signed another consent form; this case will be followed in DSS-0070-626-I due to occurrence of similar incident. CASE CLOSED
161	07	Atlanta	H	10/25/2013	FDC data revealed higher than average rate of lapsed studies in continuing review (>14%).	Remedial Actions: Improved tracking of CR submissions for timeliness by IRB staff; Multiple electronic CR reminders to PIs/study staff w/ new timeline; PI education re: CR reviewer requirements; IRB staff tracking of CR reviewer assignments; eIRB tracking CITI training w/ CR submissions. CASE CLOSED
162	00	VA Central Office	H	10/31/2013	An RCO reported that an incorrect ICD was used to enroll Veterans in the Million Veterans Program at one study site.	Remedial Actions: Corrected ICD approved by the VA Central IRB. CASE CLOSED.
163	01	VA Boston Healthcare System	I	10/31/2013	NSOC reported that a folder containing research data was deleted from a server and could not be retrieved. It was subsequently determined included PHI in the form of dates.	Remedial Actions: Facility IRM adopt Regional OI&T policies; develop detailed SOP for contacting PIs prior to transferring or archiving research data; R&D SOP for electronic research data storage; consult with local Records Manager to determine if other procedures are required. CASE CLOSED
164	20	Portland VAMC	I	11/05/2013	NSOC reported ICDs containing first, last name and last 4 SSN for two participants in a VA tinnitus research study were inadvertently placed in the incorrect mailers. Veteran A notified the team of the occurrence & will mail back the form. Veteran B will return the envelope unopened upon receipt.	Remedial Actions: Veteran A returned Veteran B's ICF; the envelope containing Veteran A's ICF was returned to the VA unopened; HIPAA notification letter being prepared for Veteran B; checklist for ICF mailings was submitted for review.
165	19	VA Salt Lake City HCS	I	11/07/2013	NSOC reported transmission of an unencrypted email from an affiliate to a VA research coordinator requesting that a previous VA research participant be contacted for another affiliate study. PHI included name, affiliate medical record number and imaging date.	Remedial Actions: Email recipients instructed to permanently delete the message; reminder sent to properly encrypt sensitive messages; other actions pending.
166	08	VA North Florida/ South Georgia HCS	H	11/13/2013	NSOC reported a research study coordinator obtained informed consent but overlooked the HIPAA authorization required with the study protocol.	Remedial Actions: PI and study coordinator education on consenting procedures including HIPAA authorizations; PI to educate study staff; data collection or disclosures on hold until authorizations signed; authorization obtained from one subject; PI to conduct weekly enrollment audits.
167	18	New Mexico VA HCS	I	11/20/2013	NSOC reported several missing laptops and computers belonging to the research service. Further details pending.	Remedial Actions: Pending

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
168	02	VA Western New York HCS	I	11/21/2013	NSOC reported that a non-profit laptop used by a VA researcher was missing and was subsequently located after a facility search was conducted. The hard drive was removed because the laptop was too old to be encrypted. Facility verified PHI was not contained on the laptop.	Remedial Actions: No actions required after determination that no PHI was contained on the laptop. CASE CLOWSED
169	23	Iowa City	H	11/21/2013	DSMB identified safety concerns in an advanced liver cancer study (potential imbalance in treatment-related deaths between the two study arms) and suspended enrollment. Facility had enrolled two subjects into this trial.	Remedial Actions: Pending
170	00	VA Central Office	H	11/22/2013	Special Review of VA Institute of Medicine (IOM) Air Force Health Study Assets Research Program (AFHS-ARP) for possible overlap with the IOM Veterans and Agent Orange study(VAO).	Conclusion: The AFHS-ARP and the VOA study are entirely independent activities, and there is no apparent opportunity for either to compromise the independence or legitimacy of the other.
171	11	Indianapolis	H	11/22/2013	Facility reported the affiliate IRB suspended this multiple myeloma treatment study due to increase in the frequency of myelosuppressive adverse events.	Remedial Actions: Sponsor amending the protocol to a lesser drug dose, IRB suspended study until amendment presented to Committee.
172	16	Little Rock	I	11/25/2013	Facility reported PHI from 2,349 Veteran subjects enrolled across 25 VA medical centers in 2 lung disease studies was found during EOC rounds in an unlocked cabinet in an unlocked room. Upon discovery, records were immediately secured by the Research Administration.	Remedial Actions: RCO conducted for-cause audit; PI to attest all research records have been secured or submitted to Research for storage; R&D to develop action plan to ensure all research records have been secured.
173	08	San Juan	H	11/26/2013	Facility reported that 27 ICDs for a were not scanned into CPRS within 2 business days as required by site SOP (study of blood glucose after facet joint, epidural and trigger point injections).	Remedial Actions: The PI submitted all twenty-seven ICDs and HIPAAs for scanning on October 28, 2013; in addition, re-training of the research team was indicated and must be completed within 2 weeks of receipt of the IRB letter.
174	16	Little Rock	I	11/26/2013	NSOC reported that research data on 65 subjects in spreadsheet format had not been moved from an email mailbox to a network drive and was inadvertently deleted when a Research Co-Investigator left the VA. The report stated no privacy violation occurred. The study is being administratively closed.	Remedial Actions: Must ensure process of requesting network folder to store data and subsequent storage of data; other actions pending.
175	18	Phoenix VA HCS	I	11/26/2013	NSOC reported inadvertent transmission of an internal unencrypted email to an incorrect recipient with a payment voucher attachment containing name and last four SSN of up to 38 research participants.	Remedial Actions: PO received confirmation all copies of the email were deleted from Outlook; research staff trained to encrypt emails with payment voucher attachments; Research Service wide dissemination of Federal Record and retention educational materials provided by Records Manager. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
176	23	Minneapolis	H	11/26/2013	DSMB notified facility to suspend enrollment in this advanced liver cancer study due to safety concerns (potential imbalance in treatment-related deaths between the two study arms). Two subjects had been enrolled at facility but previously withdrawn due to disease progression).	Remedial Actions: Pending
177	04	VA Pittsburgh HCS	I	11/27/2013	NSOC reported that labels were printed incorrectly for a research mailing. The labels contained the correct address but incorrect name. No other PHI or PII was involved.	Remedial Actions: Research staff advised to perform QA review when preparing mailing labels. CASE CLOSED
178	05	VA Maryland HCS	I	12/02/2013	NSOC reported a patient complained to the Patient Advocate Office that a post card was received with first and last name, address and diagnosis (multiple sclerosis). Issue brief provided to the VISN by Research.	Remedial Actions: Facility clarified this was not a research related incident and was specific to a MS Center of Excellence educational event regarding telemedicine. CASE CLOSED
179	06	Durham	I	12/03/2013	NSOC reported transmission of an unencrypted email containing names and last four SSNs to study team members. All members except one were located internally at the VA and one recipient was located at the affiliate.	Remedial Actions: Sender has confirmed that all recipients including the affiliate email completely deleted the email or it was successfully recalled; Research Service wide Information Security and Privacy training(Town Hall style); specific research coordinator retrained by PI and PO. CASE CLOSED
180	03	VA New York Harbor HCS	I	12/04/2013	NSOC reported a folder containing 25 research consent forms went missing. The forms contained the subject's full name and full SSN.	Remedial Actions: Letters offering credit protection services for 25 Veterans; other actions pending.
181	12	Milwaukee	I	12/05/2013	NSOC reported a missing desktop computer used for research. The last known inventory date was Dec 2012. A second search was unsuccessful and research personnel had no information about its current location.	Remedial Actions: Immediate inventory of all research equipment, secure storage of computers with PII or PHI stored securely if not in use; tag VA equipment more clearly; other actions pending.
182	02	VA Western New York HCS	I	12/06/2013	NSOC reported that facility research department cannot find two desktop computers assigned to their inventory list. Investigation underway to determine if PHI was involved.	Remedial Actions: Inventory completed in research building; frequency of inventories will be increased; Research Department Staff reeducated on importance of safeguarding equipment and reporting lost IT equipment in a timely manner; no PHI based upon facility investigation. CASE CLOSED
183	08	VA North Florida/ South Georgia HCS	I	12/10/2013	NSOC reported an unencrypted research laptop provided by a study sponsor was missing from a locked room that was only accessible by electronic key. The report stated the only PII on the laptop was DOB.	Remedial Actions: Pending
184	00	VA Central Office	I	12/11/2013	NSOC reported ICDs and HIPAA authorizations were missing for two participants at one site of the Million Veteran Program study. A search for the documents is ongoing.	Remedial Actions: Pending

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
185	09	VA Tennessee Valley HCS	I	12/11/2013	NSOC reported ICDs and HIPAA authorizations were missing for two MVP participants. A search for the documents is ongoing at this time.	Remedial Actions: Pending
186	00	VA Central Office	H	12/13/2013	CIRB reported that an expired coronary stent was implanted in a study participant at one study site. The patient does not appear to have been harmed.	Remedial Actions: Patient advised of the event and is stable in clinical follow-up 18 months after the event;; other actions pending.
187	00	VA Central Office	H	12/13/2013	CIRB reported that he study coordinator at one site of a multicenter study of tests for detection of colon cancer consented a participant 30 minutes after the participant had received medications that could impair decision making.	Remedial Actions: Consent invalidated, study coordinator received additional training, CSP Coordinating Center verified no other participating site was using this type of invalid consent process.
188	00	VA Central Office	H	12/13/2013	CIRB reported that the overall PI for a multicenter study of tests for detection of colon cancer found there was no protocol procedure for follow-up to ensure subjects received and returned test kits, resulting in delay in the diagnosis of cancer in one patient and the risk of delay for others	Remedial Actions: Participating sites notified of issue; study team developing a report to identify pending test kits requiring follow-up; other actions pending.
189	00	VA Central Office	H	12/13/2013	The VA Central IRB determined that an SAE occurring in a multi-center study of treatment for depression was possibly related to the research. A participant experienced weakness, lightheadedness, fainting, heaviness in the chest and tingling/numbness in the extremities due to hyperventilation.	Remedial Actions: Pending
190	00	VA Central Office	H	12/13/2013	The VA Central IRB found numerous instances of insufficient and inadequate study documentation in the conduct of a multicenter study of treatment for high blood pressure at one study site.	Remedial Actions: Local study coordinator relieved of her position; Regulatory Audit by local RCO and site visit by National Study Team.
191	05	DC VAMC	H	12/13/2013	NSOC reported that research PHI (participants' initials) was shared with a non-VA facility (affiliate) on a study on palliative care in people living with AIDS	Remedial Actions: PO recommended retraining PI and study team on handling and safeguarding PHI during research, and attend upcoming research compliance education seminar.
192	06	Durham	I	12/17/2013	NSOC reported a research participant failed to return two devices used for smoking cessation, despite promises to return the devices. No identifiers are contained on either device; PHI on the encrypted android phone consists of facial image (subjects are instructed to record only profile images).	Remedial Actions: Postage-paid mailer sent to participant without a response; Research participant returned devices after phone calls; no loss of PHI; facility revised NSOC ticket. CASE CLOSED

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
193	08	Miami	H	12/17/2013	NSOC reported that a patient was consented to perform exams to determine eligibility criteria to participate in the research study; however, HIPAA authorization was not obtained.	Remedial Actions: Modification to the RCO?s initial reporting, to include the PO. Education to the PI to disseminate understanding that a HIPAA waiver for initial screening does not apply when actively conducting research thru interventions. CASE CLOSED.
194	08	Tampa	H	12/17/2013	NSOC reported a case of noncompliance where a study coordinator entered Veteran research participant full name into a study's sponsor database. Only Date of Birth (DOB) as identifier was allowed.	Remedial Actions: Immediate removal of data. CASE CLOSED
195	08	San Juan	I	12/18/2013	NSOC reported a document containing PHI (full name and full SSN) was found unattended on a research service copier machine located in a secure room.	Remedial Actions: Facility clarified this document was not related to a research participant. Reporting to ORO therefore not required. CASE CLOSED
196	16	Houston	H	12/18/2013	Facility provided study information to an individual who no longer held a VA appointment.	Remedial Actions: IRB determined that the noncompliance was not serious or continuing.
197	01	VA Boston Healthcare System	I	12/19/2013	NSOC reported an accidental erasure of research data. A database server that maintains survey responses was erroneously decommissioned and the server backup could not be restored. In addition, facility did not report to ORO according to required timelines.	Remedial Actions: Pending
198	08	VA North Florida/ South Georgia HCS	I	12/20/2013	NSOC reported that two unencrypted laptops used for VA research were not accounted for during an inventory assessment.	Remedial Actions: Pending
199	12 NE	Hines	H	12/20/2013	Facility reported that a DSMB report suspended enrollment of a melanoma study arm due to an unusually high number of Grade 5 toxicities. No enrollment had yet occurred at the facility.	Remedial Actions: Facility to provide DSMB summary and reported timeframes of the event; study team submitted amendment; IRB approved amendment.
200	20	VA Puget Sound HCS	H	12/23/2013	CIRB-managed unanticipated problem consisting of some participants in a colorectal screening study not receiving or not returning test kits.	Remedial Actions: Review of processes that will identify pending kit orders in real-time allowing lab personnel to address issues preventing kits from being mailed.
201	20	Portland VAMC	I	12/24/2013	NSOC reported an unsealed envelope with ICD, HIPAA authorization, and picture/voice consent for one Veteran was left over the weekend in a hallway box in a non-public non-access controlled area. Documents contained full name, last 4 SSN. Risk of exposure low.	Remedial Actions: Pending

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
202	08	VA North Florida/ South Georgia HCS	I	12/26/2013	NSOC reported that Veteran A received Veteran B's research study related information thus disclosing Veteran B's PHI.	Remedial Actions: Veteran B will be sent a HIPAA notification letter; pending.
203	22	VA Loma Linda HS	I	12/31/2013	NSOC reported one un-redacted page of data was inadvertently sent to a research sponsor. Investigation underway to determine the data that may have been compromised.	Remedial Actions: Pending

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

The Director of each VA research facility is required to report promptly to ORO any serious or continuing noncompliance in the facility's research program. ORO requires that the facility develop an acceptable remediation plan and monitors implementation of the plan until remediation is complete.

Summary

- 41 = Cases Continuing from Previous Calendar Year
- 57 = New Cases – January 1 through March 31
- 54 = New Cases – April 1 through June 30
- 57 = New Cases – July 1 through September 30
- *48 = New Cases – October 1 through December 31
- 216 = Total New Cases in Calendar Year
- 257 = Total Cases (Continuing Plus New) in Calendar Year

* Includes 7 cases from Third Quarter Report

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	07	Augusta	A	03/03/2008	Facility reported IACUC did not have nonscientist member Oct/Nov 2006; HVAC deficiencies were not corrected in a timely manner, and IACUC members had not completed all training requirements.	Remedial Actions: Appointing nonscientist to IACUC; re-review of affected protocols; correcting HVAC problems; and completing IACUC member training. CASE CLOSED.
2	05	DC VAMC	H	03/11/2011	Facility reported an unanticipated problem with inpatient pharmacy vaccine refrigerator (temps too high); Study meds from 2 studies were stored there; sponsor instructed PI to destroy meds	Remedial Actions: Study medications are now stored in the research pharmacy refrigerator; temp monitored manually -daily; Facility Management Service formed Integrated Project Team (IPT) meeting weekly. CASE CLOSED.
3	16	Houston	P	03/21/2012	Research Service Line review of e-IRB database found PI of an orthopedic registry study started study without submitting for R&DC review; failed to obtain a valid HIPAA authorization from 55 Veteran participants; employed a non-VA coordinator to enroll Veterans; sent data to a non-VA institution	Remedial Actions: Administrative hold placed on study; PI to submit protocol to R&DC for review and approval before resuming research procedures; credit monitoring offers to Veterans; protocol amendment; ensure all VA research is conducted in accordance with VHA 1200.05. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
4	19	VA Salt Lake City HCS	H	05/16/2012	Facility reported two cardiac studies had been suspended to new enrollment pending approval of the Corrective Action Plan required due to PI's previous SNC.	Remedial Actions: ICD revisions; include adequate placebo justification in IRB application; affiliate IRB must accept the PI's response/completion of the corrective action; issue start date of a 1-year improvement plan. CASE CLOSED.
5	07	Atlanta	H	05/19/2012	Facility reported unauthorized disclosure to affiliate of identifiable information (date of visit for study tests not indicated on HIPAA) of 104 subjects, for multi-site study HIV associated Emphysema; VA approved study, NIH funded.	Remedial Actions: Suspend enrollment for new subjects; amendment revisions regarding disclosure; study staff training; ICF and HIPAA revisions. CASE CLOSED.
6	03	VA New York Harbor HCS	H	07/11/2012	Facility reported disclosure of PHI of ten research subjects without a HIPAA authorization on a systolic blood pressure intervention trial.	Remedial Actions: Study coordinator educated and design problems corrected; data from involved participants permanently deleted from the database. CASE CLOSED.
7	09	VA Tennessee Valley HCS	S	07/13/2012	Facility reported a chemical spill involving the research area.	Remedial Actions: Clean-up of spill; chemical waste removed to the waste storage facility. CASE CLOSED
8	12	Madison	H	08/13/2012	Facility reported in a Gulf War Veteran brain imaging study the results of urine drug screenings for 65 subjects were mistakenly entered into CPRS.	Remedial Actions: PI is removing the urine sample results from CPRS. CASE CLOSED
9	02	VA Western New York HCS	H	08/23/2012	Facility reported that PO detected unapproved research (during Environment of Care Rounds) and unauthorized use of PHI by two medical students. The students were collecting data from CPRS for an unapproved research study of Clostridium Difficile Infection in the Intensive Care Unit.	Remedial Actions: PI and medical student counseled and education conducted, PI's studies suspended. PI suspended from conducting research for 3 year period; PI intensive re-education curriculum completed; PI to serve on IRB to gain experience. CASE CLOSED.
10	01	VA Boston Healthcare System	H	08/27/2012	Facility report describes pervasive non-compliance with a specific PI who is responsible for 8 active studies in the area of behavioral health. Non-compliance includes informed consent issues.	Remedial Actions: All PI's studies suspended to new enrollment until remedial actions addressed; PI and study staff education; Mock Informed Consent training; PI assurance of adequate time/resources to properly run 8 studies; identify person with secondary responsibility to assist PI. CASE CLOSED.
11	16	Houston	H	09/17/2012	Facility reported PI conducted research without R&DC approval and submitted a manuscript for publication using the research. This retrospective study involving 35 patients aimed at helping elucidate the efficacy of the posterior surgical approach using several objective and subjective criteria.	Remedial Actions: PI instructed to cease all research activities; Administrative Hold to be continued until all required documentation is completed, reviewed by relevant committees and PI is notified of approval to initiate research. CASE CLOSED.
12	18	Phoenix VA HCS	H	09/24/2012	Facility reported the duplicate enrollment of an individual in an online medical record to Reduce Limb Amputations in Persons with Diabetes study.	Remedial Actions: Develop corrective action plan; provide re-training of proper consenting procedures; implement monitoring of consent process. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
13	22	VA Long Beach HS	S	10/01/2012	Facility reported unauthorized access into a BSL-3 Laboratory	Remedial Actions: Notification of MCD; VA Police service investigation; Review of access records; Research Security Subcommittee review; training regarding access to research building; follow-up with employee health. CASE CLOSED.
14	16	Jackson	H	10/05/2012	Facility reported non-compliance involving conducting research without current IRB approval. The study is an evidence-based pilot project related to a Resource Care Map for Rural Elderly Caregivers.	Remedial Actions: Re-consent 5 subjects; Submit amendment to increase size; Education from IRB and RCO provided to PI; PI must submit a mentor to IRB for approval. CASE CLOSED.
15	10	Cleveland	H	10/11/2012	Facility reported data collection in a colonoscopy study was initiated prior to RDC approval.	Remedial Actions: Procedural training for PI/LSI on requirement for RDC approval prior to data pull. Remedial actions completed. CASE CLOSED.
16	07	Charleston	R	10/18/2012	Facility reported the R&DC inadvertently closed an aortic tissue analysis study that remained open with the Affiliate IRB.	Remedial Actions: Study reviewed at next R&DC meeting; Acting RCO performed regulatory compliance audit of study prior to next R&DC meeting; plan to cross-reference close-out procedures between IRB and R&DC. CASE CLOSED
17	07	Atlanta	H	11/01/2012	Facility reported serious continuing noncompliance re: PET scan study for PTSD (closed to enrollment). PI did not inform IRB and R&DC of IND for [O]15; did not submit annual reports to FDA; and did not submit project to FDA as amendment to IND.	Remedial Actions: PI training; report filed with FDA; Clinical trials audit to be conducted; PI and study team training completed before new submissions accepted. All actions completed. CASE CLOSED
18	07	Atlanta	H	11/01/2012	Facility reported serious continuing noncompliance re: PET scan study for PTSD prevention in Iraqi Veterans (closed to enrollment). PI did not inform IRB and R&DC of IND for [O]15; did not submit annual reports to FDA; and did not submit project to FDA as amendment to IND.	Remedial Actions: PI training; report filed with FDA; Clinical trials audit to be conducted; PI and study team training completed before new submissions accepted. All actions completed. CASE CLOSED.
19	07	Atlanta	H	11/01/2012	Facility reported serious continuing noncompliance re: PET scan study of memory and hippocampus in twins w/ PTSD (closed to enrollment). PI did not inform IRB and R&DC of IND for [O]15; did not submit annual reports to FDA; and did not submit project to FDA as amendment to IND.	Remedial Actions: PI training; report filed with FDA; Clinical trials audit to be conducted; PI and study team training completed before new submissions accepted. All actions completed. CASE CLOSED.
20	04	Clarksburg	H	11/05/2012	Facility reported IRB suspended Pharma-sponsored atrial fibrillation study of DU-176b Versus Warfarin. Suspension due to documentation backlog related to staff turnovers (sponsor monitors and facility coordinators).	Remedial Actions: Study suspension; IRB audit of documentation; report to FDA, OHRP and Sponsor; hiring of new study coordinator; improved PI supervision. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
21	01	VA Connecticut HCS	H	11/07/2012	Facility reported that a new PI over-enrolled subjects into a health Outcomes study for Veterans receiving mental health care services. PI subsequently enrolled eight additional subjects after being notified to cease enrollment.	Remedial Actions: PI to submit amendment for additional subjects; PI and staff to obtain continuing education; data not to be used from the 8 subjects enrolled after cease enrollment notification. CASE CLOSED
22	11	Ann Arbor HCS	H	11/09/2012	Facility reported noncompliance for an unfunded protocol involving the analysis of dietary labeling of oral chemotherapy prescriptions. The PI modified the approved study and added a sub-study that did not receive IRB or RDC approval.	Remedial Actions: Study presentation withdrawn from medical conference; all research activities and the unapproved sub-study stopped; cannot use database for any research. Suspension lifted, PI RAP completed; education of PI/staff on conducting VA research. Remedial actions complete. CASE CLOSED.
23	01	Providence	H	11/16/2012	Facility reported that enrollment on a CSP study (A Point of Care Randomization Study Comparing Insulin Administered Using a Sliding Scale versus a Weight Based Basal-Bolus Regimen) has been temporarily stopped by the coordinating site due to unanticipated problem related to delayed insulin order.	Remedial Actions: Enrollment temporarily stopped at participating sites; revisions were made to CPRS screens to mitigate similar problems in future. CASE CLOSED.
24	22	VA Loma Linda HS	H	11/16/2012	PI of CSP 565(Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy - VA Nephron-D study) failed to report incarceration of subject. CSP later halted Protocol 565 due to high potassium levels and acute kidney function changes.	Remedial Actions: Detention authorities must be contacted to discontinue incarcerated subject from continuing study drugs. CASE CLOSED.
25	23	Iowa City	H	11/21/2012	Facility reported three full-time VA staff incorrectly listed as study staff on three affiliate university ophthalmologic studies; one VA staff consented two university subjects without authorization.	Remedial Actions: Remove VA personnel from affiliate university protocol rosters. CASE CLOSED
26	01	VA Boston Healthcare System	H	11/29/2012	Facility report of two Traumatic Brain Injury and Stress Disorder studies that recruited participants whose age exceeded the parameters in the eligibility criteria.	Remedial Actions: PI and study staff education. Study amendment submitted and approved. Self-audits with IRB reporting required. CASE CLOSED.
27	08	Tampa	H	11/29/2012	Facility reported research conducted without obtaining HIPAA Authorizations on 80 participants in a homeless index study based on interviews.	Remedial Actions: The PI is obtaining the HIPAA Authorizations before initiating the chart review phase of the study in which data is collected. PI self-reported this incident. OHRP was notified. CASE CLOSED,

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
28	09	Memphis	H	11/30/2012	Facility reported serious programmatic noncompliance of 75 WOC appointments have expired; 13 other's status is unknown; 3 appointments have been expired for more than 2 years.	Remedial Actions: Human Resources and Research Service are reviewed WOC appointments for accuracy; Research service to store Excel list on secure, shared, folder so human resources can help maintain accurate WOC records; Remedial actions complete, CASE CLOSED.
29	18	Phoenix VA HCS	H	12/04/2012	Facility reported release of a partial recruitment list of subjects who failed pre-screening without consent or HIPAA authorization in a diabetic foot ulcer study.	Remedial Actions: Recovery of disclosed information. CASE CLOSED.
30	04	VA Pittsburgh HCS	H	12/06/2012	Facility reported that the IRB failed to report that the PI had failed to report a SAE within three days of becoming aware of the SAE. The study is a Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with recurring or Metastatic Head and Neck Cancer.	Remedial Actions: Internal audits of all SAE and UAP reports; global reminder to investigators detailing steps to be followed when submitting SAE and UAP reports. CASE CLOSED
31	02	VA Western New York HCS	H	12/11/2012	Facility reported unanticipated problem related to safety in a CSP treatment study of kidney function in diabetic patients.	Remedial Actions: Subjects contacted via certified letter; Study close-out procedures underway at facility. Study medications returned to the VA. CASE CLOSED.
32	01	White River Junction	H	12/17/2012	Facility reported a UPR in a study of veterans with mild TBI and/or PTSD funded by US Army Medical Research and Materiel Command. Randomization occurred correctly but dispensation was incorrect (due to technical problem) for 2 of 3 study treatment arms. No AEs occurred that required unblinding.	Remedial Actions: Randomization list updated for two of the three treatment arms, technical check developed to ensure randomization and dispensation match; PI education provided regarding reporting responsibilities. CASE CLOSED.
33	21	San Francisco VAMC	A	12/17/2012	Facility reported possible unapproved procedures (skin biopsies) in mice.	Remedial Actions: IACUC investigation; suspension of animal privileges for research staff member(s) involved; counseling, training and mentoring for research staff; development of written SOP. CASE CLOSED.
34	16	Central Arkansas VHS (Little Rock)	H	12/18/2012	Facility reported IRB suspended this investigator initiated retrospective chart review study on anti-diabetic agents and colorectal cancer. Suspension was due to repeated lapses in IRB approval.	Remedial Actions: PI to complete VA-required research training on schedule as required. CASE CLOSED.
35	16	Central Arkansas VHS (Little Rock)	H	12/19/2012	Facility reported noncompliance was discovered during an audit of a previously reported noncompliance event. A death, determined to be NOT related, was not reported in a timely manner.	Remedial Actions: Explanation of late reporting and a plan to prevent future occurrences. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
36	16	Houston	H	12/20/2012	Facility reported that the affiliate suspended a protocol after it found that the protocol file was not current as it applies to IND and FDA documentation. The study measures changes in Dopamine when Modafinil is used as a Treatment for Cocaine Dependence.	Remedial actions: PI to provide missing documents and responses to IRB. CASE CLOSED.
37	21	VA Central California HCS	H	12/20/2012	Facility reported 19 subjects enrolled in a cardiac study were not paid for participating as stipulated in the ICD, constituting continuing noncompliance.	Remedial Actions: Pay remaining study subjects; Develop policy instructing PIs how to obtain funds to pay study subjects; Update ICD to include subject withdrawal information. CASE CLOSED.
38	10	Cleveland	A	12/26/2012	Facility reported controlled substance (ketamine cocktail) inventory discrepancy.	Remedial Actions: SRS and IACUC review; return controlled substance cocktail to Pharmacy Services. CASE CLOSED.
39	04	VA Pittsburgh HCS	H	12/28/2012	Facility reported survey participants were able to review survey responses on a Share Point that was supposed to be accessed by study investigators only on a study of the problem of bullying in healthcare.	Remedial Actions: Enrollment suspended; PI provide and demonstrate a secure method to collect survey data; Either remove free text field from survey or provide compelling justification for keeping the free text field. CASE CLOSED.
40	17	VA North Texas HCS	H	12/28/2012	Facility reported a local PI voluntarily suspended enrollment of a vein graft study due to safety/efficacy concerns, pending review by DSMB and IRB.	Remedial Actions: Enrollment suspended; PI will maintain all active subjects on the study medication pending reviews; other actions pending. CASE CLOSED.
41	21	San Francisco VAMC	A	12/28/2012	Facility reported protocol suspension due to unapproved procedures (implantation of mini osmotic pumps) in mice.	Remedial Actions: IACUC review and protocol suspension. CASE CLOSED.
42	05	VA Maryland HCS	H	01/04/2013	Affiliated HRPO audited a Merit-awarded blinded controlled trial involving diet and physical activity to improve mobility and diabetic neuropathy outcome measures. IRB suspended enrollment based on findings and PI's inadequate CAP	Suspended study to new enrollment, other actions pending. CASE CLOSED.
43	01	White River Junction	H	01/08/2013	Facility reported a PTSD study was placed on Administrative Hold due to medication dosage errors.	Remedial Actions: New enrollment halted; Coordinating Center for the study performed audit on kit assignment and randomization assignment and found them to be correct. Audit is planned of the kit manufacturer. Additional layer of checks institutes post randomization. CASE CLOSED.
44	01	VA Connecticut HCS	H	01/09/2013	Facility reported apparent noncompliance of obtaining consents and HIPAA Authorizations on incorrect forms (4 of 5 subjects) on an innate immune mechanisms COPD study	Remedial Actions: PI will try to re-consent and obtain new HIPAA Authorizations; if so, will use data, if not, will not use data. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
45	07	Columbia	H	01/15/2013	Facility reported that an honest broker provided access to full data set to PI, Co-I in a pilot study of renal disease progression.	Remedial Actions: R&DC unanimously concluded that closing this retrospective data study would cause no harm to subjects. Study closed. CASE CLOSED
46	06	W.G. (Bill) Hefner VA Medical Center	H	01/16/2013	Facility report a missing consent form for one subject in a schizophrenia and bipolar disorder genetic questionnaire study.	Remedial Actions: CIRB required subject to be withdrawn; data not used. CASE CLOSED
47	16	Central Arkansas VHS (Little Rock)	H	01/17/2013	NSOC report received that noted the IRB discovered a privacy violation regarding recruitment. The facility does not know how many Veteran records were accessed, nor how many Veterans' PHI was collected/used. Also, the language of the combined consent did not have all required elements.	CASE CLOSED (combined with Central Arkansas VHS (Little Rock) 01/22/2012 – HIPAA below).
48	04	VA Pittsburgh HCS	H	01/19/2013	Facility reported PIs not reporting SAEs and UAPs to IRB1 within reporting timeline, and IRB1 not reporting the apparent serious or continuing non-compliance to IRB2. Internal audit identified 40 such instances.	Remedial Actions: Conduct another internal audit of submitted SAEs and UAPs; Re-evaluate current non-compliance reporting policies, procedures, and practices to minimize risk of delayed reporting; Written reminders to PIs regarding reporting timelines. CASE CLOSED.
49	04	VA Pittsburgh HCS	H	01/19/2013	Facility reported that their Clinical Trials Center (CTC) failed to report SAEs and UAPs involving risks to subjects or others within required timeframe. Internal audit conducted by CTC identified 21 such instances.	Remedial Actions: A QA reviewer position has been created for timely review of reportable events; PIs will receive written reminders from IRB of reporting requirements; Human Research Protection Workgroup to re-evaluate current adverse events and unanticipated problems reporting policies CASE CLOSED.
50	16	Jackson	H	01/22/2013	Facility reported that a PI initiated research without R&DC or IRB approval. The PI had submitted a request for Initial Review of the study and subsequently began data collection based upon a research employee's email that chart review could begin.	Remedial Actions: PI immediately ceased data collection; research employee was counseled; statement added to research website and forms portal that study initiation could not begin until written ACOS notification of approval; PI to sign statement of understanding of submission/approval process. CASE CLOSED.
51	16	Central Arkansas VHS (Little Rock)	H	01/22/2013	Facility reported that a subject was hospitalized for hypertensive crisis, which is not an expected adverse event as a participant in this study. The IRB reviewer determined that participation in the study and treatment with Losartan may have led to increased risk.	Remedial Actions: Study medication was discontinued during in-patient treatment, and not reinitiated. The subject recovered and was discharged. CASE CLOSED.
52	16	Central Arkansas VHS (Little Rock)	H	01/22/2013	Facility reported that HIPAA authorization or waiver could not be located for participants in a mental health medication adherence study.	Remedial actions: Regulatory audit will be conducted; IRB suspended all research activity in this protocol pending audit results; protocol to be re-reviewed. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
53	21	VA Palo Alto HCS	H	01/22/2013	Facility reported that an investigator conducting a QA review of records in an imaging study of discarded prostate tissue identified that 2 subjects signed ICDs but not HIPAA authorizations.	Remedial Actions: The data have been removed from the database and will not be analyzed, disclosed, or used for research purposes. CASE CLOSED.
54	22	VA San Diego HS	H	01/22/2013	Facility reported 11 human subject studies conducted by the same PI had been suspended after an anonymous allegation of research impropriety involving 1 of his human subjects protocol (age-related macular degeneration).	Remedial Actions: Affiliate IRP was reminded that only designated IRBs may take action on VA protocols; suspension lifted. CASE CLOSED.
55	22	VA San Diego HS	H	01/22/2013	Facility reported an apparent unanticipated problem involving risks to participants or others due to a dosage error. Dosage was not titrated up at the correct visit as per the protocol. This is a cognitive symptoms treatment trial for patients with TBI and/or PTSD.	Remedial Actions: Overall PI issued an "administrative hold" at all six study sites in this trial until the root cause of the dosage error was identified and eliminated. CASE CLOSED.
56	18	Phoenix VA HCS	H	01/23/2013	Facility reported the IRB's determination of serious and continuing noncompliance in a human studies protocol involving diabetic treatment of skin ulcers when an SAE was not reported within the required timelines.	Remedial Actions: PI provided a RAP to prevent this type of noncompliance from reoccurring. CASE CLOSED
57	03	VA New Jersey HCS	A	01/24/2013	Facility reported a significant deficiency involving temperature and humidity in the VMU.	Remedial Actions: Space heaters in animal rooms to control temperature; plan to check and replace control units and valves for the various HVAC units within VMU. CASE CLOSED.
58	05	DC VAMC	A	01/24/2013	Facility reported a fire in the animal research facility.	Remedial Actions: Evacuation of animals; notification of PI's. CASE CLOSED.
59	23	Iowa City	A	01/25/2013	Facility reported a noncompliance related to euthanasia procedures in mice.	Remedial Actions: Training of individual involved and other lab members. CASE CLOSED.
60	08	Tampa	H	01/29/2013	Facility reported that the IRB suspended enrollment in a study regarding: "Measuring upper limb prosthetic device usage for grasp and non-manipulative tasks" due to finding during continuing review that the PI did not disclose a financial conflict of interest.	Remedial Actions: The PI submitted a conflict of interest management plan to the IRB, R&DC and OGC. The determination by OGC was that there is no apparent COI situation and that a COI plan is not required at this time. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
61	10	Cincinnati	I	01/29/2013	Facility reported possible data breach related to former employee. Investigations conducted by facility Police, ISO and the VA OIG found that the employee did access files without authorization but these files were not research-related, did not leave the secure VA server and no data breach occurred.	Remedial Actions: Investigations revealed no cause for legal action; facility to ensure that permissions for electronic folder access are set properly to authorized individuals only. CASE CLOSED
62	16	Fayetteville	H	01/29/2013	Facility RCO reported that the affiliate IRB was not providing draft IRB minutes within 3 weeks as required.	Remedial Actions: develop a MOU with Central Arkansas VHS to utilize their IRB instead of Jackson's VAMC; Central Arkansas VHS' IRB uses IRBNet, which will make draft minutes available in three weeks. CASE CLOSED.
63	23	Minneapolis	H	02/01/2013	Facility reported a lapsed IRB approval of an ear, nose, and throat consults study; citing serious noncompliance because it represents a persistent failure to adhere to the policies that govern VA research.	Remedial Action: IRB Chair contacted the PI to address immediate plans to resolve this lapse. CASE CLOSED.
64	22	VA Greater Los Angeles HS	A	02/04/2013	Facility reported that the IACUC did not implement the newest edition of the Guide for the Use and Care of Laboratory Animals by December 2012, as required.	Remedial Actions: Use the checklist provided by ORD during program reviews and facility inspections. CASE CLOSED.
65	04	Clarksburg	H	02/05/2013	Facility reported IRB terminated Pharma-sponsored atrial fibrillation study of DU-176b Versus Warfarin, Substudy A-Health Economics Survey and Substudy B-Biomarker (blood sample), for data integrity/administrative issues.	Remedial Actions: IRB terminated studies; PI appeal on hold pending PI FOIA for IRB records. Facility must report any action changes to ORO. CASE CLOSED.
66	16	Central Arkansas VHS (Little Rock)	H	02/06/2013	Facility reported that the IRB determined that no evidence existed that an animal study actually involved human subjects research.	Remedial Actions: None. CASE CLOSED.
67	16	Central Arkansas VHS (Little Rock)	H	02/06/2013	Facility reported that this investigator-initiated retrospective chart review on the relationship between use of alcohol and tobacco and colon pathology was found to be noncompliant with submitting continuing reviews on time.	Remedial Actions: PI submitted closure required for this study; PI to be reminded of requirement to follow all submission guidelines, particularly continuing review for future submissions. CASE CLOSED.
68	16	Central Arkansas VHS (Little Rock)	H	02/06/2013	Facility reported that a subject who met exclusion criteria was enrolled in a study where he received extended dual-antiplatelet therapy (Plavix + Aspirin (ASA)) vs. placebo + ASA, after 12 months of standard of care clinical treatment on Plavix and Aspirin (ASA) therapy.	Remedial Actions: PI to either withdraw subject and not use data OR provide a compelling justification for the subject to remain in the study; provide a plan to inform the subject that they did not meet criteria OR justification for withholding this info from subject. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
69	05	VA Maryland HCS	H	02/11/2013	Facility reported IRB suspended study due to incorrect dosing (increased amounts of radiation exposure) on DXA scans performed on 19 subjects, and an inadequate corrective action plan submitted by the PI.	Remedial Actions: PI sent affected participants an IRB-approved letter and submitted a revised RAP to IRB; VA and University RSOs reviewed and approved corrective actions (letter, radiation ordering SOP). CASE CLOSED.
70	06	Durham	A	02/13/2013	Facility reported mice housed under a closed protocol.	Remedial Actions: PI assurance to remove or transfer all animals prior to study closures; additional oversight and review of study closures by VMU supervisor and IACUC coordinator. CASE CLOSED
71	06	Durham	S	02/13/2013	Facility reported the conduct of preliminary research activities on a research safety protocol prior to review and approval by the SRS and R&DC.	Remedial Actions: Submission of all research forms to the Research Office; SRS review of research protocol; R&DC review of research protocol; submission of formal explanation for noncompliance by the PI. CASE CLOSED.
72	17	VA North Texas HCS	A	02/15/2013	Facility reported the discovery of an adverse event during an announced post-approval monitoring visit for an animal protocol involving mice.	Remedial Actions: PI counseled study personnel on the facility tumor burden policy; IACUC review and approval of an amendment to reduce the frequency of tumor measurements to twice weekly. CASE CLOSED.
73	04	VA Pittsburgh HCS	H	02/20/2013	Facility reported that study team of a smoking cessation study failed to report three instances of apparent serious non-compliance within five days of becoming aware of the events.	Remedial Actions: Suspension of enrollment; appointment of a Co-I to the study; education of PI and study staff. CASE CLOSED
74	21	VA Palo Alto HCS	H	02/20/2013	Facility reported PI of advanced optical imaging genitourinary study self-identified the research was initiated after IRB approval, but without SRS or R&DC approval.	Remedial Actions: Initial reviews by the SRS and R&DC; RAP to include staff training. CASE CLOSED.
75	02	Syracuse	H	02/21/2013	CIRB suspended CSP#574 Community-Acquired Pneumonia trial based upon safety concerns revealed in SMART audit	Remedial Actions: CIRB suspended enrollment; RCO to audit all PI's protocols; CIRB has directed PI to implement a corrective action plan. CASE CLOSED.
76	07	Charleston	A	02/21/2013	Facility reported the discovery of the death of eight weanling mice on an active animal protocol.	Remedial Actions: VMU staff was retrained on the importance of daily cage surveillance; the frequency of cage changes was increased from once every two weeks to weekly. CASE CLOSED.
77	16	Central Arkansas VHS (Little Rock)	H	02/26/2013	Facility reported lapses in continuing review of a protocol dealing with parent-child interaction therapy for two consecutive years.	Remedial Actions: Submit continuing review to IRB; complete requested modifications. CASE CLOSED.
78	18	Phoenix VA HCS	H	02/26/2013	Facility reported that protocol materials (e.g., patient instruction, questionnaire, offloading walker, wound care items, and home care kits) were used without IRB review and approval in a diabetic wound study.	Remedial Actions: The IRB submission checklist form was revised to include prompts that subject materials must be reviewed and approved; study closed as sponsor decided not to re-open this site for additional enrollment. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
79	02	Syracuse	H	02/28/2013	Facility reported that PI on a bladder cancer clinical trial identified that a resident obtained consent without the PI adding to the study team or properly training him, resulting in consent errors and failure to obtain HIPAA authorizations.	Remedial Actions: IRB determined no harm to subjects; PI may not use data from the 2 participants; RCO to review study files and educate the PI and study team. CASE CLOSED.
80	02	VA Western New York HCS	A	03/07/2013	Facility reported the conduct of animal research by a PI with an expired WOC appointment.	Remedial Actions: Retrain research office staff on procedures for tracking appointment expiration dates; send notifications one month prior to WOC expiration; ensure that expiration dates on badges and WOC appointment letters correspond; renew PI WOC appointment. CASE CLOSED.
81	16	Central Arkansas VHS (Little Rock)	H	03/11/2013	Facility reported a violation of enrolling subjects without verifying subjects met inclusion/exclusion criteria. This is a pilot study collecting patient data for an access measure.	Remedial Actions: Confirm inclusion/exclusion criteria; update protocol to clearly outline enrollment; study coordinator to use screening and enrollment checklist. CASE CLOSED.
82	06	Durham	H	03/12/2013	A local RCO identified a potential protocol deviation in a low risk multi-site study in which VA staff are interviewed about an initiative to improve acute stroke care practices.	Remedial actions: The VA Central IRB determined there was no noncompliance with approved protocol. Study team submitted an amendment clarifying that study sites are not engaged in human subjects research and consenting of subjects and record-keeping will be done by the study team. CASE CLOSED.
83	21	San Francisco VAMC	A	03/12/2013	Facility reported a deviation from approved procedures in a sheep protocol.	Remedial Actions: modification of analgesia; IACUC amendment approval. CASE CLOSED.
84	01	White River Junction	A	03/13/2013	Facility reported rats were being used for research and as sentinels without approved protocols.	Remedial Actions: ACORPS have been approved for use of rats in research and as sentinels; Research Service is developing training for new investigators; Research and Development Committee formed an ad hoc subcommittee to address training and communication issues with new investigators. CASE CLOSED.
85	01	White River Junction	H	03/13/2013	Facility reported programmatic non-compliance in a prostate cancer study. The R&DC approved an amendment involving collection of data from pregnant partners and child of participant.	Remedial Actions: R&DC Approval letter was not sent; PI and study staff informed to not enroll any pregnant women or children into the study, Education regarding the requirement for CRADO waiver provided to PI and study staff.
86	02	Albany	H	03/13/2013	Facility reported that the IO has withdrawn support and ordered termination of a suicide study for reasons not related to research.	Remedial Actions: Return funds and terminate study. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
87	05	VA Maryland HCS	H	03/13/2013	Facility reported PI on VA funded multiple sclerosis study self-reported conducting surveys not described in protocol or ICD 27 participants enrolled before deviation was discovered.	Remedial Actions: IRB approved PI's amendment including: participant notification letter, revised re-consent ICD and ICD for newly enrolled participants. Data will be removed if participant or LAR does not sign re-consent ICD. CASE CLOSED.
88	12	Chicago HCS	H	03/15/2013	Facility reported a suspension of 2 colorectal protocols following a complaint of possible noncompliance related to delegation of responsibilities, collection and handling of biopsy samples, IC process, and transfer of PHI.	Remedial Actions: RCO audit; review of SOPs to ensure consistency; review of VA staff WOC status and credentials; review of VA staff training; study suspended; PI addressed concerns so suspension lifted; Remedial actions complete, CASE CLOSED.
89	17	VA Central Texas HCS	H	03/15/2013	Facility reported two instances of unauthorized transmission and unauthorized disclosure of subject's PHI; who were enrolled in a cancer study.	Remedial Actions: Data/transmission deleted; staff re-educated. CASE CLOSED.
90	12	Madison	A	03/20/2013	Facility reported unintentional loss of mice due to lack of feed.	Remedial Actions: New signage and cage markers when mice are weaned or added to the colony; review of feeding policy and new signage requirements with ARF staff. CASE CLOSED.
91	20	VA Puget Sound HCS	A	03/20/2013	Facility reported a lapse in annual protocol review involving rodent specie(s).	Remedial Actions: Monthly review and comparison of all active projects; review of potential replacement database software programs to manage IACUC and functions, including protocol expiration dates. CASE CLOSED.
92	17	VA North Texas HCS	A	03/22/2013	Facility reported an adverse event on an active animal protocol involving a live rat that was not properly euthanized.	Remedial Actions: Personnel must retake all IACUC Collaborative Institutional Training Initiative (CITI) courses; personnel must be retrained on all protocols and standard operating procedures related to the use of rats; personnel must be retrained on rat handling and injection procedures. CASE CLOSED.
93	17	VA North Texas HCS	A	03/22/2013	Facility reported an adverse event regarding instability in staffing within the occupational health program for employees working with animals.	Remedial Actions: Review of existing records; animal facility personnel and researchers to complete questionnaire; occupational physician assigned to animal program. CASE CLOSED.
94	04	Philadelphia	H	03/25/2013	Facility reported unauthorized research activity of chart review of 567 charts conducted by a physician who was collecting PHI on prospective subjects with attempt to correlate used of antiepileptic drugs and increase in risk of suicide.	Remedial Actions: Research activity reviewed; physician informed to cease activity: R&DC and IRB determined study not to be a research activity; IRB issuing additional guidance to facility personnel. Actions determined to be complete. CASE CLOSED.
95	15	VA Kansas City Medical Center	H	03/25/2013	Facility reported failure of the PI/research staff to obtain signature on ICD prior to conducting research; repeat occurrence in this study of adult-diagnosed schizophrenia.	Remedial Actions: PI and study staff education; no research procedures can be initiated without a signed ICD reviewed first by PI. CASE CLOSED..

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
96	12 NE	Hines	H	03/27/2013	Facility reported that a DMC safety report in a leukemia study was not reported within the required 5 days.	Remedial Actions: Verify increased safety monitoring, inform patients, and increased consultation; approve new ICD. CASE CLOSED.
97	23	Iowa City	A	03/28/2013	Facility reported noncompliance involving canine procedures (inadequate sanitation, improper handling of anesthetics, expired drugs, improper personnel protective clothing) following a semi-annual facility inspection.	Remedial Actions: Suspension of animal procedures; IACUC investigation; research staff retraining; discontinued use of non-pharmaceutical grade fluids; removal of expired drugs; observation of animal procedures by VMO; continued lab inspections; IACUC review and approval of protocol. CASE CLOSED.
98	01	White River Junction	H	03/29/2013	Facility reported prostate cancer study suspension due to R&DC approval prior to IBC review and approval. One subject had been consented; no study evaluations had yet occurred and will not occur until IBC approval obtained.	Remedial Actions: Staff education; R&D Committee education; quality improvement team chartered; IBC review and approval of protocol, update MOU with affiliate IBC.
99	08	VA North Florida/ South Georgia HCS	H	04/02/2013	Facility reported 2 HIPAA authorizations not obtained when informed consent was obtained for a safe community driving program for combat Veterans.	Remedial Actions: The subjects were contacted and HIPAA obtained from one, the other subject was withdrawn from the study. PI checklist for enrollment has been created to prevent future occurrences. CASE CLOSED.
100	15	Columbia	H	04/04/2013	Facility reported a potential privacy violation by a PI who took photos of 22 enrolled Veterans without obtaining Consent for Use of Picture and/or Voice (VA Form 10-3203) in this randomized dog training study.	Remedial Actions: PI education; submission of deviation report and amendment form to the IRB; Re-consent of subjects; Remedial actions complete, CASE CLOSED.
101	04	VA Pittsburgh HCS	H	04/05/2013	Facility reported suspension of new enrollment in a treatment trial for subjects with previously untreated Multiple Myeloma due to an invalid consent form. The IRB did not yet approve the ICD language in a submitted amendment request.	Remedial Actions: Subjects enrollment suspended; PI revise proposed study withdrawal language and clarify whether procedures to be performed are standard of care or research procedures in the Informed Consent Form. CASE CLOSED
102	12 NE	James A. Lovell Federal Health Care Center	H	04/05/2013	Facility reported receipt of a DMC safety report in a leukemia study being conducted at the facility.	Remedial Actions: Verify increased safety monitoring, inform patients, and increased consultation; approve new ICD. CASE CLOSED
103	12 NE	James A. Lovell Federal Health Care Center	H	04/05/2013	Facility reported that a DMC safety report in a leukemia study was not reported within the required 5 days.	Remedial Actions: Develop procedures and conduct training to ensure non-compliance cases are reported within required timeframes. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
104	17	VA North Texas HCS	H	04/08/2013	Facility reported suspension of new enrollment in a surgery/discharge criteria study because of possible unethical recruitment practices; 3 of 19 subjects were recruited on the same day of the surgery.	Remedial Actions: Co-PI and study coordinator removed from study; PI received HRPP training; procedures to prevent coercion of subjects and enrollment of ineligible subjects implemented; subjects re-consented; suspension lifted. CASE CLOSED.
105	08	Tampa	S	04/09/2013	Facility reported failure to meet annual review deadline for SRS review of a service dogs for Veterans with PTSD protocol.	Remedial Actions: Facility will amend their administrative processes to ensure reminders are sent at 7 days and 24 hours prior to annual review deadlines. CASE CLOSED.
106	23	Minneapolis	A	04/09/2013	Facility reported unapproved personnel participating in animal procedures involving pigs.	Remedial Actions: Training of staff. CASE CLOSED.
107	07	Charleston	H	04/10/2013	Facility reported 23 VA subjects were enrolled in research study prior to approval by the R&DC and ACOS/R. Study involves the collection of demographic information and a self-report questionnaire.	Remedial Actions: No additional research until R&DC approval; amendment with IRB-1 re compensation; approved amendment resubmitted to R&DC; reportable event filed with IRB-1. CASE CLOSED.
108	16	Jackson	H	04/12/2013	Facility self-reported that while conducting the annual CR of this protocol, the IRB reviewer discovered that the PI enrolled two female Veterans. Approved protocol only includes male Veterans. This study assesses the effects of CPAP among patients with GERD and obstructive sleep apnea	Remedial Actions: PI cannot use data; PI must notify two subjects that their data will not be used; modification was submitted and approved by the IRB to include all Veterans. CASE CLOSED
109	05	VA Maryland HCS	H	04/16/2013	Study suspended for failure to replace departing PI.	Remedial actions: IRB approved amendment to appoint a new PI, awaiting ORD decision on whether VA Merit award can be transferred to the new PI. ORD verbally approved transfer of PI. IRB will lift suspension upon receipt of ORD's written confirmation. CASE CLOSED.
110	22	VA Greater Los Angeles HS	A	04/18/2013	Facility reported the suspension of a protocol involving rats.	Remedial Actions: Protocol suspension; animals euthanized; project terminated by Principle Investigator, who will no longer work at the facility; IACUC voted to finalize the project. CASE CLOSED.
111	22	VA Greater Los Angeles HS	A	04/18/2013	Facility reported the suspension of a protocol involving rats.	Remedial Actions: Correction of all safety and sanitary concerns; monitoring and training. CASE CLOSED.
112	01	White River Junction	H	04/19/2013	Facility self report of UPR consisting of incorrect study drug dosing for one participant in a drug study of veterans with PTSD.	Remedial Actions: Enrollment hold; Measures have been taken to ensure no such further dose escalation errors can be made in the randomization process. CASE CLOSED.
113	21	VA Palo Alto HCS	H	04/22/2013	Facility reported that a cardiothoracic surgeon obtained tissue samples for research purposes without patient consent.	Remedial Actions: Remedial training provided to PI and staff; and implemented monthly RCO ICD audits for a period of 4 months. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
114	16	Central Arkansas VHS (Little Rock)	H	04/23/2013	Facility reported 20 subjects had been enrolled against exclusion criteria	Remedial Actions: the staff member who inappropriately enrolled subjects is no longer employed by VHA; additional protocol training for staff; the data for the 20 affected subjects removed from dataset; protocol modification approved by IRB. CASE CLOSED.
115	16	Central Arkansas VHS (Little Rock)	H	04/23/2013	RCO Audit Found the SRS inappropriately exempted a study that aspirates bone marrow from subjects.	Remedial Actions: Study staff to provide documents in order for SRS to re-review protocol and proof of outdated training. CASE CLOSED.
116	01	VA Connecticut HCS	H	04/24/2013	Facility reported apparent serious non-compliance in that a PI removed PHI data from the VA and stored in her office at Kean University, NJ in a study involving the impact of stress indicators through animal-assisted intervention.	Remedial Actions: Suspend all study activity; assign new PI; remove PI to co-investigator; educate research team; obtain HIPAA signatures; and amend study for further enrollment if necessary. CASE CLOSED
117	20	Portland VAMC	A	04/25/2013	Facility reported improperly calibrated animal irradiator and unapproved transport of mice to and use of Affiliate irradiator.	Remedial Actions: Facility has approved funding for service and calibration of the VA-housed irradiator; all Investigators were notified in 04/10/13 email that animal transport to Affiliate must be part of an approved protocol or added by amendment before the activity occurs. CASE CLOSED.
118	23	Iowa City	A	04/25/2013	Facility reported a noncompliance involving unapproved procedures (retro-orbital injections) in mice.	Remedial Actions: IACUC review of amendment; retraining of laboratory personnel. CASE CLOSED.
119	12	Milwaukee	S	04/26/2013	Facility reported a research safety incident involving a potential toxic exposure.	Remedial Actions: Additional employee interviews; continued air quality monitoring; and further investigations and discussion of the incident at the next monthly SRS meeting. CASE CLOSED.
120	16	Oklahoma City	H	04/26/2013	Facility reported that a password-protected laptop that contained PHI on VA and OU study participants was stolen from an employee's car. The study is a clinical trial of the On-X Valve using Low Dose Anticoagulation.	Remedial Actions: study participants notified by letter; subjects offered one-year free of credit monitoring service. CASE CLOSED.
121	05	VA Maryland HCS	H	04/29/2013	IRB suspended study enrollment based on internal audit findings re: multiple uses of inaccurate HIPAA Authorization, failure to apply exclusion criteria and early withdrawals of participants during baseline assessment process	Remedial Actions: Re-trained study team, now, two staff check HIPAA form during enrollment, retain current approved HIPAA in CICERO (eIRB system), letter to participants requesting them to sign and return corrected HIPAA form. IRB lifted suspension. CASE CLOSED.
122	06	Durham	S	04/29/2013	Facility reported lapses in SRS continuing review.	Remedial Actions: Approval of continuing review; review of documentation. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
123	18	New Mexico VA HCS	H	05/01/2013	Facility reported that results from a Cardiology QI activity were submitted to a national meeting and accepted for poster presentation. IRB determined that the poster must be withdrawn and incident reviewed as noncompliance by the IRB. No further actions were required for this incident.	Remedial Actions: Developed a process to assist investigators in the review of new projects that will include an assessment as to whether the activity is research or QI activity. CASE CLOSED
124	22	VA Greater Los Angeles HS	I	05/02/2013	Facility reported 5 ICDs and HIPAA Authorizations are missing (126 subjects enrolled) in a gout study. PHI includes names and SSNs. PI subsequently reported concerns that documents and binders were moved out of place in her office.	Remedial Actions: Thorough search conducted; IRB granted permission to contact the 5 subjects to sign ICD and Authorization; research documents re-located, door locks changed and new padlock mechanisms installed in the cabinets. CASE CLOSED
125	12 NE	Hines	H	05/06/2013	The DMC reported to the facility that a subject in a PTSD treatment trial experienced an unanticipated AE consisting of a slow heart rate and an elevated cortisol level. Currently this subject is the only enrollment in the study; also reported that the study blind had been broken.	Remedial Actions: Protocol amendment with exclusion criteria revisions, ECG prior to medication initiation, in-person check-up 48 hrs. after medication initiated; revise ICD to clarify risks; obtain FDA approval to continue study. CASE CLOSED
126	21	VA Palo Alto HCS	A	05/07/2013	Facility reported unanticipated loss of animal life (mice) during an irradiation procedure.	Remedial Actions: PI consideration of age and strain-specific sensitivities to irradiation procedures; confirm irradiation timer is functioning properly; staff retraining. CASE CLOSED.
127	22	VA San Diego HS	S	05/07/2013	Facility reported termination of an MOU with another VA Facility for use of its IBC.	Remedial actions: None, reported for informational purposes only. CASE CLOSED.
128	20	VA Puget Sound HCS	H	05/08/2013	Facility reported that four subjects were enrolled in a substance use disorder study that did not meet inclusion/exclusion criteria; specifically, subjects were unable to provide 3 verifiable contacts.	Remedial Actions: Remedial training for PI and staff and protocol modification to revise exclusion criterion for future recruitment. CASE CLOSED.
129	23	Minneapolis	S	05/08/2013	Facility reported initiation of VA research without written notification from the ACOS Research that the project may begin.	Remedial Actions: Review of both protocols under a new combined project; PI has been counseled and educated; All work under both protocols has been suspended. CASE CLOSED.
130	20	Portland VAMC	H	05/14/2013	Facility reported that a study team internal audit found that two hard-copy ICDs could not be located for two subjects in a lung cancer study. Incident reported to NSOC; however, the missing ICDs were subsequently found in secure storage.	Remedial Actions: Subject notification not required since missing ICDs were located in secure storage. CASE CLOSED
131	07	Charleston	H	05/17/2013	Facility self-reported via NSOC that four subjects did not sign HIPAA Authorizations.	Remedial actions: All subjects to sign current HIPAA; No data used as all are screen fails; Study closed with IRB. CASE CLOSED

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
132	05	VA Maryland HCS	H	05/21/2013	Affiliate IRB reported an unanticipated problem involving risks to subjects or others consisting of misplaced PHI in a brain activation study following bilateral arm training.	Remedial Actions: PI confirmed that data security procedures in protocol were still in effect; IRB-approved participant notification letter from MCD; PI accounted for security of study records; discussed the event with PO, HARPO, and University auditor. CASE CLOSED
133	22	VA Greater Los Angeles HS	H	05/21/2013	Facility reported 1 missing HIPAA authorization for a specimen acquisition study utilizing samples from bone marrow biopsies.	Remedial Actions: Have subject resign HIPAA authorization and maintain forms in a locked cabinet in a secure location. CASE CLOSED.
134	08	VA North Florida/ South Georgia HCS	H	05/24/2013	Facility reported a protocol deviation in a device study for early detection and treatment of cardiac issues. The IRB determined this deviation to be serious noncompliance.	Remedial Action: PI reported to IRB sponsor and OHRP. The IRB determined serious noncompliance. The consent was not changed no additional risks determined. R&DC agreed with IRB's determination. CASE CLOSED.
135	08	VA North Florida/ South Georgia HCS	H	05/24/2013	Facility reported a retrospective chart review study (minimal risk) was conducted outside of the date limits approved by the IRB. "Appropriate use of Myocardial Perfusion Imaging in the VA."	Remedial Actions: Reported NC to the IRB; the PI submitted an amendment, amendment approved by the IRB; daily record counts by the PI have been implemented. CASE CLOSED.
136	05	DC VAMC	H	05/28/2013	Deviations found by NIOSH: 1) a subject's BP was measured after spirometry rather than before, value (195/112) would have excluded participant; 2) subject attempted spirometry testing 24 times (3 sessions of 8 attempts) contrary to the spirometry protocol (1 session).	Remedial Actions: Revised protocol to emphasize testing order, clarify spirometry contraindication, plan to develop emergency SOP; all technicians were retrained. CASE CLOSED. Re-classified as externally identified noncompliance, Table 2a, Item 106.
137	04	VA Pittsburgh HCS	H	05/30/2013	Facility reported suspension of new enrollment on a pharmacogenetics of alcohol dependence study due to PI not adhering to approved protocol and not reporting deviations, and UAPs and SAEs as per VHA and local policies.	Remedial Actions: PI and study staff education; PI complete review of all study records and report any events that required reporting; develop plans to ensure future adherence to approved protocol and all deviations/non-compliance reporting requirements. CASE CLOSED.
138	09	Louisville	I	05/30/2013	Facility reported a retired PI of a closed ophthalmology study entered all paper data electronically into the secure VA Research server and destroyed all paper records, including original consent forms (43 participants).	Remedial Actions: RCO verified all electronic files are stored on the secure VA research server; PO verified that the paper destruction method fulfilled regulations; RCO to continue PI and research staff education with emphasis on records retention requirements. CASE CLOSED
139	02	VA Western New York HCS	S	05/31/2013	RCO Audit found protocol noncompliance due to a lapse in SRS continuing review.	Remedial Actions: Review of all VA Central IRB studies; completion of continuing reviews by the SRS; revisions to the SRS SOP to include the processing of IRB studies; re-training of Research Office staff. CASE CLOSED.
140	17	VA North Texas HCS	I	05/31/2013	Facility reported unauthorized transfer of research records including full name, full SSN, DOB, ICD and clinical notes/reports for six participants in a venous ulcer study.	Remedial Actions: Research records were returned to the VA research service; letters were sent offering credit protection services. CASE CLOSED

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
141	05	VA Maryland HCS	A	06/05/2013	Facility reported unapproved animal procedures on mice under an approved protocol, lack of IBC approval for breeding transgenic mice. Lack of post-operative monitoring of mice.	Remedial Actions: Stop unapproved procedures, remind all staff that amendments must be submitted to change protocols; IBC approval must be obtained when needed, animals must be monitored appropriately following surgery. CASE CLOSED.
142	12 NE	Hines	A	06/10/2013	Facility reported deviations that occurred on two approved animal protocols (rodent).	Remedial Actions: Principal Investigator submitted requests to modify approved protocols; requests for modifications reviewed and approved by IACUC. CASE CLOSED.
143	16	Central Arkansas VHS (Little Rock)	H	06/14/2013	Facility reported the research pharmacy dispensed expired medications to four subjects in a prevention of postoperative Nausea and Vomiting in Surgical Patients.	Remedial Actions: Expired study medication removed from shelf & destroyed; drug expiration date reminder created; lot# & expiration date will be recorded on release slip; affected subjects will receive notification of medication error; & data collected for the 4 subjects must be withdrawn; remedial education of pharmacy team. CASE CLOSED.
144	15	VA Kansas City Medical Center	H	06/18/2013	Facility reported prescribing error and unintentional break of the study blinding of this schizophrenia symptom trial.	Remedial Actions: RDC to initiate an ad hoc subcommittee to investigate PI actions. CASE CLOSED.
145	21	San Francisco VAMC	A	06/18/2013	Facility reported an error in post-operative pain management in sheep.	Remedial Actions: Temporary removal of one VMU technician from duties with large animals pending personnel review and action; retraining of VMU staff; increased VMU staff supervision and increased communications between VMU supervisor and staff on weekends. CASE CLOSED.
146	22	VA Greater Los Angeles HS	H	06/18/2013	Facility reported review of a carcinoid study (now closed) revealed that the PI did not report non-local SAE or submit latest versions of the Investigator Brochure. No subject enrollment throughout its course at the facility.	Remedial Actions: Education to PI and study team regarding timely submission of reports to IRB. CASE CLOSED.
147	18	Phoenix VA HCS	H	06/20/2013	Facility reported study staff inadvertently wrote another Subject B's SSN onto Subject A's ICD for a joint surgery study; then crossed out the incorrect SSN and wrote the correct number. The document was scanned into CPRS; however, both SSNs were visible on the document.	Remedial Actions: Subject was re-consented; the compromised ICD (including the scanned copy) was recovered; study staff trained. CASE CLOSED
148	20	Boise VAMC	H	06/20/2013	Facility reported unapproved research, involving two studies (cardiopulmonary resuscitation and distance learning DOD funded) conducted by the same PI, that could be potentially exempt from IRB.	Remedial Actions: Submit studies for review and approval; PI re-education; improved internal program oversight methods.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
149	06	W.G. (Bill) Hefner VA Medical Center	H	06/26/2013	Facility reported one team member on a protocol did not have a scope of practice and another team member was not added to that protocol.	Remedial Actions: An amendment to add the missing research team member and a new Scope of Practice for the other team member. IRB approved subject info letter requesting re-consent. If not obtained data will not be used. CASE CLOSED
150	04	VA Pittsburgh HCS	A	06/27/2013	Facility reported inappropriate euthanasia of mice.	Remedial Actions: PI and staff retraining; PI submission of corrective action plan; letter of reprimand to file. CASE CLOSED.
151	05	DC VAMC	H	06/28/2013	Facility reported informed consent issues on a cardiovascular study. Five subjects were consented with a document that contained information not approved by the IRB and did not contain the IRB stamp. Four forms contained the signature of consent informant not authorized for consenting.	Remedial Actions: Re-consent affected subjects; education of research team. CASE CLOSED.
152	10	Cincinnati	A	06/28/2013	Facility reported protocol noncompliance involving the prohibited transfer of rats from the original protocol to a protocol with a higher pain category.	Remedial Actions: PI retraining on affiliate animal transfer policies, increased monitoring to ensure continued compliance, exclusion of data collected outside of compliance from publication. CASE CLOSED.
153	01	White River Junction	R	07/01/2013	Facility Self-Report of RDC not performing annual review of exempt protocols.	Remedial Actions: Activities on projects ceased pending CR; PI re-education on the requirement of CR for research activity to continue; Research Service develop a tracking system to prevent recurrence, including sending out annual reminders in Outlook each new calendar year. CASE CLOSED
154	23	Minneapolis	H	07/03/2013	Facility reported that study staff-identified the noncompliant use of an outdated consent form to enroll 15 subjects in a prostate cancer testing study.	Remedial Actions: PI implementation of procedures to prevent recurrence. CASE CLOSED.
155	06	Durham	A	07/05/2013	Facility reported an unanticipated loss of animal life.	Remedial Actions: Approval of revised standard operating procedures. CASE CLOSED.
156	01	VA Boston Healthcare System	S	07/05/2013	Facility reported a contractor was exposed to blood splatter while servicing a blood tube.	Remedial Actions: Contractors instructed to wear protective equipment when working in VA laboratories. CASE CLOSED.
157	05	VA Maryland HCS	H	07/05/2013	The VAMHCS affiliate (UMB) IRB reported an UPIRSO directly to NERO but no details were provided. The event involved the MVP study, for which the VA CIRB is the IRB of record, not the VAMHCS affiliate. This was a duplicate report of RISP/CIRB case.	Duplicate report by the affiliate IRB of their review of a UPIRSO on a protocol (MVP) for which they were not the IRB of Record. CASE CLOSED

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
158	16	Central Arkansas VHS (Little Rock)	H	07/08/2013	Facility reported a subject in a study designed to test the safety and efficacy of the Misago Peripheral Self Expanding stent, developed an 80% stenosis at the edge of the stent placement.	Remedial Actions: Currently enrolled subjects to be informed of the additional risk of the edge stenosis. CASE CLOSED.
159	08	San Juan	H	07/08/2013	Facility reported an inclusion criteria protocol violation in a colon cancer study.	Remedial Actions: The PI will hold monthly staff meetings. The PI submitted to the IRB a clarification on the instrument used to determine the cancer stage used in the protocol. The data erroneously collected was removed from the sample. CASE CLOSED.
160	22	VA Long Beach HS	H	07/09/2013	Facility reported one subject was enrolled in a gait study without HIPAA authorization or waiver. This noncompliance was identified by IRB during continuing review.	Remedial Actions: With IRB approval, the PI has obtained the HIPAA authorization. CASE CLOSED
161	05	VA Maryland HCS	H	07/10/2013	Facility reported protocol deviation on a breast cancer survivor study - participant received a multi-slice CT scan instead of a spiral scan.	Remedial Actions: Re-educated staff, revised CT order SOP, PI, study coordinator. & clinician to verify & double check orders, CT documentation sheet to be placed in subjects' charts, retro audit of GRECC scanning studies, consult Radiology on future CT studies. CASE CLOSED.
162	22	VA San Diego HS	A	07/12/2013	Facility reported loss of animal life in rats.	Remedial Actions: Retraining; review standard operating procedures. CASE CLOSED.
163	06	W.G. (Bill) Hefner VA Medical Center	H	07/12/2013	Facility reported prior to site visit that cardiology grad student pre-op quality improvement project had student listed as PI.	Remedial Actions: Student PI replaced by mentor PI; Study closed; Policies revised. CASE CLOSED
164	10	Cleveland	S	07/22/2013	Facility reported a shipment containing blood samples and brain slices was not properly labeled.	Remedial Actions: Additional Department of Transportation training for research staff; addendum to research protocol safety survey. CASE CLOSED.
165	21	VA Palo Alto HCS	H	07/23/2013	Facility reported that a retrospective TBI study had been initiated after IRB approval, but prior to R&DC approval.	Remedial Actions: Voluntary administrative hold placed on this protocol; audit of all of the PI's protocols; additional training provided to PI. CASE CLOSED.
166	08	Tampa	H	07/24/2013	Facility reported an IRB determination of serious noncompliance in a homelessness study to the MCD outside of the required 5 business days.	Remedial Actions: The IRB reviewed this case of apparent serious noncompliance and determined it to be serious. The action plan approved was to report noncompliance the same day that the determination is made. CASE CLOSED
167	09	Lexington	A	07/26/2013	Facility reported a deviation of a protocol (failure to adhere to weight loss criterion) involving mice.	Remedial Actions: PI to submit a modification to the ACORP; additional training for staff; staff to read the protocol and sign documentation they understood the protocol. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
168	09	Lexington	A	07/26/2013	Facility reported a deviation of a protocol involving mice (conducting tail biopsies outside of the protocol-defined age range and not using the required anesthesia.	Remedial Actions: Additional training of staff; PI must seek IACUC approval to perform tail-snips; staff must read the protocol and sign documentation that they understand the protocol. CASE CLOSED.
169	18	Phoenix VA HCS	H	07/26/2013	Facility reported that ISO reviews were significantly delayed and that the IRB determined this constituted serious (programmatic) noncompliance.	Remedial Actions: ISOs must complete all required reviews; facility hired a (third) ISO; IRB will monitor review timelines. CASE CLOSED.
170	05	DC VAMC	H	07/29/2013	Facility reported PTSD Clinical Trial was suspended due to contractor reliability issues and dosing errors related to the Interactive Web Response System (IWRS).	Remedial Actions: PI reported that the DC site never used the IWRS, doses were and are hand calculated. IRB agreed that safety concerns had been addressed fully and reinstated enrollment. CASE CLOSED.
171	00	VA Central Office	H	07/29/2013	Facility reported an ineligible participant was enrolled in a CSP colorectal cancer screening protocol at one study site. There was no harm to the subject.	Remedial Actions: Responsible research coordinator removed from the study; new coordinator to be trained. The ineligible participant was withdrawn from the study. CASE CLOSED.
172	12	Chicago HCS	H	07/30/2013	Affiliate IRB reported lapse in IRB approval for this macular disease reading rehabilitation protocol.	Remedial Actions: Provide number of currently enrolled subjects; list subjects (with study ID) for whom stopping participation may cause harm; assess each subject for risk of stopping study activities and need to continue research interventions; submit continuing review or final report. CASE CLOSED
173	22	VA Greater Los Angeles HS	H	07/30/2013	Facility reported that 14 Veterans medical records were accessed for screening purposes without HIPAA authorization in a resistant prostate cancer treatment study.	Remedial Actions: PI must stop accessing patient records without authorization; modify protocol; and receive additional training. CASE CLOSED.
174	06	McGuire Veterans Affairs Medical Center	H	07/31/2013	Facility reported that sponsor of diabetes drug has instructed sites to transition all subjects off drug because of lack of efficacy and increased risk. No local SAE's. Subjects being notified.	Remedial Actions: All subjects completed end-of-treatment visits; All subjects transitioned to alternate treatment options; No adverse events reported. CASE CLOSED
175	01	Providence	A	07/31/2013	Facility reported tail biopsies of 13 mice at 33 days of age, without anesthesia. Procedure was not in the approved protocol.	Remedial Actions: Investigator stopped biopsies until protocol is amended; VMO and VMU supervisor developed SOP on tail clipping that was approved by the IACUC and distributed to all investigators; formal training with the investigator and staff prior to additional biopsies. CASE CLOSED.
176	07	Tuscaloosa	H	07/31/2013	Facility reported that the RCO did not conduct a triennial study audit for one observational community living center study within the prescribed timeframe. The IRB is going to review this issue at their next convened meeting.	Remedial Actions: Review of RCO auditing timeline; Completion of delinquent audit; Renew CITI certs. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
177	20	VA Puget Sound HCS	A	07/31/2013	Facility reported inappropriate post-operative analgesia in mice.	Remedial Actions: IACUC review; continued monitoring of PI surgeries by VMO. CASE CLOSED.
178	01	VA Boston Healthcare System	S	08/01/2013	Facility reported a WOC was injured while working on a piece of biorepository laboratory equipment.	Remedial Actions: Deck changed and door locks activated; new waste chute allows install of door that prevents the placement of hands into the machine. CASE CLOSED.
179	20	VA Puget Sound HCS	H	08/01/2013	Facility reported that a waiver of HIPAA authorization was approved in a Diabetes study that did not qualify for a waiver and 12 subjects were enrolled without provision of HIPAA authorization.	Remedial Actions: Obtain HIPAA authorization; revise protocol review practices. CASE CLOSED.
180	08	San Juan	H	08/06/2013	Facility reported 12 studies missing the decision and the expedited review eligibility category in the IRB minutes of the next convened meeting and in the letter conveying the IRB's decision to the investigator.	Remedial Actions: The IRB requested a note to file be sent to each investigator notifying the IRB approved expedited category. The R&D Office will inquire if the database can be re-programmed to display the expedited category on the letter. Educational capsules at IRB Meetings. CASE CLOSED.
181	23	Minneapolis	H	08/07/2013	Facility reported that blood was collected from approximately 1000 Veterans prior to provision of informed consent in the CSP Million Veteran Program.	Remedial Actions: Study suspension; LSI change; LSI response to all requirements for remedial actions from the CIRB and the SMART team; suspension lifted; enrollment to resume. CASE CLOSED.
182	11	Indianapolis	A	08/08/2013	Facility reported noncompliance involving humane endpoints in mice.	Remedial Actions: IACUC investigation; submission of protocol amendment. CASE CLOSED.
183	03	VA New York Harbor HCS	H	08/08/2013	NSOC reported missing HIPAA authorizations in a study of veterans with heart arrhythmias.	Remedial Actions: Education of PI, co-PI and study staff, obtain 5 missing HIPAA authorizations. CASE CLOSED.
184	04	VA Pittsburgh HCS	H	08/12/2013	Facility found an unauthorized individual was accessing and using PHI on a study of prevention of major depression in later life.	Remedial Actions: Written assurance from study PI that the unauthorized individual will not access PHI until approved on the study by the IRB. CASE CLOSED
185	18	Phoenix VA HCS	H	08/14/2013	Facility reported that an ineligible subject (a hospice patient with end-stage disease) was enrolled in this (VA CSP study) randomized, parallel-group trial of two strategies for colorectal cancer screening for average risk adults that requires long-term follow-up over 10 years.	Remedial Actions: The CRC who enrolled the ineligible subject was removed and replaced; ineligible subject withdrawn from study. CASE CLOSED
186	19	VA Eastern Colorado HCS	H	08/14/2013	Facility reported that noncompliant consenting procedures were used to enroll approximately 120 Veterans in a VA CSP study of colorectal cancer. Subjects were randomized and PHI had been collected prior to documentation of informed consent and HIPAA authorization.	Remedial Actions: Administrative hold placed by VA CIRB; retraining of LSI and study staff regarding consenting procedures; changed consenting processes. CASE CLOSED

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
187	04	VA Pittsburgh HCS	H	08/16/2013	Facility found a participant (Control Group) in study "Improving Outcomes in Suicidal Veterans" was incarcerated and remains in jail. Participant (not receiving research intervention) was withdrawn from study effective immediately.	Remedial Actions: None required. CASE CLOSED
188	17	VA Central Texas HCS	H	08/20/2013	Facility reported protocol deviations in a human study involving vascular grafts. Two ankle brachial indices were not performed and an incorrect ultrasound was not performed.	Remedial Actions: Correct deficiencies and re-educate staff on timeliness of reporting protocol deviations. CASE CLOSED.
189	17	VA North Texas HCS	H	08/22/2013	Facility reported that sponsor is ending this cardiovascular study early due to recommendations from the DSMB.	Remedial Actions: Notify subjects of early study termination; schedule end of trial visits and post follow-up visit per instructions; follow Sponsor-close-out protocol. CASE CLOSED
190	15	St Louis	H	08/26/2013	Facility reported a study suspension of a human subjects protocol. A study survey related to sexual orientation and health care utilization collected PHI that was not discussed in the risk assessment section of the PI proposal and not reviewed by the IRB.	Remedial Actions: Data collected may be used after removal of zip codes; remedial actions complete. CASE CLOSED.
191	21	VA Sierra Nevada HCS	S	08/26/2013	Facility reported a protocol involving the use of a viral vector vaccine containing human genes did not go through IBC review and approval.	Remedial Actions: Register the IBC with NIH-Office of Biotechnology Activities. CASE CLOSED.
192	07	Atlanta	A	08/28/2013	Facility reported protocol suspensions involving mice.	Remedial Actions: IACUC investigation; submission of detailed remedial action plan by PI to IACUC; enhanced post approval monitoring by IACUC. CASE CLOSED.
193	22	VA San Diego HS	A	08/30/2013	Facility reported an unauthorized person (student) was allowed to enter the Facility and permitted to participate in animal research.	Remedial Actions: Student prohibited from conducting research and entering research areas until appointment is obtained; Investigator will amend protocol to add student and remind staff not to allow entry of personnel without personal security access card. CASE CLOSED.
194	09	Memphis	H	09/04/2013	Facility reported dispensing an investigational drug to one subject under a pharmaceutical-sponsored hypercholestremia protocol that had not yet received R&DC review and approval.	Remedial Actions: Acting IRB Chair and COS determined that since the subject was in the placebo arm of the study they should stop taking the investigational drug; subject should be re-consented following R&DC review and approval of the study. CASE CLOSED.
195	06	Durham	I	09/05/2013	Facility reported transmission of an internal unencrypted email containing a cardiovascular telemedicine study participant's name, email address, and phone number. The participant had sent the email to a research team member who then forwarded it unencrypted.	Remedial Actions: Emails with VASI deleted from sender and recipient mailboxes; responsible person instructed to use PKI for all emails with VASI and was advised that My HealtheVet portal is the only approved communications tool for Veterans to send emails to providers. CASE CLOSED

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
196	04	VA Pittsburgh HCS	H	09/05/2013	Facility reported unauthorized use of non-Veterans (>107) PHI from data warehouse for enrollment in survey study of racial and ethnic disparities in satisfaction with VA healthcare.	Remedial Actions: IRB suspension of recruitment and enrollment; protocol modification; recruitment letter modification; recruitment script modification. CASE CLOSED.
197	04	VA Pittsburgh HCS	I	09/06/2013	Facility reported that some of the contents of the VISN 4 Mental Illness Research, Education and Clinical Center shared drive were not secure. Access to study specific files and folders containing III and PHI data were not restricted to authorized research staff.	Remedial Actions: Policy put in place for physical review of IRB approved study staff before access to a dataset is permitted; OIT restricted logical access to data. CASE CLOSED
198	16	Houston	H	09/10/2013	Facility self-reported that the PO discovered apparent, serious noncompliance during a review of a category I HIV outreach and prevention study that involve data from children without CRADO approval. The data analysis study did not actively recruit children.	Remedial Actions: IRB's discussion on the 13 manuscripts published from the data (deferred to R&DC). R&DC imposed no corrective actions. CASE CLOSED.
199	16	Central Arkansas VHS (Little Rock)	H	09/11/2013	Facility reported that appropriate waivers for ICD and HIPAA Authorization were not in place. Protocol is an observational, post-marketing study for patients who have had a Myocardial Infarction, required stents and would be treated with a drug that prevents clotting of the arteries.	Remedial Actions: IRB determined that criteria for approval of waivers of informed consent and HIPAA authorization were adequately justified, and that no additional corrective actions were required. CASE CLOSED.
200	12	Milwaukee	A	09/11/2013	Facility reported inappropriate euthanasia in a rat.	Remedial Actions: Retraining; increased post-approval monitoring surveillance by IACUC. CASE CLOSED.
201	21	VA Palo Alto HCS	A	09/11/2013	Facility reported performance of unapproved animal manipulations within a protocol involving mice.	Remedial Actions: Staff retraining; PI will ensure all procedures are listed in protocol; improved communication and coordination within his staff. CASE CLOSED.
202	01	White River Junction	H	09/12/2013	Facility self-report of affiliate IRB committee membership issues.	Remedial Actions: Research halted at the facility, active protocols undergoing detailed review to ensure appropriate approval.
203	07	Atlanta	H	09/17/2013	Facility reported one invalid HIPAA authorization and missing HIPAA authorizations (3 subjects) in study assessment of diabetes and inflammatory bowel disease.	Remedial Actions: PO/ISO review; no future data use w/out signed HIPAA; HIPAA training for PI and study team. CASE CLOSED.
204	07	Atlanta	H	09/17/2013	Facility reported unauthorized study staff member access to database with PHI in cardiology genetic risk assessment study (data analysis).	Remedial Actions: PO/ISO review; PI retakes Human Subjects Protections training; study closure; RCO audits of current studies; PI mentoring.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
205	16	Shreveport	H	09/18/2013	Facility self-reported that a subject in the MVP study had blood drawn prior to signing an ICD and HIPAA authorization.	Remedial Actions: Clinical phlebotomists will be educated not to draw research blood samples until signed informed consent and HIPAA documents have been verified; consent subject or destroy blood sample.
206	05	VA Maryland HCS	H	09/19/2013	Facility reported the IRB suspended a venous thromboembolism prophylaxis study due to concerns about inconsistencies between protocol and ICD arising from numerous recent modifications to both documents.	Remedial Actions: PI must rewrite protocol and ICD to incorporate required descriptions of procedures, eligibility criteria, usual care, sponsorship, in consultation with the Clinical Research Training Mentoring Program.
207	06	Durham	H	09/20/2013	Facility reported that a nutritional study failed to obtain HIPAA authorizations for subjects.	Remedial Actions: Subjects contacted and will be given option to sign HIPAA at next scheduled visit; staff education related to need to obtain both ICD and HIPAA Authorizations at enrollment.
208	06	Durham	A	09/25/2013	Facility reported unanticipated loss of animal life due to a leaking water valve (mice).	Remedial Actions: All cages inspected twice a day; valve inspection and cleaning; gaskets replaced. CASE CLOSED.
209	08	Tampa	H	09/27/2013	Facility reported research staff obtaining data for a study were going to other participating VAMC's and not obtaining HIPAA authorizations from staff interviewed as part of a study on patient dignity and safe handling with spinal cord injury.	Remedial Actions: The JAHVH study team has been educated to verify local policies prior to conducting studies outside JAHVH. Dallas and Hines reported to their respective IRBs and both determined the issue to be serious noncompliance, RAPs have been completed at all three facilities.
210	09	Memphis	H	10/01/2013	Facility reported PI failure to provide documents required to close this PTSD study.	Remedial Actions: No remedial actions required. CASE CLOSED.
211	16	Central Arkansas VHS (Little Rock)	H	10/03/2013	Facility Self-Reported a UPR determination by the convened IRB. The sponsor of this active, greater than minimal risk study, has suspended treatment in Arm A due to a greater number of grade 5 serious adverse events than expected. The local facility does not have any subjects enrolled in this Arm.	Remedial Actions: PI to close Arm A; provide IRB with revised protocol, ICD and other related documents concerning the closure of Study Arm A.
212	21	VA Palo Alto HCS	A	10/04/2013	Facility reported unanticipated death of mice.	Remedial Actions: Review of shipping procedures. CASE CLOSED.
213	12 NE	Hines	A	10/07/2013	Facility reported unanticipated loss of animal life on an active animal protocol (rat).	Remedial Actions: Retrain VMU staff on policies pertaining to special husbandry requirements; retrain research staff on post-operative observation duties. CASE CLOSED.
214	09	Lexington	A	10/07/2013	Facility Self Report	Remedial Action: Purchase and use pharmaceutical grade dimethyl sulfoxide. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
215	08	San Juan	H	10/07/2013	Inclusion issues and lack of follow-up on a Prevalence of Secondary Osteoporosis study evaluated in Primary Care Clinics at VA Caribbean Healthcare Systems, San Juan, Puerto Rico.	Remedial Actions: The PI will verify in CPRS whether the subjects had required tests and will refer the subjects to their primary physician. The IRB determined that additional reporting to OHRP was required. The study was temporarily suspended by the IRB. CASE CLOSED.
216	21	VA Palo Alto HCS	A	10/07/2013	Facility self-reported unanticipated loss of animal life (mouse) following parabiosis surgery.	Remedial actions: Submit amendment to include a pilot study comparing two parabiosis methods; Lab personnel will receive training from personnel experienced with parabiosis surgery that includes peritoneal attachment. CASE CLOSED.
217	17	VA Central Texas HCS	I	10/08/2013	Facility reported that documents containing PII and/or PHI were found in an unsecured cabinet. The documents were related to past/closed studies dating between 1993 and 1995.	Remedial Actions: Records were inventoried and secured by research management; PO recommended remedial training on security of PHI and PII for all research staff. CASE CLOSED
218	23	Minneapolis	H	10/08/2013	Facility reported 24 of 51 subjects were enrolled in a genetic epidemiology lung study using an inaccurate HIPAA.	Remedial Actions: HIPAA and consent forms to be reviewed by multiple members before use; corrected HIPAA forms to be signed by subjects at follow-up visit. No data use or disclosure without HIPAA authorization. Case Closed.
219	01	VA Connecticut HCS	A	10/09/2013	Facility reported unapproved breeding procedures performed in mouse colonies.	Remedial Actions: Animals moved to a holding protocol; submission of an amendment. CASE CLOSED
220	07	Columbia	H	10/16/2013	Facility reported that an additional sub-study tube of blood for a lung cancer drug study was drawn and sent to sponsor lab. Facility is not approved for the sub-study. Identifiers on the blood sample tube included DOB and draw date.	Remedial Actions: Sample destroyed; Subject notified; RCO to monitor next enrolled subject; training & education for the staff. CASE CLOSED
221	02	VA Western New York HCS	H	10/18/2013	Facility reported one signed HIPAA Authorization for a subject in a DOD funded study of suicide prevention could not be located. The missing document was later located.	Remedial Actions: PI education regarding local procedures; PI to file deviation report to IRB, IRB requires PI to attend IRB meetings as "guest" for training purposes; PI to create enrollment checklist; missing HIPAA Authorization found. CASE CLOSED.
222	17	VA North Texas HCS	A	10/21/2013	Facility reported a protocol deviation in which a mouse was allowed to exceed the protocol approved weight loss of 20%.	Remedial Actions: Report to ORD, OLAW and AAALAC; the IACUC will investigate if post-operative procedures were properly followed; The PI will receive a letter requesting adherence to all IACUC policies regarding postsurgical monitoring and submitting amendments.
223	07	Charleston	A	10/21/2013	Facility reported unanticipated death of mice due to inadequate husbandry practices.	Remedial Actions: VMU staff to ensure consistent procedures, easily accessible food for weanlings, daily checks increased to twice daily, staff encouraged to report directly to IACUC. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
224	01	White River Junction	R	10/24/2013	Facility reported one subject in a CIRB approved depression study did not meet inclusionary criteria. The subject was taking an exclusionary drug at the time of enrollment.	Remedial Actions: Staff education, review of inclusion/exclusion criteria and event reporting procedures; remediation plan developed, enrollment placed on hold until completion of training.
225	06	McGuire Veterans Affairs Medical Center	A	10/29/2013	Facility reported deviations on a mouse protocol consisting of failure to follow ACORP parameters defining need for euthanasia.	Remedial Actions: Protocol suspended; investigator must submit new protocol with current procedures and submit an action plan to include staff re-training and keep treatment records on individual mice. CASE CLOSED.
226	21	VA Palo Alto HCS	A	10/30/2013	Facility reported unauthorized research was conducted in a protocol involving mice.	Remedial Actions: The Principal Investigator must submit an amendment and the staff must appropriately mark cages and read the protocol prior to starting procedures. CASE CLOSED.
227	16	Little Rock	H	11/01/2013	Facility reported a subject was enrolled into a prevention of postoperative nausea and vomiting study against exclusion criteria.	Remedial Actions: Education; complete deviation/violation form; and provide justification for the IRB to consider the continued use of the subject's data.
228	17	VA Central Texas HCS	H	11/04/2013	Noncompliance identified by ORO RCEP and reported by the facility. Local site investigator for the Million Veteran Project left the facility and the replacement was not approved by the VHACO CIRB for several months. ICDs incorrectly referenced the former investigator during this period.-	CIRB review - not serious or continuing; amendment approved to change LSI and ICD; no further actions required. Case Closed.
229	08	Orlando VAMC	H	11/08/2013	Facility reported the approved IRB consent lacked the required VA injury statement. Two subjects signed the consent prior to identification of the issue. Additionally, VA Form 10-9012 Investigational Drug Information Record) was found to lack required signatures.	Remedial Actions: The PI re-consented the subject with the correct ICD. Changes were made to the IRB reviewers checklist so that injury language will be carefully reviewed in the future. Training for IRB, R&DC members and research personnel was initiated. CASE CLOSED.
230	10	Cincinnati	H	11/12/2013	Facility reported a PI conducted a medical records search of at least 245 records to identify potential research subjects for a diabetes study without first obtaining a waiver of HIPAA authorization.	Remedial Actions: HIPAA waiver requested; Privacy Officer to notify 13 subjects invited to participate in this study by mail to alert them their medical records were accessed inappropriately; 245 patients whose records were accessed may not participate in the study; HIPAA training. CASE CLOSED
231	04	VA Pittsburgh HCS	H	11/13/2013	Facility reported sponsor suspension of new enrollment on CALGB 80802-Phase III Randomized study in patients with Advanced Hepatocellular Carcinoma (HCC). DSMB review noted a potential imbalance in treatment related deaths between the two study arms.	Remedial Actions: New enrollment suspended. CASE CLOSED

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
232	08	Tampa	A	11/22/2013	Facility reported the performance of unapproved procedures on a rat assigned to an active animal protocol.	Remedial Actions: The Principal Investigator must re-train all research personnel on approved procedures detailed in each approved animal protocol. CASE CLOSED.
233	01	VA Connecticut HCS	S	11/22/2013	Facility reported an incident involving a research procedure using fluoroscopy which results in exposing research subjects to ionizing radiation.	Remedial Actions: Retraining; submittal of an updated protocol safety survey. CASE CLOSED.
234	03	Bronx	S	11/25/2013	Facility reported unapproved use of Dual-energy X-ray absorptiometry (DXA) scanning equipment in rats.	Remedial Actions: SRS review; Radiation safety subcommittee review and approval. CASE CLOSED.
235	16	Little Rock	H	11/25/2013	Facility reported sponsor notification that a stent graft system was recalled after the release wire used during implantation of the device fractured in 3 subjects, forcing 2 subjects to go from endovascular to open surgical repair. Recruitment into this study at the facility is closed.	Remedial Actions: None required by IRB because the protocol is closed to enrollment, and no local SAEs occurred. CASE CLOSED.
236	07	Augusta	A	11/26/2013	Facility reported inadequate euthanasia procedures in mice.	Remedial Actions: Training; limiting access to necropsy room; use of a euthanasia log; identification of carcass bags. CASE CLOSED.
237	11	Indianapolis	S	11/27/2013	Facility reported failure to receive Institutional Biosafety Committee approval prior to initiation of research.	Remedial Action: Submission of protocol for Institutional Biosafety Committee approval prior to re-initiation of research. CASE CLOSED
238	23	Minneapolis	A	11/27/2013	Facility reported unanticipated loss of animal life in rats.	Remedial Actions: IACUC review; discontinued use of defective equipment; installation of dial-out alarms as a safety precaution and/or purchase of newer, safer equipment alternatives. CASE CLOSED.
239	01	Providence	H	12/06/2013	Facility reported IRB's failure to report to ORO suspension of a study evaluating use of topical investigational agent in Diabetic patients for treatment of diabetic foot ulcers due to protocol deviation	Remedial Actions: Study suspension; refresher training for IRB members by RCO.
240	05	VA Maryland HCS	H	12/08/2013	Facility reported a blood sample was taken from a VAMHCS patient who is not a participant in a pharmacogenetics study.	Remedial Actions: Pending
241	22	VA Greater Los Angeles HS	H	12/09/2013	Facility reported a PI failed to obtain annual renewal for two oncology studies (laryngeal cancer and prostate cancer).	Remedial Actions: IRB re-approved protocol with understanding that further late submissions will result in project closure. CASE CLOSED.
242	05	VA Maryland HCS	A	12/09/2013	Facility reported that 2 violations of an IACUC-approved animal protocol had occurred: The approved number of mice was exceeded; and the approved endpoint was extended.	Remedial Actions: The PI and staff attended training on animal regulations; the PI must provide a plan of corrective actions, including methods to prevent future non-compliance; PI must acknowledge that future non-compliance will result in suspension of research activities. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
243	18	New Mexico VA HCS	H	12/10/2013	Facility reported a research assistant performed venipuncture within three protocols (MVP and two mental health studies) despite the scope of practice not including venipuncture. The assistant is trained and certified in venipuncture.	Remedial Actions: Research Scope of Practice and VetPro updated to reflect training and certification in venipuncture procedures.
244	16	Little Rock	A	12/10/2013	Facility reported eight protocols that had lapsed continuing reviews.	Remedial Actions: Synchronized database with corrected expiration dates; automatic generation of reminders for protocol expiration dates. CASE CLOSED.
245	08	Miami	S	12/11/2013	Facility reported an accidental needle stick injury to a researcher working with mice.	Remedial Action: Use a new needle/syringe for each injection; wipe the syringe between mice; use at least two individuals when injecting large numbers of mice. CASE CLOSED.
246	04	VA Pittsburgh HCS	S	12/11/2013	Facility reported a lapse in an IBC annual review.	Remedial Actions: Submission of annual review; IBC review of incident. CASE CLOSED.
247	01	VA Connecticut HCS	H	12/12/2013	Facility reported nine subjects were entered into a study on Veterans at risk for hospital readmission without signed consent forms, HIPAA authorizations, or picture/voice consents. No PHI data left the facility.	Remedial Actions: PI and research team education; PI continue to closely monitor the study; participants to be re-contacted to obtain consents and authorizations; data will not be used for those who do not provide consents and authorizations.
248	18	Phoenix VA HCS	I	12/18/2013	Facility reported a CRC inadvertently gave a research subject her husband's cell phone number instead of her own number. The subject called the husband's cell phone; therefore the subject's name and phone number were accidentally disclosed to the husband who is not involved in the research study.	Remedial Actions: Pending
249	11	Indianapolis	S	12/18/2013	Facility reported incorrect review and approval of a non-exempt research activity involving recombinant DNA (rDNA).	Remedial Actions: IBC review; report to NIH-OBA; increased attentiveness to non-exempt research activities involving rDNA during protocol reviews. CASE CLOSED.
250	21	San Francisco VAMC	H	12/19/2013	Facility reported a PI of a chronic obstructive pulmonary disease observational study arranged for 4 subjects to undergo an additional blood draw prior to IRB approval of an amendment despite the research nurse manager informing the PI this draw was not yet authorized.	Remedial Actions: IRB warned PI that such future offense could result in suspension; other actions pending.
251	21	San Francisco VAMC	H	12/19/2013	Facility reported the conduct of a retrospective chart review of patients treated for glaucoma without R&DC approval.	Remedial Actions: Cessation of unapproved research pending VA approval and established a plan to ensure prompt reporting to ORO.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
252	11	Indianapolis	H	12/20/2013	Facility reported staff member on lung cancer study removed VA data outside VA protected environment. Data was returned to PI without incident.	Remedial Actions: Pending
253	15	Columbia	A	12/20/2013	Facility reported inappropriate euthanasia in mice.	Remedial Actions: IACUC review; SOP revised to reflect correct flow rate; regular inspection of equipment to ensure proper functioning; posted contact information on equipment in case of malfunction. CASE CLOSED.
254	08	Miami	S	12/20/2013	Facility reported a lapse in SRS continuing approval due to a clerical error.	Remedial Actions: In the case of future approval lapses, the administrator will immediately notify the Principal Investigator, stating that research procedures must not be performed until contingencies are addressed and full approval is secured. CASE CLOSED.
255	22	VA Loma Linda HS	I	12/23/2013	Facility reported the inadvertent disclosure of a deceased subject's address to the study sponsor. This was a study of type 2 diabetic and acute coronary syndrome patients.	Remedial Actions: Information shredded by sponsor; other actions pending.
256	01	Bedford	A	12/23/2013	Facility reported a deviation and protocol suspension of a study using mice.	Remedial Actions: Training; submission of an amendment. CASE CLOSED.
257	09	Memphis	H	12/26/2013	Facility reported a CIRB determination of serious noncompliance for a CSP colorectal cancer study consisting of invalid consent of one subject. The subject was consented 30 minutes after receiving sedation for another procedure.	Remedial Actions: Pending

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

VHA facility-based Research Compliance Officers (RCOs) must conduct annual informed consent audits and triennial regulatory audits of all research studies. The director of each research facility is required to report promptly to ORO any apparent serious or continuing noncompliance identified in these audits. ORO conducts remote reviews of these reports, requiring that the facility develop an acceptable remediation plan and monitoring implementation of the plan until remediation is complete.

Summary

- 44 = Cases Continuing from Previous Calendar Year
- 59 = New Cases – January 1 through March 31
- 91 = New Cases – April 1 through June 30
- *51 = New Cases – July 1 through September 30
- 54 = New Cases – October 1 through December 31
- 255 = Total New Cases in CY2013
- 299 = Total Cases (Continuing Plus New) in Calendar Year

* Includes 1 case misclassified in in Third Quarter Report

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	01	VA Boston Healthcare System	H	06/25/2011	RCO Audit found 20/20 participants in a lipid medication adherence study did not use IRB approved and stamped IC. Two HIPAA not dated. One HIPAA different date than witness.	Remedial Actions: Education provided (mock informed consent process); re-consent attempted - 7 subjects could not be contacted. Data for those 7 subjects cannot be used. CASE CLOSED.
2	01	VA Boston Healthcare System	H	05/29/2012	RCO ICD Audit of cardiovascular study found missing ICD and HIPAA (1), use of expired consent form (1), missing witness signatures (6) and other documentation problems.	Remedial Actions: Contact 9 subjects and re-consent; obtain written clarification from subjects who signed HIPAA revocation of authorization in error; PI to clarify reason for date inconsistencies. CASE CLOSED.
3	22	VA Greater Los Angeles HS	H	06/18/2012	RCO found missing HIPAA authorization for four subjects enrolled in a human protocol on studying the Dopamine D2 Receptors in Striatum of Social Drinkers. The PI did not use the date-stamped ICD to enroll subjects.	Remedial Actions: RCO must conduct a for-cause audit of all the on-site study records for this protocol; PI must obtain HIPAA authorization from subjects. CASE CLOSED.
4	07	Columbia	H	06/22/2012	RCO audit of a PTSD study found that ICDs were not signed for 15 subjects; incorrect ICD signed	Remedial Actions: ACOS/R requested a RCO for-cause audit; temporary suspension of recruitment and enrollment for both studies. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
5	03	VA New York Harbor HCS	H	07/12/2012	RCO audit found in a colonic inflammation study that PI enrolled subjects using amended ICD documents (HIPAA and ICD as standalone documents), but failed to obtain HIPAA authorization from 24 participants.	Remedial Actions: Staff education; obtain missing HIPAA Authorizations; 16 subjects unable to provide authorization were withdrawn from study. CASE CLOSED.
6	03	VA New York Harbor HCS	H	07/12/2012	RCO audit found one subject had signed wrong version of consent on a pilot study using telephone intervention to enhance adherence and improve quality of life in congestive heart failure patients.	Remedial Actions: Staff education; specific remedial training on informed consent processes for PI and study team members. CASE CLOSED.
7	03	VA New York Harbor HCS	H	07/12/2012	RCO audit of a study addressing major quality issues in heart failure care found 29 subjects had signed a VA ICD which did not have the IRB approval stamp.	Remedial Actions: Staff Education; specific education on consent procedures for PI. CASE CLOSED
8	03	VA New York Harbor HCS	H	07/12/2012	RCO audit of a study using eye movement tracking as marker of neurologic integrity in neurologically impaired patients found ICDs without dated HIPAA signature, patient signatures, dated signature of person obtaining consents, and ICDS without improper documentation of informed consent by proxy	Remedial Actions: NSOC report generated; Research Coordinator educated; IRB determined PI cannot use data obtained using unapproved method and IRB representative must be present during surrogate consent process for the next 5 subjects consented. CASE CLOSED.
9	03	VA New York Harbor HCS	H	07/16/2012	RCO Audit of a retrospective analysis of cardiac imaging studies found documentation missing in meeting minutes to support IRB exemption and RDC approval.	Remedial Actions: Staff education and increased attention to documentation details. CASE CLOSED.
10	01	VA Boston Healthcare System	H	07/20/2012	RCO Audit of pre-operative patient education study indicated ICD irregularities. Signed, stamped version of ICD was not used and signatures were not correctly dated.	Remedial Actions: Staff education, mock informed consent training provided, plan for ensuring proper consent process submitted, PI re-consented all 46 subjects. CASE CLOSED.
11	04	VA Pittsburgh HCS	H	07/27/2012	RCO regulatory audit identified that research procedure (provider survey) was conducted on 8 physicians without informed consent (ICD) or without a waiver of ICD. Study focused on determining impact of a Plain Language Prostrate Cancer Decision Aid on subject's decision making experience.	Remedial Actions: PI will not use the survey data at this time; data stored securely; specific education of PIs and IRB members on provider participation in research. CASE CLOSED.
12	03	VA New York Harbor HCS	H	08/01/2012	RCO ICD Audit of a diabetic skin flora study found missing HIPAA Authorizations and no CPRS documentation of study participation for 73 subjects.	Remedial Actions: Staff education. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
13	03	VA New York Harbor HCS	H	08/01/2012	RCO ICD Audit of hypertension study discovered 3 (out of 144) missing HIPAA Authorizations.	Remedial Actions: Staff education; data removed from study. CASE CLOSED.
14	03	VA New York Harbor HCS	H	08/01/2012	RCO ICD Audit of variations in the use of CPRS-enabled exam room computers found that 12 non-patient participants had missing HIPAA Authorizations.	Remedial Actions: Staff education provided; IRB determined that apparent noncompliance was not serious and not continuing. CASE CLOSED
15	01	VA Boston Healthcare System	H	08/10/2012	RCO Audit of study of Medication Reconciliation found missing consent documents, procedures being conducted that are not described in the protocol and lack of participant consent for audio recording.	Remedial Actions: Study suspended pending follow up audit by RCO; Staff education; re-consent participants, 4 participants who did not sign VA Form 10-3203 - IRB determined data may not be used. CASE CLOSED.
16	02	Canandaigua	H	09/13/2012	RCO audit found PI amended IRB approved procedure (assignment of trainers to either immediate or delayed training condition) without submitting amendment to IRB for approval. Study is an evaluation of training video addressing suicidal thoughts and behavior in substance abuse treatment.	Remedial Actions: Assurance PI will make compliance a goal of his annual performance review; conduct monthly review of protocols with study coordinator to ensure compliance and make review available to the IRB. RCO conduct audits of all PI protocols for compliance. CASE CLOSED.
17	16	Central Arkansas VHS (Little Rock)	H	09/18/2012	RCO regulatory audit conducted noted no documentation in Research Administration or investigator records of SRS approval for a study of subjects with Critical Limb Ischemia and no Options for Revascularization.	Remedial Actions: Develop and SRS SOP for exemption determinations. CASE CLOSED.
18	21	VA Sierra Nevada HCS	H	09/24/2012	RCO audit found multiple instances of informed consent noncompliance involving all 13 ICDs within 1 human protocol on smoking cessation.	Remedial Actions: Implement additional training (regarding process of informed consent and HIPAA authorization) to students and novice investigators. CASE CLOSED.
19	05	VA Maryland HCS	H	09/26/2012	RCO regulatory audit of a Ribavirin Pharmacokinetics study of Hepatitis C Virus revealed 9 findings. Expired IRB approval; research initiated before R&DC approval; Fellow not credentialed; subject file lost & training not complete. RCO unable to review subject records due to PI delays.	Remedial Actions: Audit findings sent to IRB and R&DC; IRB determined that the PI had addressed all audit findings previously and no further actions were required. CASE CLOSED.
20	11	Detroit	H	10/23/2012	RCO audit of 24 consents found 7 participants signed expired ICFs; 5 participants did not sign a HIPAA authorization form for this Genomic blood collection study	Remedial Actions: PI required to halt study recruitment; RCO provided education to study team; IRB requiring a remedial action plan be submitted by PI; study amendment submitted to update ICD. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
21	16	Central Arkansas VHS (Little Rock)	H	10/23/2012	RCO ICD audit of this randomized double-blind study comparing combinations of lisinopril or placebo & losartan in subjects with diabetic nephropathy revealed that: 14 subjects were not consented during their next visit, 1 subject did not sign a HIPAA and 1 subject did not sign correct substudy ICD	Remedial Actions: Obtain HIPAA authorization; report missed appointments & visits; correct & update CPRS; obtain consent for passive f/u subjects; obtain consent for the DNA substudy; provide justification for the inclusion of research data collected from subjects during lapse; etc. CASE CLOSED.
22	04	VA Pittsburgh HCS	H	10/25/2012	RCO regulatory audit of head, neck and lung cancers study identified that PI failed to report SAE within 5 business days of becoming aware of the SAE.	Remedial Actions: PI education on noncompliance reporting; maintenance of separate electronic file that allows tracking reportable events submissions and review until program can reliably track and report these events. Internal audits of SAE and UAP reports submitted. CASE CLOSED.
23	17	VA North Texas HCS	H	10/25/2012	RCO audit found a letter of notification from the Sponsor terminating a head and neck cancer protocol at this site due to ongoing concerns of PI oversight.	Remedial Actions: PI transitioned 1 subject to commercially available medication, and implemented inclusion/exclusion verification processes for future subject enrollments; the IRB will revise its SOP for reporting of sponsor suspensions and terminations. CASE CLOSED.
24	05	DC VAMC	H	10/30/2012	RCO audit found 34 of 36 subjects in a War Related Illness and Injury Study Center (WRIISC) data repository study were consented without obtaining HIPAA authorization. PI self-reported failing to obtain HIPAA authorizations from ~30 participants.	Remedial Actions: PI is following up with participants will use no data until HIPAAs are obtained. IRB accepted corrective actions and PO concurred. IRB also informed DCVAMC PIs that HIPAA is now a separate document. CASE CLOSED.
25	05	DC VAMC	H	10/30/2012	RCO audit of myeloma family study found 7 subjects were consented without obtaining HIPAA authorization.	Remedial Actions: IRB determined that no PHI was collected from relatives, so HIPAA did not apply. R&D Program reminded PIs of new ICDC format (stand-alone HIPAA). CASE CLOSED.
26	09	VA Tennessee Valley HCS	H	11/12/2012	RCO Regulatory Audit found apparent non-compliance for this anesthesia risk quality improvement project as the IRB approved this study as expedited without waivers of informed consent or HIPAA authorization, inappropriate RDC approval, and failure of the PI to submit continuing approval forms.	Remedial Actions: IRB chairperson, IRB administrator, and RCOs to review all exempt studies to verify proper IRB determination; CASE CLOSED
27	08	Miami	H	11/13/2012	RCO audit found one research personnel participating in research without the required scope of practice in the CSP #563 trial titled: Prazosin and Combat Trauma PTSD.	Remedial Actions: The PI has completed the required local scope of practice for this individual and the form was submitted to the Research Office for review and approval. The PI was re-trained. CIRB determination was not serious or continuing. CASE CLOSED.
28	16	Houston	H	11/14/2012	RCO Audit found in a non-invasive screening for high glaucoma risk male veterans study the PI exceeded the study sample size approved by the IRB by 142.	Remedial Actions: PI must apply for modifications in advance; data collected can be used. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
29	04	Philadelphia	H	12/05/2012	RCO ICD Audit of study on insulin therapy effects on colorectal polyps in diabetics found 3 subjects had not signed HIPAA Authorizations and research notes were not entered in CPRS.	Remedial Actions: No data use until HIPAA signatures obtained; RCO regulatory audit; actions completed. CASE CLOSED
30	04	Philadelphia	H	12/05/2012	RCO ICD Audit of study on intimate partner violence patient needs and perspectives found unsigned HIPAA for one subject.	Remedial Actions: Obtain HIPAA signature; submit protocol deviation to IRB; no data use until HIPAA signed. CASE CLOSED.
31	04	VA Pittsburgh HCS	H	12/06/2012	RCO regulatory audit found that PI of a Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in patients with recurrent or metastatic head and neck cancers failed to submit a report of a SAE within 3 days of becoming aware of the SAE.	Remedial Actions: PI education on timeliness of noncompliance reporting and on the newly developed electronic IRB submission database; QA reviewer position created for timely review of reportable events. CASE CLOSED
32	21	VA Palo Alto HCS	H	12/06/2012	RCO audit of a cancer pain management study found that 1 of 3 enrolled subjects provided informed consent but did not sign a HIPAA authorization.	Remedial Actions: Subject's data withdrawn from the research study. CASE CLOSED.
33	17	VA North Texas HCS	H	12/10/2012	RCO audit identified IND (controlled substance) storage noncompliance in a postoperative recovery study.	Remedial Actions: Pharmacist will obtain and dispense investigational drug; Research Pharmacy SOP revised. CASE CLOSED.
34	01	Bedford	H	12/18/2012	RCO Audit found one HIPAA authorization form that was not signed by the subject.	Remedial Actions: The research team was reminded to ensure all consent-related documents are complete at the time of enrollment. CASE CLOSED.
35	22	VA San Diego HS	I	12/18/2012	RCO Audit of psychiatric study found that a former psychiatry resident destroyed in error 121 signed HIPAA Authorizations and 23 ICDs due to misinterpreting the affiliate IRB's instructions related to a previous noncompliance case.	Remedial Actions: The protocol is closed and the data had not been used; IRB concluded that research participants were not exposed to substantive harm or risk and required no additional actions. CASE CLOSED
36	02	Canandaigua	H	12/19/2012	RCO audit identified discrepancies in the dates on "IRB Acceptance - Notification" letters signed by the IRB Chair to the study PI. Study is a survey of difficulties and treatment interests for detox patients.	Remedial Actions: Facility to contact IT to determine whether revision can be made to MIRB system to remove the automatically populated date from the signature line. Alternate plans to pursue new electronic protocol submission system (IRBNet). CASE CLOSED.
37	06	Durham	H	12/20/2012	RCO audit reported that PI of a long-term cancer observational study discovered that signatures were missing on consent forms and HIPAA.	Remedial Actions: Prohibit the future use of both written and verbal consent for the same request. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
38	16	Central Arkansas VHS (Little Rock)	H	12/20/2012	RCO Regulatory Audit found subjects in a combat stimuli psycho-physiologic study were not re-consented on the revised ICD, as required by the IRB. 15 subjects, who were enrolled at the time of the informed consent revision, had not been re-consented at the six month follow up visit.	Remedial Actions: Provide explanation for failure to obtain consent and collection of informed consent on outdated ICD, and outline a plan to prevent future problems in projects under the leadership of this PI. CASE CLOSED.
39	04	Philadelphia	H	12/21/2012	RCO ICD audit of a patient-centered intervention study (Knee Replacement)found one ICD did not have the signature of the Person Obtaining Consent and another ICD had pages 1 and 2 of the ICD missing.	Remedial Actions: re-consent the subject missing the signature of the person obtaining consent with the full version of the approved ICD; either locate the missing pages of the ICD or re-consent the patient with the full version of the approved ICD. All actions completed. CASE CLOSED.
40	04	VA Pittsburgh HCS	H	12/21/2012	RCO audit of Health Behavior Change for Hospitalized Veterans study found one subject enrolled in the study lacked the required, signed HIPAA authorization.	Remedial Actions: Signed HIPAA required for subject to continue in the research; PI assurance HIPAA authorization added to packet to avoid re-occurrence; changes made to computer system to make consent and HIPAA documents available to researchers in same location as study workplace. CASE CLOSED.
41	11	Ann Arbor HCS	H	12/21/2012	RCO Regulatory audit of this renal dietary trial found the interval between initial approval and first continuing review [420 days] violate the requirement for IRB continuing review.	Remedial Actions: IRB coordinators to ensure they input correct continuing review date into IRB database; And consult with RDC coordinator when there is a transfer in PI. Remedial actions complete. CASE CLOSED.
42	21	VA Palo Alto HCS	H	12/21/2012	RCO audit found HIPAA authorizations were not sought from 17 subjects enrolled in blood draw study seeking biomarkers for improved diagnosis of lung nodules.	Remedial Actions: PI may attempt to obtain documented permission to use the collected data, but was not granted permission to use data or samples collected from subjects who have not signed an ICD and a HIPAA authorization form. CASE CLOSED.
43	02	VA Western New York HCS	H	12/31/2012	RCO review of two retrospective chart reviews found that both studies initiated and completed without ISO, PO, IRB, or R&DC approvals and that the ACOS never generated the letter to proceed with the studies.	Remedial Actions: ISO and PO to review checklists for privacy and security concerns, staff reminded of requirement to await final written approval prior to initiation of research and required review prior to publications. CASE CLOSED.
44	08	Bay Pines	H	12/31/2012	RCO re-audit of a community-based housing services for homeless Veterans study found 3 ICDs not available during the first audit; 2 of these 3 subjects did not sign a HIPAA Authorization. IRB had suspended the study due to the result of the first audit.	Remedial Actions: Study previously suspended and is now closed. PI was educated by RCO during suspension. No additional actions required. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
45	20	Portland VAMC	H	01/03/2013	RCO audit found that (199) patient health records reviewed without IRB approval; records were reviewed outside of the IRB approved time frame; and the PI collected and used PHI without IRB approval for up to 699 Veterans in a retrospective chart review pneumothorax study.	Remedial Actions: Amend the protocol to allow review of health records. CASE CLOSED.
46	20	VA Puget Sound HCS	H	01/03/2013	RCO audit found HIPAA authorization was not obtained from 1/24 subjects enrolled in a data repository and subject registry memory study.	Remedial Actions: Data restricted from entry into data repository; remedial training of study staff. CASE CLOSED.
47	21	VA Palo Alto HCS	H	01/07/2013	RCO audit found one subject did not sign a HIPAA authorization form in a VA Merit study that aims to develop measures to diagnose TBI and PTSD through acquisition of brain images and blood samples.	Remedial Actions: PO and IRB determined that data could not be used with HIPAA authorization or express permission; PI obtained a 'Release of Information' form to permit data use. CASE CLOSED.
48	21	VA Palo Alto HCS	H	01/07/2013	RCO audit found six HIPAA authorization forms documented an incorrect HIPAA expiration date in a rehabilitation study to help OEF/OIF veterans overcome driving-related distress.	Remedial Actions: Noncompliance determined to be serious (not continuing); no use of data from subjects without HIPAA authorization; PI to request Release of Information or revised HIPAA authorization (including prior data). No further actions required by IRB or R&DC. CASE CLOSED.
49	16	Houston	H	01/08/2013	RCO audit for this category 1 study that investigates the mechanisms of clinical responses to multidirectional treadmill training in persons with Parkinson's disease who experience gait and balance problems revealed that 5 subjects did not sign a HIPAA authorization (ICD was signed).	Remedial Actions: Education. CASE CLOSED.
50	09	Louisville	H	01/09/2013	RCO regulatory audit found expired CITI training (Collaborative Institutional Training Initiative) for this cancer surveillance study.	Remedial Actions: Staff to complete required training. Remedial action completed. CASE CLOSED.
51	01	VA Boston Healthcare System	H	01/11/2013	RCO Audit of study of Parkinson's Disease found data collected from 248 participants after the waiver of HIPAA Authorization had expired.	Remedial Actions: Reported to NSOC, PI and staff education. Study Amended and IRB approved a revised HIPAA waiver. CASE CLOSED.
52	02	Canandaigua	H	01/11/2013	RCO audit found on a study of a brief intervention for hospitalized Veterans that eight subjects were consented using consent forms with past IRB expiration date and PI enrolled subjects in the study during the period when continuing review approval remained pending.	Remedial Actions: PI will establish an automated system to identify consent and study expirations dates; IRB required re-consenting of the subjects; PI submitted and IRB approved amendment to protocol for re-consenting the subjects and use of data. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
53	08	Miami	H	01/11/2013	RCO found 10 informed consent documents used after a new version was approved by the IRB on a blood pressure intervention trial.	Remedial Actions: The investigator received education from the RCO. CASE CLOSED.
54	08	Miami	H	01/23/2013	RCO audit of a VA merit review lung disease study with a missing HIPAA authorization.	Remedial Actions: Credit monitoring service was offered to the Veteran, He also signed a new HIPAA authorization. The study team was re-educated by the RCO. CASE CLOSED.
55	11	Ann Arbor HCS	H	01/23/2013	RCO ICD audit of a home program mobility enhancement study revealed 1/56 ICDs was missing the Person Obtaining Consent's signature.	Remedial actions: The person who obtained consent signed the original and mailed a copy to the subject apologizing for error; A note to file was created regarding this action; IRB office to create a ICD review checklist for use by study teams; CASE CLOSED.
56	09	Louisville	H	01/24/2013	RCO audit revealed noncompliance for an unfunded retrospective chart review that evaluated patients on a diabetes medication. The PI collected prospective data which was not approved by the IRB.	Remedial Actions: Education provided to PIs on retrospective vs. prospective data collection; PI to send retraction letter to manuscript publisher; Publisher acknowledged letter and retracted manuscript from website; Remedial Actions Complete, CASE CLOSED.
57	23	Minneapolis	H	01/24/2013	RCO audit found that all 10 subjects and been improperly consented into a human subjects study looking at unsaturation levels of fatty acids.	Remedial Actions: PI was a VA employee (not a contract employee as originally believed) when the noncompliance occurred, resolving the PO concern. CASE CLOSED.
58	11	Indianapolis	H	01/25/2013	RCO audit found noncompliance in a stress reduction study of VA staff sponsored by HSR&D. The study team used ICDs that did have the approval stamp on them due to printer issues.	Remedial Actions: RCO provided a tutorial on how to set computer settings so that "stamps" are printed on documents; Remedial actions complete, CASE CLOSED.
59	11	Indianapolis	H	01/25/2013	RCO audit of an unfunded colorectal cancer marker study found multiple issues with the ICD, HIPAA, and other regulations (PI failure to complete previous remedial actions, provide appropriate staff supervision; continued errors despite training, use of white-out on ICD, use of LAR w/o IRB approval.	Remedial Actions: IRB recommended all tissue samples be destroyed; ORD halted study funding; PI resigned from VA; only those samples that were properly collected using a VA ICD and HIPAA Authorization are being kept for 6 months while trying to find another PI to take over the study. CASE CLOSED.
60	11	Detroit	H	01/27/2013	RCO Audit of this joint replacement outcomes study finds 4 ICF's missing, 8 missing signature pages, and 4 missing participant signatures.	Remedial Actions: Study recruitment halted; PI to receive training and education on PI responsibilities and the ICD process; Continuing review of study set at 6 months; At next Continuing review PI to submit copies of signed ICDs. CASE CLOSED
61	22	VA Greater Los Angeles HS	H	01/31/2013	RCO audit identified programmatic problem that although each subject has a paper VA 10-9012, they are not being scanned into each subjects' CPRS medical record.	Remedial Actions: R&DC determined that henceforth all subjects enrolled in an investigational drug study will have a study-specific VA 10-9012 scanned into their electronic medical record; additional remedial action not required. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
62	04	Philadelphia	H	02/04/2013	RCO Triennial Audit found 4 subjects did not sign HIPAA authorizations in survey study of Family History on Insomnia of Alcoholics. VA funded (local).	Remedial Actions: Protocol deviation submitted to IRB; PI obtaining HIPAA Authorizations; RCO all-research educational bulletin re: HIPAA procedures. CASE CLOSED
63	07	Columbia	H	02/04/2013	RCO Audit of protocol measuring importance of immune parameters in PTSD found a HIPAA form was not signed.	Remedial Actions: Real-time RCO ICD audits for 6-months. CASE CLOSED.
64	07	Tuscaloosa	H	02/04/2013	RCO Audit of a study for PTSD treatment in 0/F/OEF Veterans found amendments to the study, involving apparently substantive protocol changes, were adjudicated by the IRB during expedited review.	Remedial Actions: IRB re-review the amendments at convened IRB meeting. CASE CLOSED.
65	11	Ann Arbor HCS	H	02/07/2013	RCO regulatory audit found a lack of required scope of practice forms, and lack of PI training in this bladder cancer treatment study.	Remedial Actions: Study and PI research privileges suspended; research office developed action plan to ensure all research staff complete human subjects training; all studies transferred to another investigator. Remedial actions complete. CASE CLOSED.
66	08	VA Caribbean HCS (San Juan)	H	02/08/2013	The RCO found several items of noncompliance in 51 ICDs and 51 HIPAA authorizations on a study assessing the health literacy and anticoagulation control among patients undergoing warfarin therapy.	Remedial Actions: The IRB required the PI to ensure that all team members who obtain informed consent are trained, ?face to face? by the RCO before obtaining consent. In addition, the IRB required a third person present to observe the informed consent process for the next 5 subjects. CASE CLOSED.
67	16	Houston	H	02/08/2013	RCO audit revealed 14 subjects did not sign HIPAA. This greater than minimal risk is a randomized, double-blind, placebo-controlled, parallel-arm, fixed dose treatment trial for female PTSD vets.	Remedial Actions: subjects to sign HIPAA; PI was re-trained by the RCO and Director of Operations on the procedures for obtaining and documenting subjects' HIPAA authorization. CASE CLOSED.
68	18	Phoenix VA HCS	H	02/08/2013	RCO audit of a cardio/diabetic study found that study medication dosage was changed by an unauthorized individual.	Remedial Actions: Orders will be recorded in CPRS within a "reasonable period". Co-PI or Sub-PI will also record orders. CASE CLOSED.
69	21	San Francisco VAMC	H	02/08/2013	RCO audit of a behavioral study found consent was not documented in CPRS for any of the 12 subjects; 7 signed outdated ICDs; only first page of the ICDs included the IRB approval stamp; and 1 subject's ICD and HIPAA authorization was not signed by the person obtaining consent.	Remedial Actions: Consent notes for all subjects enrolled entered into CPRS, revised protocol to ensure consents are scanned, re-training of staff. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
70	16	Houston	H	02/12/2013	RCO audit revealed that this risk category 3 tissue banking repository study comparing TLR-related genes in the colonic mucosa of patients with CRA fosters an inflammatory microenvironment had one study participant who did not sign a separate HIPAA authorization.	Remedial actions: Research Office to meet with PI to review procedures for obtaining and documenting HIPAA. CASE CLOSED.
71	17	VA South Texas HCS	H	02/13/2013	RCO audit found unauthorized research staff performed procedure in a human diabetic study.	Remedial Action: Educating PI and study coordinator to ensure all engaged personnel have proper documentation/approvals. CASE CLOSED.
72	21	VA Palo Alto HCS	H	02/13/2013	RCO audit found 11 subjects did not sign HIPAA authorization forms at the time of enrollment in a human ophthalmology study.	Remedial Actions: Data collected will not be used, disclosed or transferred; PI committed to obtaining all research documents properly in the future and need to document subject's authorization to use PHI prior to study initiation. CASE CLOSED.
73	22	VA Loma Linda HS	H	02/13/2013	RCO ICD audit of a cancer biomarker study discovered 1/1 missing HIPAA authorization.	Remedial Actions: Use the Enrollment Checklist to ensure proper subject consenting; add a study coordinator to properly maintain records. Remedial actions complete. CASE CLOSED.
74	08	Miami	I	02/14/2013	NSOC reported one missing signed HIPAA Authorization containing the subject's full SSN. The subject signed a letter to the facility indicating that he remembered signing the document and signed another Authorization. Incident being managed by SRO DSS-0067-546-H.	Remedial Actions: Veteran signed new HIPAA Authorization; was offered credit protection services. CASE CLOSED.
75	21	San Francisco VAMC	H	02/15/2013	RCO audit found multiple consent-related issues in a sleep study to evaluate the links between PTSD, sleep, and cardiovascular disease.	Remedial Actions: Retraining of PI staff; modification of PI consent processes. CASE CLOSED.
76	10	Cincinnati	S	02/19/2013	RCO audit found a protocol with lapses in SRS continuing review.	Remedial Actions: SRS approval of continuing reviews; development and maintenance of a tracking spreadsheet; notification of study personnel; periodic protocol audits with presentation of findings at quarterly budget meetings; CASE CLOSED.
77	21	VA Palo Alto HCS	H	02/20/2013	RCO audit found that an unauthorized person obtained consent from one subject in a lung cancer study.	Remedial Actions: PI has withdrawn the data obtained; Informed consent and HIPAA authorization counseling for the PI and the nurse; Requirement for the nurse to register with the Research Service and complete all required training. CASE CLOSED.
78	21	VA Palo Alto HCS	H	02/20/2013	RCO Audit of a gastrointestinal endoscopy study found 46 subjects were enrolled with ICD but without HIPAA authorization.	Remedial Actions: IRB reminded the PI to obtain participant agreement for the use of protected health information. PI has planned to obtain authorizations. PI will not use or disclose the data obtained from the research subjects until getting authorizations. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
79	21	VA Palo Alto HCS	H	02/21/2013	RCO audit identified two unauthorized individuals obtaining informed consent in a radiation-induced dry mouth study.	Remedial Actions: Staff retrained; data collected from unauthorized individuals removed from study. CASE CLOSED.
80	21	VA Palo Alto HCS	H	02/21/2013	RCO audit of a motor unit recruitment muscular study identified 7 subjects did not sign HIPAA authorization forms.	Remedial Actions: Print out consent and HIPAA forms simultaneously; remind staff to obtain HIPAA as separate document; review regulatory documents upon enrollment; PI not to use data unless obtain participant's authorization obtained. CASE CLOSED.
81	16	Houston	H	02/22/2013	RCO audit revealed that this minimal risk study aimed at collecting longitudinal outcome data from all Veterans screened in the Trauma Recovery Program at MEDVAMC had 15 subjects who did not complete the required HIPAA authorization.	Remedial Actions: PI received training on obtaining and documenting HIPAA by the RCO and AO; PI will try to obtain HIPAA authorization from participants. CASE CLOSED.
82	01	Bedford	H	02/25/2013	RCO Audit found HIPAA authorization forms had not been obtained from three subjects in a study involving patient-centered medical homes.	Remedial Actions: Obtain HIPAA authorizations. Create a checklist of forms needed for data collection. CASE CLOSED.
83	16	Central Arkansas VHS (Little Rock)	H	02/25/2013	RCO audit found 0 out of 21 ICFs had the IRB stamp of approval, nor the corresponding Research CPRS enrollment note. 5 subjects did not meet inclusion/exclusion criteria. No SRS review. PI initiated minimal risk pilot study recruiting subjects receiving standard of care for warfarin therapy.	Remedial Actions: Submit revised "Request to Transport VA Sensitive Information" form; Scan ICDs and enter medical notes for relevant subjects into CPRS; document completion of remedial education; submit modification to IRB regarding tissue repository. CASE CLOSED.
84	21	San Francisco VAMC	H	02/27/2013	RCO Audit found unapproved ICD used to document informed consent for one subject in a HPV-associated oropharynx cancer study.	Remedial Actions: PI remediation. CASE CLOSED.
85	20	Portland VAMC	I	02/27/2013	NSOC reported four missing original informed consent forms containing PHI (full names, consent dates, last 4 SSN, name of study) for three Veterans enrolled in a study of non-small cell lung cancer. Three forms were found; the other was thought to be a re-consent that remains missing.	Remedial Actions: Unable to determine whether a re-consent actually occurred; participant is currently in long-term follow-up. IRB determined that additional re-consent was not necessary. CASE CLOSED.
86	11	Ann Arbor HCS	H	02/28/2013	RCO ICD audit of intervention study to reduce violence and substance abuse found: 147/147 for screening and 31/31 for the Main Study HIPAA authorizations were not obtained; 47/147 ICDs for screening purposes and 15/31 ICDs for the Main Study were not on the most-recent IRB-approved IRB version.	Remedial Actions: PI/staff to develop process for use of approved ICD/HIPAA; meet with IRB Chair to discuss process; present re-consenting plan to Chair/IRB; give periodic updates on re-consenting progress; RCO repeat audit within 3 months. Repeat audits completed. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
87	08	Tampa	H	03/01/2013	RCO Audit of an elderly wound healing study found lack of required HIPAA authorization elements for 13 subjects and incorrect ICD version used for 5 of 7 subjects.	Remedial Actions: No remedial actions were required since the Principal Investigator (PI) closed her protocol and left the VA. CASE CLOSED.
88	16	Houston	H	03/04/2013	RCO audit conducted on a study aimed at retaining HIV-Infected Veterans in HIV Care. Audit revealed that one ICD was missing. Coordinator contacted subject, who took both copies of the ICD but was unable to locate them.	Remedial Actions: Re-consent subject; note to file explaining irregularity. CASE CLOSED.
89	22	VA Greater Los Angeles HS	H	03/07/2013	RCO audit found one ICD had been lost and 319 (of 382) subjects had signed an incorrect HIPAA authorization in a study of sleep interventions.	Remedial Actions: Re-consent for missing ICD; receipt of 280 signed HIPAA authorizations by mail with IRB-approved waiver of HIPAA authorization for the 39 remaining subjects. CASE CLOSED.
90	00	VA Central Office	H	03/11/2013	A facility RCO auditing a VA CIRB-approved study, the Low Vision Intervention Trial II, found a statement in conference call minutes that an incentive payment would be made to sites randomizing a specified number of trial participants. The RCO raised the question whether recruitment incentives are allowed in VA research.	Remedial Actions: The IRB directed the study team not to offer recruitment incentives without first consulting with the OGC Ethics Office and submitting a protocol amendment for review and approval by the IRB. The IRB concluded that serious noncompliance did not occur. CASE CLOSED.
91	08	Tampa	H	03/11/2013	RCO found an unauthorized employee conducting research using data systems to evaluate warfarin therapy at the Tampa VA and outpatient clinics, in addition data was extracted beyond the approved time periods.	Remedial Actions: No remedial action could be requested from the member of the research team conducting research without training, scope of practice or approval by the R&DC, since the study is now closed. The PI was re-educated. CASE CLOSED.
92	17	VA Central Texas HCS	H	03/15/2013	RCO audit found that an SAE in a genetics study was initially reported on 2/8/10, but was lost, and not reviewed until 15 months later (IRB determined "Not Related").	Remedial Actions: Additional IRB administrative staff and full-time RCO hired. CASE CLOSED.
93	11	Indianapolis	H	03/17/2013	RCO audit found 60 subjects signed an informed consent that was missing the IRB stamp for this serum biomarker study of heavy alcohol use.	Remedial Actions: Additional training for study staff. CASE CLOSED.
94	08	Bay Pines	H	03/18/2013	RCO Audit found that a subject consented to a research study #0280 entitled, "Speech-in-Noise Assessment in Older Adults with Hearing Loss Effects of Stimulus Variability" even though he has a legal plenary guardian assigned to him.	Remedial Actions: The remedial actions included re-education of the study staff and removal of the subject's data from the study's data analysis. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
95	17	VA North Texas HCS	H	03/18/2013	RCO audit found reports of noncompliance from the Site Monitor had not been reported to the IRB (subjects were not enrolled using the latest ICD; protocol amendments had not been submitted; and protocol exclusion criteria not met).	Remedial Actions: Protocol deviations reported to the IRB; staff and PI provided additional training; appointment of a mentor for study coordinators. CASE CLOSED.
96	01	VA Boston Healthcare System	H	03/19/2013	RCO Audit found 19 participants in a study focused on patient flow in the Emergency Department that were consented using an unstamped version of the ICD. Audio Recordings were made without obtaining audio consent on VA Form 10-3203.	Remedial Actions: Forms to be stamped, PI to re-consent participants in 90 days, mock informed consent training to be completed. Revised protocol submitted to IRB. CASE CLOSED.
97	16	Central Arkansas VHS (Little Rock)	S	03/19/2013	Facility reported the conduct of research by a PI without prior review and approval from the SRS.	Remedial Actions: PI to submit completed SRS form and all modifications to be listed in the protocol; PI to provide info on the freezer and lab to be used; personnel must have training documents uploaded. CASE CLOSED.
98	20	Boise VAMC	H	03/19/2013	RCO audit of a congestive heart failure readmissions retrospective study found that 4/45 ICDs were signed by someone other than the subject.	Remedial Actions: Remedial education, re-consent, and prohibited use of data from subjects not re-consented. No further action required. CASE CLOSED.
99	22	VA Greater Los Angeles HS	H	03/19/2013	RCO audit found that 19 subjects signed an invalid, pre-screening HIPAA Authorization associated with a behavioral study. In addition, the findings were not reported to ORO according to the required timelines.	Remedial Actions: Ensure a mechanism is implemented to ensure RCO audit findings are reported within required timeframes. Implement new system to ensure compliant initial contact for recruitment. No data use/disclosure without HIPAA. PI to conduct monthly reviews. CASE CLOSED.
100	08	Bay Pines	H	03/28/2013	Four subject's legally authorized representatives (LARs) consented using an incorrect informed consent document (ICD)for CSP 574, a clinical trial for severe community acquired pneumonia.	Remedial Actions: The CIRB is considering changing the titles of the ICDs to make it clear when to use each of them. PI received training. The RCO will review the next 3 consents to confirm the appropriate ones were used. CASE CLOSED.
101	21	San Francisco VAMC	H	03/28/2013	RCO audit found in an Extended Care Treatment study the participant and/or person who obtained consent did not sign and/or date the consent or HIPAA authorization; an outdated consent document was use; and SSNs were not documented on the HIPAA authorization.	Remedial Actions: RAP to include new consent-related administrative QA/QI procedures. CASE CLOSED.
102	09	VA Tennessee Valley HCS	H	03/29/2013	RCO audit of an unfunded, prospective, data collection, study on stem cell transplant patients found apparent two subjects were consented after the study had expired.	Remedial Actions: RCO to provide education to PI and research staff on use of electronic IRB application system; two participants to be re-consented. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
103	15	Columbia	H	03/29/2013	RCO audit of an unfunded ocular retrospective chart review study found PI completed only affiliate human subjects training, research office did not maintain all training records; PI did not maintain all IRB and RDC correspondence	Remedial Actions: PI to complete training; RCO to provide education to PI on correspondence retention; Research office to review and update all training records. Ensure affiliate IRB is requiring VA approved training. CASE CLOSED.
104	04	Philadelphia	H	04/01/2013	RCO ICD Audit discovered an ICD in study on Intra-operative Imaging with EC 17 that a subject's signed ICD did not have the signature of the person obtaining consent and the date of signature. VA funded.	Remedial Actions: Protocol deviation report to IRB. Subject data will not be used. Study staff to conduct just-in- time quality review of ICDs to ensure completeness. All actions determined to be complete and CASE CLOSED.
105	21	San Francisco VAMC	H	04/01/2013	RCO audit found in a study evaluating behavioral and neural effects, one instance where a signed HIPAA authorization was not obtained.	Remedial Actions: No use of data obtained without HIPAA authorization; PO to improve HIPAA guidance provided to PIs. CASE CLOSED.
106	21	San Francisco VAMC	H	04/01/2013	RCO audit found in study evaluating health professionals in relation to team care a signed HIPAA authorization was not obtained for one study participant.	Remedial Actions: No use of data obtained without HIPAA authorization; PO to improve HIPAA guidance provided to PIs. CASE CLOSED.
107	21	VA Palo Alto HCS	H	04/01/2013	RCO audit found in a study on human diaphragm fiber atrophy seven subjects did not sign HIPAA authorization forms at the time of research study enrollment. None of the collected data had been shared or disclosed.	Remedial Actions: PI hired administrative staff; established processes to track enrollment documentation. CASE CLOSED.
108	21	VA Palo Alto HCS	H	04/01/2013	RCO audit found in a study of Anemia in the Elderly that one unauthorized person obtained consent from subjects.	Remedial Actions: Informed consent obtained by authorized personnel only. CASE CLOSED.
109	06	McGuire Veterans Affairs Medical Center	H	04/02/2013	Facility reported that an RCO audit discovered two subjects who have completed a pressure ulcer treatment study did not sign an informed consent or HIPAA.	Remedial Actions: Training for PI and staff on obtaining proper informed consent; Subject data will not be used; PI leaving the VA and will closed the study. CASE CLOSED
110	20	VA Puget Sound HCS	H	04/02/2013	RCO audit found in a study on Patients' and Providers' Perceptions of Communicating an Adverse Event that on 6 out of 6 reviewed consent forms the IRB stamp was missing.	Remedial Actions: Re-consent subjects; review handbook with specific attention to the consent requirements. CASE CLOSED.
111	22	VA San Diego HS	H	04/02/2013	RCO audit found consent-related noncompliance involving two subjects in a smoking cessation study; ICDs were not signed until after research started.	Remedial Actions: Revised study operating procedures, re-education of staff, and addition of study staff. CASE CLOSED.
112	01	VA Boston Healthcare System	H	04/05/2013	RCO For Cause Audit identified serious non-compliance with FDA IND requirements in a dermatology study.	Remedial Actions: PI to submit required IND report to FDA; IRB requiring PI to appear at IRB meeting to discuss lack of response to requirements and verify submission of IND. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
113	04	VA Pittsburgh HCS	H	04/05/2013	RCO audit found that research interactions were done with homeless subjects for a Primary Care and Service Customization study without obtaining informed consent; unauthorized use of VA research-related PHI; participation of a staff in conduct of the research outside the approved scope of practice.	Remedial Actions: PI and staff education on compliance; PI meeting with ACOS/R&D to discuss PI responsibilities. CASE CLOSED.
114	04	VA Pittsburgh HCS	H	04/05/2013	RCO regulatory audit of a Primary Care Quality and Service Customization for the homeless project found IRB did not ensure subjects were consented prior to prescreening and allowed staff to participate in the conduct of research without the required credentialing and approved scope of practice.	Remedial Actions: Compliance education; written assurance by IRB to prevent similar recurrence. CASE CLOSED
115	23	Minneapolis	H	04/05/2013	RCO audit of a Sound Wave Protocol as Tinnitus Treatment study found 1 ICD missing and 1 ICD without signature of the person obtaining consent.	Remedial Actions: PI to submit unanticipated problem report and data for the un-consented subject will not be used. CASE CLOSED.
116	01	Bedford	H	04/08/2013	RCO audit found 2 human subjects studies involving brain tissue banks had not received annual SRS review.	Remedial Actions: SRS review. CASE CLOSED.
117	09	Memphis	A	04/09/2013	RCO audit found an expired protocol involving mice.	Remedial Actions: PI and VMU Supervisor notified of protocol expiration; information to be presented at next R&DC meeting and IACUC meeting. CASE CLOSED.
118	11	Ann Arbor HCS	H	04/09/2013	RCO informed consent audit found that 2 research staff did not have the required VA Scope of Practice or delegation to conduct informed consent procedures or obtain consent for this meditation pilot study.	Remedial Actions: Education to PI and staff on consenting process and new process of consenting offsite at affiliate; person delegated by PI will be VA employee/WOC with current Scope of Practice; re-consent the 2 enrolled subjects. CASE CLOSED.
119	18	Phoenix VA HCS	H	04/09/2013	RCO audit found that HIPAA authorization forms signed by 8 subjects did not include current protocol information on, or disclosures to, a newly hired non-VA clinic in a study to control cardiovascular risk in Diabetic patients. NSOC report submitted.	Remedial Actions: Obtain valid HIPAA authorizations, do not use data without HIPAA authorization. CASE CLOSED.
120	08	San Juan	H	04/12/2013	RCO Audit found ICDs and HIPAA deficiencies consisting of missing printed names, headers missing or discrepant dates. Study objective was validation of the Spanish Version of a Caregiver Grief Inventory in a Puerto Rican Sample.	Remedial Actions: The IRB required the PI to assure all ICDs and HIPAA are reviewed for accuracy at the time of completion. The PI must request a third person be present and observe the informed consent process for the next 5 subjects. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
121	16	Houston	I	04/15/2013	RCO Audit found a note in the Research Pharmacy file that six folders for subjects in a cocaine dependence treatment study had inadvertently fallen into the trash and were picked up by housekeeping (not retrievable). Subject files included names, last 4 SSN, medical history, and prescriptions.	Remedial Actions: Notification letters to six veterans; Pharmacist reminded of requirement for immediate PO notification; pharmacist training regarding secure maintenance of records; pharmacist to ensure records are stored securely within ring binders. CASE CLOSED
122	08	Miami	H	04/16/2013	RCO audit found a failure to obtain IRB approval on Amendment #1 in a phase II hepatitis study.	Remedial Actions: Pending.
123	17	VA Central Texas HCS	H	04/16/2013	RCO audit found a reported SAE in a post deployment functioning study had not been reviewed within 5 days as required.	Remedial Actions: Additional IRB administrative staff and full-time RCO hired. CASE CLOSED.
124	20	Portland VAMC	H	04/17/2013	RCO audit found that during a study of low fat diet and multiple sclerosis, samples were processed before study approval was finalized.	Remedial Actions: The IRB chair will meet monthly with the research team to follow all active research studies. The RCO will audit all open studies for this PI. CASE CLOSED.
125	22	VA Greater Los Angeles HS	H	04/17/2013	RCO audit found during a review of a study investigating hospital readmission 1 subject out of 4 reviewed consented on a non-approved document.	Remedial Actions: IRB determinations that consent was informative, if not fully compliant; re-consent recommended, not required. PI plan to ensure the use of current ICD approved by IRB, with no additional actions required. CASE CLOSED.
126	23	Iowa City	H	04/18/2013	RCO audit found in a human subjects study of gait analysis that 3 of 3 consent documents lacked IRB approval stamp, lacked HIPAA authorization, lacked voice/picture consent, and entry in medical records.	Remedial Actions: Obtain subject re-consent, HIPAA, and voice/picture consent. Place study note in medical records. No use or disclosure without HIPAA. RCO to review corrective actions as completed. CASE CLOSED.
127	11	Ann Arbor HCS	H	04/19/2013	RCO ICD audit found apparent noncompliance in a continence study for post radical prostatectomy men. The study was low risk, and consent was obtained for 3 subjects by researchers who were not authorized to obtain consent, and did not possess Scopes of Practice at the time consent was obtained.	Remedial Actions: PI opted to re-consent participants with VA consent forms. CASE CLOSED.
128	17	VA Central Texas HCS	H	04/19/2013	RCO report of noncompliance - failure to report an SAE in a post deployment functioning study within 5 days	Remedial Actions: Training on SAE reporting provided to the PI. CASE CLOSED.
129	21	VA Palo Alto HCS	H	04/19/2013	RCO ICD audit found five subjects enrolled in a cancer study signed ICDs, but not HIPAA authorizations that would allow release of information gained from autopsy results.	Remedial Actions: PI will obtain proper authorization and not use data if proper authorization is not obtained. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
130	22	VA San Diego HS	H	04/19/2013	RCO audit found that an unauthorized person signed the consent and HIPAA authorization for a subject enrolling in an OEF/OIF study who was unable to sign due to an injured wrist.	Remedial Actions: IRB determination that the noncompliance was not serious or continuing. PI must attempt to obtain compliant consent and HIPAA authorization. Data obtained may be used. No further action required. CASE CLOSED.
131	23	Minneapolis	H	04/19/2013	RCO identified consent-related noncompliance in a CIRB study (Million Veteran Program). The subject's pre-printed name was manually crossed off without initialing/dating and a different last name written in by hand. Signature appears to match the hand-written name.	Remedial Actions: CIRB determination that the reported concern does not constitute noncompliance. No further action required. CASE CLOSED.
132	09	Mountain Home	H	04/24/2013	RCO audit found 18 of 69 subjects signed an outdated ICD for this observational/diagnostic evaluation study.	Remedial Actions: All 18 subjects were re-consented; Remedial actions complete, CASE CLOSED.
133	17	VA Central Texas HCS	H	04/26/2013	RCO audit found that a local SAE that occurred within a behavioral study involving Veterans with PTSD, had not been reported to the IRB within 5 days	Remedial Actions: Training on SAE reporting provided to the PI. CASE CLOSED.
134	17	VA Central Texas HCS	H	04/26/2013	RCO audit found that an SAE, that occurred within (but was unrelated to) a Phase 3 safety and efficacy IND cancer study, had not been submitted to the IRB within required timelines.	Remedial Actions: RCO provided training on SAE reporting. CASE CLOSED.
135	22	VA San Diego HS	H	04/26/2013	RCO audit found that 3 out of 5 subjects did not appear to meet enrollment criteria in a study designed to treat headaches related to mild TBI.	Remedial Actions: Amended exclusion criteria and implementation of a monitoring plan; IRB determination that the noncompliance was not serious or continuing. CASE CLOSED.
136	22	VA San Diego HS	H	04/26/2013	RCO audit found one ICD and one HIPAA authorization had not been signed by the subject in a study that uses genomic information to develop a specialized diet for weight loss.	Remedial Actions: Obtain compliant documentation of consent and HIPAA authorization. CASE CLOSED.
137	07	Tuscaloosa	H	04/29/2013	RCO Audit found missing scopes of practice documents; and 3-co-investigators not listed on the delegation of responsibility log in a mindfulness meditation therapy for PTSD study.	Remedial Actions: Completed training; completed scopes of practice; and updated delegation of responsibility form. CASE CLOSED.
138	09	Louisville	H	04/30/2013	RCO audit found incomplete CPRS data entry for 1 out of 33 participants in this suicide risk assessment group therapy project.	Remedial Actions: The additional research template notes were added to the subject's CPRS Records; Remedial actions complete, CASE CLOSED
139	01	VA Boston Healthcare System	H	05/02/2013	RCO Audit of Traumatic Brain Injury and Stress Disorders study revealed procedures were being conducted that were not part of the protocol.	Remedial Actions: Staff education, PI must amend protocol and revise ICD. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
140	09	Memphis	H	05/03/2013	RCO audit found that a wound healing supplement for spinal injuries was not routed through the pharmacy; an adverse event (death of enrolled subject prior to study treatment) was not reported; protocol deviations were not reported; case report forms were missing for 11/29 subjects.	Remedial actions: PI handbook was updated; Research enrollment/subject note template was updated; Research Assurance Officer hired to educate PIs. CASE CLOSED.
141	16	Houston	I	05/06/2013	NSOC reported an RCO Audit found that one consent form containing full name and last four SSN was missing.	Remedial Actions: PI initiated training and created detailed flow chart for handling, logging, and securing documents for staff; PI elected not to re-consent or seek a waiver and will not use this one participant's data. CASE CLOSED
142	23	Sioux Falls	H	05/06/2013	RCO Audit found that a study of combination antibiotic adverse events amended the protocol without receiving IRB approval.	Remedial Actions: Submit protocol amendment; re-educate/remind PIs of the need for IRB review and approval in advance of protocol changes. CASE CLOSED.
143	15	VA Kansas City Medical Center	H	05/07/2013	RCO audit found one out of 130 reviewed consents in this vascular/diabetes treatment study was missing several pages including the signature page.	Remedial Actions: Re-consent affected subject. CASE CLOSED.
144	21	San Francisco VAMC	H	05/07/2013	RCO audit found one subject did not sign HIPAA Authorization; data elements were not specified in 187 HIPAA Authorizations; and outdated ICD was used for 130 subjects. This is a TBI, PTSD, and memory study in retired military service members. PO determined no data was used or disclosed.	Remedial Actions: Review of informed consent/HIPAA authorization guidance for new PIs/new protocols; affected subjects to sign proper HIPAA authorizations or PI will not be able to use the data. CASE CLOSED
145	17	VA North Texas HCS	I	05/08/2013	NSOC reported one missing signed informed consent containing the Veteran's name and full SSN. A copy of the consent had previously been scanned into CPRS.	Remedial Actions: One year credit protection service was offered to Veteran; research staff will receive a reminder email related to the importance of safeguarding Veteran's PHI. CASE CLOSED
146	23	Iowa City	H	05/08/2013	RCO audit found documentation of HIPAA Authorization could not be located for 11 of 12 subjects enrolled in the prior 12 months into a Rheumatoid Arthritis Registry.	Remedial Actions: Privacy ticket closed. PI to obtain valid HIPAA authorization and consent and provide training to prevent a recurrence. PI to provide a follow-up report to the IRB. CASE CLOSED
147	03	Bronx	I	05/09/2013	RCO Audit found informed consent documents for two research participants are missing. Incident reported simultaneously to NSOC.	Remedial Actions: Two subjects were offered credit monitoring services. CASE CLOSED
148	16	Houston	H	05/09/2013	Two subjects consented after study closed. Study purpose is to determine if testosterone is predictive of postoperative recovery in knee replacement patients.	Remedial Actions: AO/R to counsel PI on ; R&DC sent a reminder letter concerning process of CR; data cannot be used; reported to OHRP. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
149	22	VA San Diego HS	H	05/09/2013	RCO Audit of a cardiology study identified five of six subjects signed ICDs but did not sign HIPAA authorizations; and one subject signed a HIPAA authorization, but not an ICD; none of the ICDs were stamped by the IRB	Remedial Actions: Submit deviation report; re-educate Co-PI and staff; implement master log to document consent process; increased auditing will be performed by the RCO. CASE CLOSED
150	02	Albany	A	05/10/2013	RCO audit found a Conflict of Interest (the IACUC reviewer of the protocol had contributed to the funding of a study involving rabbits).	Remedial Actions: IACUC notification, IACUC re-review of protocol. CASE CLOSED.
151	01	VA Boston Healthcare System	H	05/13/2013	RCO audit of alcoholism study found one expired consent form; 12 missing HIPAA Authorizations and additional tests administered that were not included in the protocol.	Remedial Actions: Staff education, suspension to new enrollment, study sponsor notification, protocol to be reviewed and amended if necessary. CASE CLOSED.
152	22	VA San Diego HS	H	05/13/2013	RCO audit found that one of 13 subjects had not provided HIPAA authorization in this study of cardiovascular risk in major surgery.	Remedial Actions: Obtain subject's signature on the HIPAA authorization; PO conduct review of noncompliance; PI complete human research protection program training. CASE CLOSED
153	22	VA Greater Los Angeles HS	H	05/14/2013	RCO Audit found that 0/21 subjects enrolled in a chronic obstructive pulmonary disease (COPD) had signed HIPAA Authorization forms.	Remedial Actions: Subjects were notified of the oversight; HIPAA authorization obtained from all subjects; a checklist was implemented to ensure compliant consent processes; IRB permited the use of data collected prior to documentation of valid authorization. CASE CLOSED.
154	17	VA North Texas HCS	H	05/15/2013	RCO audit found eight local consented staff members had not signed HIPAA Authorization; two VA employees conducting interviews of subjects locally did not have scopes of practice.	Remedial Actions: Documented HIPAA authorization was obtained from all subjects and Scope of Practice documents are on-file for all staff members. CASE CLOSED.
155	18	Southern Arizona VA HCS	H	05/15/2013	RCO identified investigators conducting international VA research without CRADO approval.	Remedial Actions: ORD review determines that a CRADO waiver will not be required because it was compliant with the governing VA Directive at the time of its approval. CASE CLOSED.
156	16	Houston	I	05/16/2013	RCO ICD Audit of a study of quality-of-life outcomes in cancer patients identified two missing HIPAA Authorization forms and two missing ICDs. PII consisted of full name. Incident reported to the NSOC.	Remedial Actions: Subjects have been re-consented and HIPAA Authorizations obtained; additional PI and study staff training; plan to file ICD and HIPAA forms immediately; quarterly internal audits per subject with use of a checklist. CASE CLOSED
157	21	San Francisco VAMC	H	05/16/2013	RCO Audit identified one unsigned HIPAA authorization in a study of cortical hyper-arousal during sleep.	Remedial Actions: Obtain signature on HIPAA authorization form. CASE CLOSED.
158	08	Miami	I	05/17/2013	RCO Triennial Audit found one subject's ICF and HIPAA Authorization were missing. Electronic copies of the missing documents were located in the subject's CPRS record.	Remedial Actions: One subject received a letter offering credit protection services; staff education to prevent future occurrences. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
159	09	Huntington	H	05/20/2013	RCO audit found that 8 subjects enrolling in a study for post traumatic nightmares signed Informed Consents that were missing the IRB stamp on all pages.	Remedial Actions: Subjects re-consented with IRB stamped consent. Update note in CPRS. CASE CLOSED.
160	00	VA Central Office	H	05/22/2013	A routine RCO audit on May 8-16, 2013 identified 12 serious adverse events at one study site that were not timely reported to the VA Central IRB for CSP 10-07, the SPRINT systolic blood pressure study.	Remedial Action: training for local study site staff on reporting requirements, notice to all study sites of reporting requirements, audit of reportable events by local RCO after six months.
161	03	Northport	H	05/22/2013	Routine RCO audit on May 8th-May 16th, identified 12 serious adverse events were not reported to the VA Central IRB on SPRINT CSP #10-07.	Actions: LSI reported SAEs to VACIRB; DCO ORO informed; LSI to submit protocol deviation; PI notification to all study sites of reporting requirements; local RCO audit in 6 months. ORO CO notified. CASE CLOSED.
162	23	Sioux Falls	H	05/22/2013	RCO Audit identified missing HIPAA Authorizations and no evidence that informed consent was obtained prior to research procedures for 7 of 7 enrollees in a PTSD study. In addition, ICD irregularities were noted; e.g., missing initials, missing CPRS notes, ICDs not scanned into CPRS.	Remedial Actions: R&D Coordinator placed an administrative hold on study, prohibiting new enrollment; SOP for Investigators is being modified; RCO to provide research compliance education to PI; develop competency training for new Investigators. CASE CLOSED.
163	11	Ann Arbor HCS	A	05/30/2013	RCO audit found noncompliance in respect to an individual who had not completed their Without Compensation paperwork including an Animal Scope of Practice.	Remedial Actions: IACUC notification; R&D Coordinator is now also reviewing protocols; new section added to protocol requiring the investigator to include dates of completion of WOC paperwork. CASE CLOSED.
164	16	Central Arkansas VHS (Little Rock)	H	06/04/2013	RCO Audit of a cardiovascular disease in patients with chronic kidney disease found the study was inappropriately exempted by the SRS.	Remedial Actions: SRS re-reviewed protocol. CASE CLOSED.
165	16	Houston	H	06/05/2013	RCO ICD audit revealed 13/196 participants were consented with an expired consent document in an epidemiology and impact of Surgical Site Infection in cancer patients.	Remedial Actions: The coordinators of this study were required to attend an Informed Consent Workshop for re-education. CASE CLOSED.
166	17	VA South Texas HCS	H	06/05/2013	RCO audit of a colonoscopy study found that affiliate ICDs and HIPAA Authorization forms were used instead of VA forms; consent forms had not been scanned into CPRS and inconsistencies in the recorded dates for project approval.	Remedial Actions: Study documentation corrected; PI re-trained regarding obtaining consent and HIPAA authorization and relevant VHA policies. CASE CLOSED.
167	23	Iowa City	H	06/05/2013	RCO audit of a shelter house project found 12 of 12 subjects had not provided HIPAA Authorizations and 11 of 12 consent forms used were not the current version.	Remedial Actions: PI must obtain compliant consent and HIPAA authorization within the next 90 days. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
168	18	New Mexico VA HCS	H	06/07/2013	RCO Audit of a bipolar study found that a serious adverse event was not reported as required within 5 business days of initial awareness nor did the IRB review it within their required 5 business days.	Remedial Actions: R&DC suspended enrollment; retraining of staff on proper dosing and documentation procedures. Suspension rescinded with approval of protocol amendment. Late reporting/review determined not serious or continuing. CASE CLOSED.
169	02	Syracuse	H	06/12/2013	RCO audit identified two protocols did not receive PO review prior to IRB and R&DC approval.	Research Service will check protocols approved via expedited review or as exempt in the last 12 months to ensure they had received PO review; protocols that were not reviewed by PO will be reviewed according to specified timeline. CASE CLOSED.
170	06	McGuire Veterans Affairs Medical Center	I	06/13/2013	RCO audit of a PTSD study identified that one ICD and two HIPAA Authorizations were not found. Subjects were subsequently contacted; one possessed original document and was given copy upon returning original. Second Veteran unable to locate his document; unknown if he'd received original or copy.	Remedial Actions: IRB determined PI will re-consent and reauthorize for continued data use or cannot use data; PI will add note to file stating reason for new ICD and HIPAA Authorization acquisition, if obtained; one Veteran will be provided credit monitoring for one year. CASE CLOSED
171	07	Charleston	H	06/14/2013	RCO audit discovered HIPAA was not signed by 5 subjects and study procedures were performed.	Remedial Actions: 3 of 5 subjects have now signed HIPAA Authorizations; other 2 subjects will be mailed document to sign and return. CASE CLOSED.
172	15	VA Kansas City Medical Center	H	06/14/2013	RCO ICD audit in a NIH funded schizophrenia study found that PHI for two subjects were provided to the sponsor without signed HIPAA authorizations (1 subject no longer enrolled, other subject signed HIPAA at later date); and that two subjects did not have the ICD scanned into their medical record.	Remedial Actions: Privacy Officer review of potential privacy violation; ICDs have been re-submitted for scanning; RCO to provide training and checklist to research study teams.
173	16	Central Arkansas VHS (Little Rock)	S	06/14/2013	Facility reported noncompliance involving an approved study that was inaccurately classified as exempt from SRS oversight.	Remedial Actions: Use of electronic IRB management system (IRBNet); new SRS screening form; audit of all active studies. CASE CLOSED.
174	08	Tampa	H	06/17/2013	RCO audit found lack of a required Informed consent (IC) and HIPAA authorization in two subjects, respectively. Research activities were initiated prior to obtaining IC in one subject in the minimal risk homeless severity index study.	Remedial Actions: The IRB determined this issue to be serious noncompliance. The PI will not use the data until re-consenting. A checklist was developed to double check the signatures at the moment of consenting. CASE CLOSED.
175	16	Houston	I	06/18/2013	NSOC reported that an RCO audit found that the last page of a completed ICD is missing. The missing page contained a signature with no other identifying information and was discovered during an RCO audit.	Remedial Actions: PI will contact Veteran to re-consent and obtain signature (data will not be used if signature is not obtainable). CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
176	17	VA North Texas HCS	H	06/18/2013	RCO audit of a melanoma study found that 6 Veterans had not signed or dated the HIPAA authorization, and 6 ICDs contained signatures of unauthorized consenters.	Remedial Actions: PI informed RCO Veteran will not be re-consented; Veteran's data has been removed from study; NSOC determined no HIPAA notifications or credit protection required. CASE CLOSED
177	19	VA Eastern Colorado HCS	H	06/18/2013	RCO Audit of a Barrett's Esophagus study found one consent was not signed or dated by subject and 12 subjects were consented using the affiliate IRB document rather than the VA ICD.	Remedial Actions: Obtain documented consent from 1 Veteran; other missing (PI) signatures were obtained; staff retrained; and new coordinator hired. CASE CLOSED
178	21	San Francisco VAMC	H	06/18/2013	RCO audit found that HIPAA authorizations had not been obtained from any of the 14 patient-participants; and one ICD was not obtained from one provider-participant in a study aimed at developing educational videos about traumatic brain injury.	Remedial Actions: Inform subjects and request HIPAA authorization; implement checklist to prevent recurrence; and review and provide remedial training concerning informed consent and HIPAA related processes. CASE CLOSED.
179	21	San Francisco VAMC	H	06/18/2013	RCO audit of advanced care planning found one instance of missing documentation of informed consent and 49 instances of missing HIPAA Authorizations.	Remedial Actions: PI and affiliate HRPP retrained regarding use of VA forms for VA research. CASE CLOSED.
180	22	VA Greater Los Angeles HS	H	06/18/2013	RCO audit found that HIPAA authorization had not been obtained for all 14 subjects enrolled in a study involving blast-related mild traumatic brain injury.	Remedial Actions: HIPAA Authorizations obtained from affected subjects except one, whose data will not be used; study modification to discontinue audio recording. CASE CLOSED.
181	22	VA San Diego HS	H	06/18/2013	RCO Audit found that 2 subjects out of 32 did not sign or date their ICD. This is a study of mental health providers' attitude toward different treatment options.	Remedial Actions: Subjects will be re-consented; PI to review all ICDs. CASE CLOSED
182	22	VA San Diego HS	H	06/18/2013	RCO Audit of 4 of 5 studies related to Hepatitis C, conducted by the same PI, found missing HIPAA authorizations and ICDs that had not been signed by the subject and conduct of research by an unauthorized individual.	Remedial Actions: Obtain HIPAA authorization; unauthorized individual completed HRPP training, submitted a scope of practice and obtained VA appointment; RCO to audit all of this PI's research. CASE CLOSED.
183	04	VA Pittsburgh HCS	H	06/19/2013	RCO regulatory audit of a heart failure pharmacy-level intervention comparison study identified that research was initiated on a patient population without a waiver of informed consent.	Remedial Actions: PI compliance education; PI work more closely with the IRB and policy office on future protocols; PI continue participation in the investigator/coordinator refresher sessions; IRB review previously approved waivers at continuing review to ensure appropriateness. CASE CLOSED
184	06	McGuire Veterans Affairs Medical Center	H	06/19/2013	RCO audit of PTSD meditation study discovered a consent document with the incorrect approval date and 2 HIPAA authorizations missing PO approval stamps.	Remedial Actions: Unstamped/outdated documents found to be identical - no action required. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
185	08	Miami	I	06/20/2013	NSOC reported that an RCO audit of a closed research protocol discovered that PHI was sent to a resident's personal email account (Gmail). Based on the current information available, it appears that the data included initials, partial SSN, dates of birth, diagnoses for approximately 15K participants	Remedial Actions: PI and ISO confirmed that the data was fully removed from the personal laptop and personal email; obtain WOC appointment for affiliate biostatistician to conduct statistical work at the VA; formal facility policy for PIs to obtain preparatory to research information. CASE CLOSED.
186	02	Syracuse	H	06/21/2013	RCO audit found that the privacy review on a one-time employee survey study was not conducted prior to IRB expedited approval. Study did not involve participant medical care or require a HIPAA Authorization, and was approved for waiver of documentation of informed consent.	Remedial Actions: IRB chair and PO to generate a list of all expedited and exempt protocols that did not undergo PO review; protocols that did not receive PO review will be reviewed by PO; going forward ensure PO pre-review of the protocol followed by post-review. CASE CLOSED
187	21	San Francisco VAMC	H	06/21/2013	RCO informed consent audit found one subject (total # of subjects not identified) enrolled did not have a signed HIPAA authorization form; study involves new Pulse Sequence Programming on a Magnetic Resonance Scanner.	Remedial Actions: Contact the subject in effort to receive HIPAA authorization, and if authorization not provided disallowed use of data. CASE CLOSED.
188	22	VA San Diego HS	H	06/24/2013	RCO audit found consent-related noncompliance involving HIV Latency blood testing study; 2 of 21 subjects enrolled by unauthorized employee; and 1 subject's record was missing a HIPAA authorization form.	Remedial Actions: valid HIPAA authorization obtained; retraining for study staff regarding collaborative research; UC IRB action to remove the VA San Diego HCS as a procedure site. CASE CLOSED.
189	22	VA San Diego HS	H	06/24/2013	RCO audit of an atrial fibrillation study found that 1 of 36 subjects was enrolled by an unauthorized employee.	Remedial Actions: Unauthorized individual was restricted from conducting research; safeguards implemented to prevent recurrence; subject will be re-consented. CASE CLOSED.
190	07	Atlanta	H	06/26/2013	RCO regulatory audit of a study on patients with congestive heart failure patients and diabetes found incomplete HIPAA authorizations (20) and ICDs (5 of 20); study team member had no scope of practice.	Remedial Actions: data cannot be used; study team retake VA Privacy & HIPAA training; RCO training on preparation of ICD and HIPAA authorizations; use of Collaborative Research worksheet; study team revise policies; research service review of systemic issues. CASE CLOSED.
191	07	Atlanta	H	06/26/2013	Routine RCO audit of study on improving self-management outcomes in CHF patients with diabetes found incomplete HIPAA authorizations (20) and ICDs (5 of 20); study team member had no scope of practice.	Remedial Actions: Study team and PI re-take HIPAA and Privacy training; statistician stopped data analysis; revised HIPAA to include required disclosures and re-signed by subjects; Research Service review of systems to correct procedures prior to study initiation. CASE CLOSED.
192	21	San Francisco VAMC	H	06/26/2013	RCO audit found that the HIPAA authorization for 1 of 8 subjects in a arterio-venous fistula remodeling and maturation study was incomplete.	Remedial Actions: Research subject notified of incomplete HIPAA authorization form and asked to sign new form; PO verified that documented HIPAA authorization had been obtained from the subject. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
193	19	VA Eastern Colorado HCS	H	06/27/2013	RCO Audit of two studies (a specimen repository and Hepatitis C immunity and liver transplant model) found that ICDs and HIPAA Authorizations were signed by the subject's spouses without documentation to verify that spouses were LARS or IRB approval for LAR-based enrollment.	Remedial Actions: Retrain study staff; contact subjects to obtain compliant consent and HIPAA authorization; do not use data without consent/authorization. CASE CLOSED.
194	05	DC VAMC	H	06/28/2013	RCO ICD audit found consent issues on a cardiovascular study. Five subjects were consented with a document that contained information not approved by the IRB and did not contain the IRB stamp. Four forms contained the signature of consent informant not authorized for consenting	Remedial Actions: Re-consent affected subjects. CASE CLOSED
195	21	San Francisco VAMC	H	07/09/2013	RCO ICD Audit of a prostate cancer study found research-related activity (obtaining informed consent from 16 subjects) occurred in advance of ACOS/R letter of approval to initiate research.	Remedial Actions: PO assessed that no privacy violations occurred; PI implemented approval tracking mechanism. CASE CLOSED.
196	07	Charleston	H	07/11/2013	RCO Audit of a PTSD mindfulness study discovered 31 of 37 ICF's used the incorrect version.	Remedial Actions: Contact all participants and offer to sign correct consent form. CASE CLOSED
197	05	VA Maryland HCS	H	07/12/2013	Regulatory audit found that VA specimens for an immunology study may have been stored in an off-site non-ORD approved tissue bank (conflicting reports from PI and study POC). Scopes were absent for PI and sub-investigator during the study.	Remedial Actions: None, IRB determined to be non-serious, not continuing. No further action required. CASE CLOSED.
198	05	VA Maryland HCS	H	07/12/2013	RCO Regulatory Audit of a nursing QI study of ICU device-related problems revealed lack of documentation of eligibility for 10 participants.	Remedial Actions: None, IRB determined not serious or continuing. CASE CLOSED.
199	05	VA Maryland HCS	H	07/12/2013	RCO regulatory audit of a hip radiography versus CT scan study found missing HIPAA auth. & use of an unstamped ICD (1 participant); PI failed to report this deviation to the IRB after a 2010 ICD Audit; RCO failed to report 2010 ICD audit findings to the IRB or ORO.	Remedial Actions: None, IRB determined the incident involved non-serious, not continuing R&DC reviewed process and issues. No further action required. CASE CLOSED.
200	05	VA Maryland HCS	H	07/12/2013	Regulatory Audit of a bladder cancer clinical trial found: 2 urology residents on study team had no human research protection training or scopes of practice; subinvestigator also had no scope of practice.	Remedial Actions: Facility and affiliate are developing a compliant method for transmitting RCO Audit reports to the affiliate IRB; IRB is allowing RCO access to upload audits into e-IRB (CICERO) system. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
201	02	Albany	H	07/15/2013	RCO Audit of the MVP program identified 45 ICDs or HIPAA documents that contained unreadable text or missing information.	Remedial Actions: Utilize the MVP checklist and staple to each ICD; develop script addressing each ICD element; non-engaged staff will monitor and document ICDs reviews weekly; and RCO to audit at least 10% of ICDs obtained within a 1-month time frame. CASE CLOSED.
202	10	Dayton	H	07/15/2013	RCO ICD audit of a diabetic chronic kidney disease study discovered that 7/7 subjects did not complete HIPAA authorization forms.	Remedial Actions: Study to be closed; data will not be used; compliance education for PI and staff; remedial actions complete, CASE CLOSED
203	21	San Francisco VAMC	H	07/15/2013	RCO audit found that 55 (out of 97) subjects had not signed HIPAA authorization forms and 12 (out of 99) subjects had not signed ICDs in an unfunded study of macular degeneration.	Remedial Actions: Obtain valid HIPAA authorization and documentation of informed consent; PI to provide explanation of how incident occurred and how future recurrence will be prevented; (re)training provided for PI and staff. CASE CLOSED.
204	22	VA Long Beach HS	H	07/15/2013	RCO audit found that one subject did not sign a HIPAA authorization form at the time of enrollment in a CSP safety and efficacy study of Methylprednisolone use for severe community acquired pneumonia.	Remedial Actions: HIPAA authorization obtained; procedures implemented to ensure compliant enrollment practices. CASE CLOSED.
205	22	VA Long Beach HS	H	07/15/2013	RCO Audit found that one subject did not sign a HIPAA authorization form in a study concerning Irritable Bowel Syndrome.	Remedial Actions: Data from this subject was excluded from the study's analysis. CASE CLOSED
206	17	VA North Texas HCS	H	07/16/2013	RCO Audit found one subject had not signed an ICD for a study evaluating risk of post-polypectomy bleeding with prophylactic hemoclipping.	Remedial Actions: IRB determined not serious noncompliance, but will obtain subject's signature. CASE CLOSED
207	22	VA San Diego HS	H	07/16/2013	RCO Audit revealed that documentation of informed consent and HIPAA authorization was not present for one subject enrolled in a long-term care study for non-service-connected spinal cord injured Veterans.	Remedial Actions: Checklist established to assist with enrollment procedures; data obtained from the subject who had not provided documentation of informed consent and HIPAA authorization will not be used. CASE CLOSED.
208	07	Atlanta	H	07/17/2013	RCO ICD Audit of sub-study on vitamin D/Calcium Polyp Prevention Study found that forty-one Informed Consents and HIPAA authorizations were not entered into CPRS. Four ICDs had unsigned witness signature blocks. NCI funded.	Remedial Actions: Study coordinator training; scanning of ICDs and HIPAA authorizations into CPRS. Actions completed. CASE CLOSED
209	21	San Francisco VAMC	I	07/17/2013	RCO Audit of a physical stress and simulated crisis management study found that a signed consent document was reportedly obtained but could not be located for one participant.	Remedial Actions: IRB did not require re-consent for missing ICF. IRB required no further action; outcome of IRB redetermination for not acquiring HIPAA Authorizations is being followed separately. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
210	22	VA Greater Los Angeles HS	I	07/17/2013	RCO Audit of a dental gum recession study found that one research HIPAA authorization could not be located and was determined to be misfiled. Incident was reported to NSOC, but not according to reporting requirements.	Remedial Actions: PI educated about timely reporting requirements; subject signed another HIPAA Authorization; IRB clearly documented rationale for use of subject's data; IRB accepted PI's plan to revise document completion procedures upon participant visits; records confirmed as locked. CASE CLOSED
211	05	DC VAMC	H	07/18/2013	RCO Audit of a wellness evaluation study found one participant had not signed a HIPAA authorization, two ICDs without informant signature and one missing participant signature date.	Remedial Actions: Participant withdrew before PHI was collected, IRB found non-serious, not continuing; PI reviewed and revised consent procedures to ensure that HIPAA authorization is obtained during informed consent discussion. CASE CLOSED.
212	04	Philadelphia	H	07/21/2013	RCO Triennial and ICD Audit of an HIV Registry study with data maintained at affiliate (coordinating center) with CRADO approval; coordinating center failed to report SAEs (114) to the IRB; non WOC study member performing data entry of PHI; and study missing initial SRS approval.	Remedial Actions: NERO requesting SAE determinations; status of access to PHI by non WOC; review by PO for data breach, and review of programmatic noncompliance. CASE CLOSED.
213	23	Fargo	H	07/23/2013	RCO Audit found consent-related deficiencies (2 subjects did not have signed HIPAA authorizations); and lack of complete documentation in CPRS in a PTSD study.	Remedial Actions: Ensure approved ICDs are used; PI is attempting to re-consent subjects; RCO to witness informed consent process for all new enrollees; educate PIs on the correct consenting process. CASE CLOSED.
214	21	San Francisco VAMC	H	07/23/2013	RCO audit found that eight subjects in a schizophrenia study were consented by unauthorized study personnel.	Remedial Actions: IRB determination of serious noncompliance; PO review revealed non privacy concerns; unauthorized individuals (no longer with the SFVAMC) had valid appointments, scopes of practice, and completed training when consent was obtained. No further action required. CASE CLOSED.
215	22	VA San Diego HS	H	07/23/2013	RCO Audit found consent-related deficiencies in a study collecting data for urologic conditions. No HIPAA authorization was obtained from any of the 122 subjects; point of contact was not identified as an approved staff member; nor were ICDs signed by any staff member.	Remedial Actions: Study accrual and access to medical record data on hold; develop training SOP; request subjects provide documented consent and HIPAA authorization; sequester and not use data obtained from subjects without a valid ICD and HIPAA authorization. CASE CLOSED.
216	16	Oklahoma City	H	07/24/2013	RCO Audit found 4 active VA researchers with a Contract appointment; 3 active VA researchers with a Fee Basis appointment; and 3 active VA researchers who were not Credentialed and Privileged.	Remedial Actions: Credentialing and privileging through VetPro; Fee Basis researcher obtaining a VA paid appointment; others will be converted to, or will obtain, a WOC appointment.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
217	02	Albany	E	07/25/2013	RCO Audit of the MVP program identified 45 ICDs or HIPAA documents that contained unreadable text or missing information. Linked to NERO 0050-500-H	Remedial Actions: extensive re-training by Local Site Investigator and implementation of a script. Observation of informed consent process. Weekly monitoring of all informed consent documents. Affected Veterans were mailed clean copies of all smudged pages. CASE CLOSED.
218	16	Houston	H	07/25/2013	RCO Audit found one research subject enrolled in project after study closure.	Remedial Actions: PI re-consented participant and entered the info in CPRS. CASE CLOSED.
219	16	Houston	H	07/25/2013	RCO Audit found that the incorrect version of the ICD was used for 11 subjects.	Remedial Actions: PI to place a note-to-file in the participants CPRS record. CASE CLOSED.
220	16	Houston	H	07/25/2013	RCO Audit found the incorrect version of the ICD was used for 24 subjects. This study aims to set up a formal mechanism to prospectively contain consent to donate, collect and store human tissue	Remedial Actions: PI to discard blood vials for 3 subjects and not use their data; remaining 21 subjects will be re-consented; if subjects are re-consented, tissue will be anonymized per the protocol.
221	18	Phoenix VA HCS	I	07/25/2013	NSOC reported an RCO Audit found 5 ICDs containing full name/SSN and medical information were not scanned into CPRS. Three were found in a locked cabinet; the other two forms for one Veteran had been sent for scanning but not received.	Remedial Actions: One Veteran offered credit protection services; forms revised (now contain only last 4 of SSN, not full SSN); use of a locked box for dropping off copies for scanning; best practice recommendation to check CPRS within 2 weeks of sending research documents for scanning. CASE CLOSED
222	00	VA Central Office	H	07/25/2013	RCO audit of the MVP program at one VA Medical Center identified 45 ICDs or HIPAA documents that contained unreadable text or missing information. The VA Central IRB made a determination of serious noncompliance.	Remedial Actions: Staff re-training; study staff to use verification checklist; coordinating center review of documents; affected participants received a clean copy of all missing or illegible documentation; LSI observed consent process; staff received further training. CASE CLOSED
223	16	Houston	H	07/29/2013	RCO audit revealed 4 subjects did not signed required separate HIPAA authorization. This greater than minimal risk study tries to determine whether bacteriophage is present in the urine of subjects on a catheter.	Remedial Actions: PI received HIPAA training from Research Service and obtained HIPAA from four participants. CASE CLOSED.
224	16	Houston	H	07/29/2013	RCO Audit revealed that 79 subjects did not sign the required separate HIPAA authorization. This greater than minimal risk study investigates the association between proton pump inhibitors and immunologic recovery in HIV pts.	Remedial Actions: PI not required to obtain HIPAA authorization from subjects; PI trained on methods to obtain authorization. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
225	05	VA Maryland HCS	H	07/29/2013	RCO Audit of a myasthenia gravis study found numerous docs missing from reg. binder: R&DC approvals - initial, CR, amendment and reportable events; 2 SAEs; WOC appointments, scopes, and training certifications. Audit was reported 11/14/12 acknowledged delinquent due to staffing turnover from Oct '12 through Feb '13	Remedial Actions: Report 2 AEs to the IRB; study staff completed required VA and CITI training. IRB determined not serious, not continuing, no further action required. CASE CLOSED.
226	20	VA Puget Sound HCS	H	07/29/2013	RCO Audit found that 9 (out of 9) signed HIPAA authorization forms were for a different study and did not inform of potential use and disclosures of PHI relevant to this clinical trial of adults with pre-diabetes and early type 2 diabetes.	Remedial Actions: Request that subjects provide HIPAA authorization. Retraining for the staff member who made the error. Establishment of a second person review for document completion and accuracy. CASE CLOSED.
227	07	Atlanta	H	07/31/2013	RCO ICD Audit of study monitoring heart variability by Halter Monitor of Acupuncture discovered 18 Informed Consents had no IRB approval stamp and 51 ICDs not scanned into CPRS	Remedial Actions: PI consent of all subjects with IRB stamped form; all ICDs and HIPAA documents scanned into CPRS; study team training on policies and procedures. Actions completed and CASE CLOSED.
228	02	VA Western New York HCS	H	08/02/2013	RCO Audit of a behavioral health protocol found that required waiver of documentation of consent was not requested and approved by the IRB at the time of initial review and approval.	Remedial Actions: Committee education; PI submitted request to IRB for waiver of documentation of informed consent. CASE CLOSED.
229	16	Central Arkansas VHS (Little Rock)	H	08/06/2013	RCO audit found lapse in IRB approval and failure to scan consent into CPRS. This is a pilot intervention effectiveness study for PTSD patients.	Remedial Actions: Scan ICD into CPRS; submit completed closure documents or continuing review documents to IRB. All remedial actions were completed. CASE CLOSED.
230	05	VA Maryland HCS	H	08/06/2013	RCO audit found 12 participants in a prostate cancer trial enrolled at the affiliate without consent form and participation in non-ORD approved tissues banks. Study started at affiliate VA was added later, collaborating research was not sorted out.	Remedial Actions: IRB determined non-serious, not continuing non-compliance; accepted PI's arguments that the study predated ORO's guidance and that UMB components were not VA research. Other than using 10-1086 going forward for VA subjects, no corrective actions were required. CASE CLOSED
231	09	Memphis	H	08/07/2013	RCO audit found programmatic noncompliance of multiple studies with expired IRB approval. 4 studies had expired approvals approaching 2 years; 3 studies had expired IRB approvals greater than 20 months; for 2013,46 of 147 studies had expired approval of at least 30 days; 13 greater than 90 days.	Remedial Actions: Identify lapsed studies; IRB and Chair to determine if enrollees may continue on study in consultation with the COS; move remaining actions into case #0066. CASE CLOSED

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
232	12 NE	Hines	H	08/10/2013	RCO Audit of patient dignity and safe patient handling found HIPAA authorization was not obtained for eight staff members interviewed, and HIPAA authorization was not properly obtained for one patient participant.	Remedial Actions: Study personnel education; obtain HIPAA authorization for the eight staff interviewed within 30 days of receiving IRB communication; data obtained from one patient participant without proper HIPAA authorization cannot be used. CASE CLOSED.
233	09	Louisville	H	08/15/2013	RCO Regulatory Audit of a tumor growth study discovered one study team member's WOC status had expired.	Remedial Actions: PI was notified that the staff member must cease research activities. CASE CLOSED.
234	22	VA Greater Los Angeles HS	H	08/19/2013	RCO Audit found a HIPAA Authorization was not executed for one subject enrolled in a deep brain stimulation Parkinson's Disease follow-up study.	Remedial Actions: Pending
235	05	VA Maryland HCS	H	08/20/2013	RCO audit found failure to maintain regulatory files and destruction of files for a record review of the association between use of prescription drugs and cancer of the colon and rectum.	Remedial Actions: Educated PI and staff, PI to ensure that if aco0investigator leaves VAMHCS, the PI will obtain study records. CASE CLOSED.
236	07	Atlanta	H	08/27/2013	RCO ICD Audit of PTSD study discovered one VA subject signed an ICD which did not indicate affiliate as the Sponsor of study and PHI for one VA subject sent to affiliate for subject payment when HIPAA and ICD did not provide for disclosure to affiliate.	Remedial Actions: PO review determined no unauthorized disclosure. CASE CLOSED.
237	12 NE	James A. Lovell Federal Health Care Center	H	08/30/2013	RCO Audit of a study utilizing eye technology to assess PTSD found that no inclusion/exclusion criteria were used, no CPRS progress notes, wrong version of ICD used, wrong SSN on HIPAA and that patient data collected was neither de-identified nor placed on spreadsheets as outlined in protocol.	Remedial Actions: Education; update CPRS; determination of disposition of data collected; PIs to submit monthly enrollment reports to Research Department.
238	01	VA Boston Healthcare System	H	09/16/2013	RCO Audit of an obesity and diabetes study found one missing ICD and 7 missing HIPAA authorizations.	Remedial Actions: PI research credentialing completed; PI to re-consent one subject; PI to obtain 7 missing HIPAA Authorizations. CASE CLOSED.
239	03	VA New York Harbor HCS	H	09/17/2013	RCO Audit of an HIV study found seven missing HIPAA Authorizations.	Remedial Actions: PI and staff education; PI must obtain HIPAA authorizations from consent subjects or their data cannot be used.
240	22	VA Long Beach HS	H	09/19/2013	RCO Audit of a human subject protocol to evaluate the safety & efficacy of Methylprednisone in hospitalized veterans with severe community acquired Pneumonia found the protocol had a lapse of Safety approval.	Remedial Actions: R&DC and SRS reviewed and approved for 2012 and 2013. R&D coordinator will pay particular attention to protocols out of sync with SRS approval. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
241	05	VA Maryland HCS	H	09/19/2013	RCO Audit of a low-vision intervention trial found two study staff did not have Scopes of Practice for the three-year duration of the study.	Remedial Actions: None, CIRB determined not serious, not continuing. CASE CLOSED.
242	12 NE	Hines	H	09/25/2013	RCO Audit of a depressions outcomes study found three study team members were missing their Scopes of Practice.	Remedial Actions: Obtain Scopes of Practices, conduct training, and determine action plan for PI. CASE CLOSED.
243	03	VA New Jersey HCS	H	09/25/2013	RCO audit of a closed study on veterans with fatiguing illnesses found that a study team member did not have a Scope of Practice.	Remedial Actions: Training and education on requirements of Scopes of Practice. CASE CLOSED.
244	05	DC VAMC	H	09/27/2013	RCO Audit of a city-wide cohort HIV study found that the PI enrolled 12 participants using an outdated ICD that did not contain the IRB-required text re: collaborative research.	Remedial Actions: None, IRB determined not to be continuing noncompliance, since the ICD already contained the information required by the IRB. CASE CLOSED.
245	01	VA Connecticut HCS	H	09/30/2013	RCO Audit of a Wellness Program health outcomes study found that the PI had not signed and dated all 11 consents.	Remedial Actions: Education to PI and study staff, PI to sign consents, and PI to provide research compliance office of all signed consents during study's current study approval period. CASE CLOSED.
246	05	VA Maryland HCS	H	10/01/2013	RCO regulatory audit found that PI of a pulmonary study failed to submit amendments required by the IRB's Corrective action Plan in 2009 after a prior regulatory audit.	Remedial Actions: Modify the ICD to reconcile study description with procedures actually being performed, modify protocol to state that pulmonologist Co-Investigator will assess eligibility and document in the study records that participant has one of the chronic lung diseases in criteria.
247	21	San Francisco VAMC	H	10/02/2013	RCO Audit of a simulated crisis management study identified 0 of 45 subjects enrolled did not provide HIPAA Authorizations; IRB to determine future use and disclosure of data collected.	Remedial Actions: HIPAA waiver granted for use of existing (deidentified) data; HIPAA required for any new enrollment. All concerns resolved. Case closed.
248	23	Minneapolis	H	10/08/2013	RCO audit of the human subject protocol evaluating Isometric Lingual Strengthening Exercises found missing HIPAA authorizations and Informed Consent, lack of a PI scope of practice, missing picture/voice consent, and lack of CPRS record of enrollment for 2 subjects.	Remedial Actions: Retraining; obtaining HIPAA authorization and picture/voice consent where deficient (no data use without it); correction of electronic medical record. Case closed.
249	04	VA Pittsburgh HCS	H	10/09/2013	RCO ICD Audit on a study assessing alterations in GABA neurotransmitters in Veterans with PTSD found one subject lacked HIPAA authorization.	Remedial Actions: Data collected will not be used and PI staff education. CASE CLOSED

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
250	16	Little Rock	H	10/10/2013	RCO Audit found that one subject enrolled in a diabetes and kidney disease study did not have a HIPAA Authorization which was an outstanding required action from a previous audit.	Remedial Actions: Study staff collected a signed HIPAA Authorization. No further actions required. CASE CLOSED
251	04	Philadelphia	H	10/16/2013	RCO ICD Audit of study on adherence to long term oxygen therapy discovered 38 of 53 signed ICDs (dating back to 2007) missing.	Remedial Actions: Privacy Officer notified; study closure; no use of data; inform local records management; other actions pending.
252	08	Miami	H	10/16/2013	RCO Audit found that the research team was administering 2 screening tools for 2 different studies, prior to obtaining Informed Consent, to determine whether or not the potential subject was eligible for the studies.	Remedial Actions: PI educated his study coordinators to follow the procedure outlined in the approved protocol. IRB requested follow-up with subjects that did not meet inclusion criteria to make sure appropriate follow-up is given thru clinical care. The PI developed a safety plan. CASE CLOSED.
253	04	Philadelphia	I	10/17/2013	NSOC reported that during an RCO audit, 38 informed consent documents could not be located. PI confirmed that no research data has been disclosed outside of the VA.	Remedial Actions: PI no longer using the research data; PI intends to close study; other actions pending.
254	16	Little Rock	H	10/17/2013	RCO Audit found one HIPAA authorization was not obtained from a research participant enrolled in a liver cancer study.	Remedial Actions: confirm completion of consent progress notes; confirm update of 10-9012 for subject in CPRS; submit modification to update 10-9012 with current authorized subscribers; create CPRS notes; and complete training. CASE CLOSED.
255	08	San Juan	I	10/21/2013	Facility reported a RCO Audit identified a missing original ICD and HIPAA authorization containing full name, full SSN for one subject enrolled in an antibiotic study.	Remedial Actions: Credit monitoring services will be offered; PI to provide IRB with current procedures related to consent process and security of consent documents, then develop plan to prevent future occurrence.
256	16	Houston	I	10/21/2013	RCO Audit found that a PI (stroke swallowing study) was unable to locate one research consent form and one HIPAA Authorization. PHI consisted of Veteran's full name; did not contain full or partial SSN. It was felt documents were likely lost within protected research space and not in public areas.	Remedial Actions: PI concluded subject has been lost to follow-up and will not use the data; credit protection services not required; study staff re-education. CASE CLOSED
257	05	VA Maryland HCS	H	10/23/2013	RCO Regulatory audit found a robotic rehabilitation protocol was not followed and study procedures varied among participants, 5 of 70 participants were enrolled twice; 1 student had no CITI training until after their involvement in the study, 2 staff had no Scopes of Practice.	Remedial Actions: PI will close this study and submit a new one consistent with how he was conducting the former study in order to reconcile his new protocol with IRB terms of approval.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
258	08	Tampa	S	10/24/2013	RCO Regulatory Audit found one staff member did not have IACUC approval to work on one study involving rats. it was determined the employee had been appropriately trained, but the request was not submitted to add to the protocol personnel list.	Remedial Action: None required as the PI is retired and the protocol closed. CASE CLOSED.
259	08	Tampa	S	10/24/2013	Regulatory Compliance Audit found that four staff members working on one specific protocol involving mice were not authorized and that one staff member was not trained. However, the PI failed to submit requests for their addition to the study.	Remedial Action: None required as the PI is retired and the protocol closed. CASE CLOSED.
260	16	Houston	H	10/28/2013	RCO audit of this biorepository study designed to store and collect blood and serum for future studies revealed that 48/60 subjects signed ICDs with the wrong version date and 9 subjects signed expired ICDs.	Remedial Actions: Pending
261	16	Houston	H	10/28/2013	RCO audit of this biorepository study designed to store and collect blood and serum for future studies revealed that 57 subjects did not sign HIPAA authorization and 13 subjects signed expired ICDs.	Remedial Actions: Pending
262	15	Columbia	R	10/28/2013	RCO Audit found ACOS initiation letter and RDC approval were sent prior to final IACUC approval for this insulin/diabetes study.	Remedial Actions: A process was established to ensure that the R&DC chair would not send approval notifications to the ACOS/R until all subcommittee approvals are obtained; the process utilizes several quality assurance checks supplemented by a checklist; remedial actions complete, CASE CLOSED.
263	09	Memphis	H	10/30/2013	RCO Audit of 21 ICDs (alcohol abuse and PTSD study) found no HIPAA authorizations 3/21; IRB did not approve enrollment of non-Veterans and health record documentation missing 21/21; enrollment and progress notes not entered 11/21; signed ICD and HIPAA were not scanned 4/21.	Remedial Actions: RCO to perform audit of all studies led by this principal investigator. All PI study enrollment has been suspended until audit completions.
264	01	VA Boston Healthcare System	H	11/01/2013	RCO audit of a PTSD study found deviations from the protocol (extra assessment visits; patient data taken from another study, use of VA staff as pilot subjects).	Remedial Actions: Temporary suspension of study enrollment; PI must revise protocol to accurately reflect assessments performed and the assessment schedule; submit amendments as necessary.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
265	08	Tampa	A	11/04/2013	RCO Audit found that a PI failed to submit an amendment requesting the addition of personnel resulting in untrained and/or unapproved staff on an mouse protocol.	Remedial Action: None required as the PI is retired and the protocol closed. CASE CLOSED.
266	08	Tampa	A	11/04/2013	RCO Audit found that one staff member was not approved to work on a rat protocol. The retired PI had failed to submit a request to add the staff member to the protocol.	Remedial Action: None required as the PI is retired and the protocol closed. CASE CLOSED.
267	08	Tampa	A	11/04/2013	RCO Audit found untrained and/or unapproved staff, and lack of personnel scope of practice, on a rat protocol.	Remedial Actions: IACUC discussed incident; review of process for verifying that personnel met all requirements prior to work. CASE CLOSED.
268	05	DC VAMC	H	11/04/2013	RCO Audit found PI used an outdated ICD to enroll 11 participants into an HIV, Alcohol, Aging, and Substance Abuse Outcomes study. The study was approved but the participants were enrolled prior to receipt of the stamped IRB-approved ICD.	Remedial Actions: None, IRB determined to be not serious or continuing noncompliance. Closed Case 12.10.13
269	21	VA Palo Alto HCS	H	11/13/2013	RCO Audit of an early social development study found that data analysis related to children was being conducted without the required CRADO waiver.	Remedial Actions: Pending
270	22	VA Greater Los Angeles HS	H	11/13/2013	RCO audit noted that documentation of HIPAA authorization had not been obtained for 3 of 6 enrolled study subjects. The RCA also noted that the available documentation indicated that 3 subjects, who had completed the study, had apparently not met the inclusion/exclusion criteria.	Noncompliance was serious, not continuing. IRB and PO reviews completed. Corrective actions: data use permitted after HIPAA authorization; 1 of 3 inclusion errors was substantiated, no data use for that subject; refresher training and additional document review at enrollment. Case Closed.
271	05	VA Maryland HCS	H	11/15/2013	RCO audit found failure to obtain a HIPAA authorization for one subject in a robot-assisted ankle training study of sub-acute stroke survivors.	Remedial Actions: None - IRB determined non-serious, not continuing noncompliance. Closed case 1.2.14.
272	02	Syracuse	H	11/20/2013	RCO audit on transitions intervention to improve medication adherence and reduce readmissions study found a sub-investigator conducted research follow-up visits on subjects without IRB approval, approved scope of practice, and was using ICD not stamped by IRB and HIPAA authorization not stamped.	Remedial Actions: PI education; other actions pending.
273	08	Bay Pines	H	11/20/2013	RCO informed consent audit found a subject was consented and dispensed study medication prior to verification of exclusion criteria in a dietary supplement and PTSD study.	Remedial Actions: Pending

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
274	10	Cleveland	H	11/25/2013	RCO audit found expired WOC appointment and missing scope of practice for one research staff member on this chart review and stool collection study.	Remedial Actions: Remove staff from the study under expedited review as minor changes by the IRB.
275	10	Cleveland	H	11/25/2013	RCO audit found person obtaining consent did not sign two consents for this Phase II blood draw and chart review study of Veterans at risk for Type 2 Diabetes.	Remedial Actions: Pending
276	16	Houston	H	11/26/2013	RCO audit revealed 3 participants were consented after a brain imaging study closed.	Remedial Actions: Pending
277	08	Miami	H	11/26/2013	The RCO found a failure to obtain HIPAA authorization for one study subject in a Vitamin D study.	Remedial Actions: Modification to the RCO?s initial reporting, to include the PO. Education to the PI to disseminate understanding that a HIPAA waiver for initial screening does not apply when actively conducting research thru interventions. CASE CLOSED.
278	09	Memphis	H	12/02/2013	RCO audit found individually identifiable health information collected without a HIPAA authorization or waiver of HIPAA authorization.	Remedial actions: NSOC filed; IRB requested RCO perform an audit of all studies being conducted by this investigator. Protocol suspension until completion of RCO for-cause audit.
279	17	VA North Texas HCS	H	12/02/2013	RCO audit found that two unauthorized study staff members of a melanoma study had obtained documentation of informed consent (3 subjects) and two subjects had been enrolled without HIPAA authorization.	Remedial Actions: Pending
280	23	Minneapolis	H	12/02/2013	RCO audit of two knee arthroplasty studies found continuation of research past the IRB approval date, incomplete or absent ICDs, and unauthorized disclosure of PHI.	Remedial Actions: Notify affected subjects of unauthorized data disclosures; data may not be used that was obtained past IRB approval date and subject consent; other actions pending.
281	16	Little Rock	H	12/04/2013	RCO audit of peripheral artery disease study found use of ICD without IRB approval stamp; failure to submit 2 deviation reports; randomization of an ineligible subject; failure to report SAEs; failure to document pharmacy activities in the medical record.	Remedial Actions: Deviations reported to IRB; SAE log updated; Pharmacy updated CPRS record; will mail page 15 of ICD to subject for signature and will withdraw subject if not returned within 14 days.
282	21	San Francisco VAMC	H	12/04/2013	RCO audit found and NSOC reported that HIPAA authorizations were not obtained for four research participants and 20 HIPAA authorizations contained no expiration date.	Remedial Actions: Pending

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
283	05	VA Maryland HCS	H	12/08/2013	RCO audit found 1 of 25 participants had no HIPAA authorization in a study involving vitamin D Rx for secondary hyperparathyroidism.	Remedial Actions: IRB determined not serious, not continuing noncompliance - no remedial actions required. CASE CLOSED
284	05	VA Maryland HCS	H	12/10/2013	RCO audit found deviations on a movement & balance study for stroke & high fall risk patients - undocumented eligibility, used unapproved ICDs, enrolled participants under multiple ID numbers.	Remedial Actions: Pending
285	05	VA Maryland HCS	H	12/10/2013	RCO regulatory audit found 2 of 10 subjects were enrolled with documented evidence that they met exclusion criteria on a motor learning study. Two study team members had no scopes for the duration of the study.	Remedial Actions: Pending
286	15	Columbia	H	12/10/2013	RCO conducted regulatory audit of a retrospective chart review of calcium and vitamin D. PI conducted unapproved prospective/retrospective research using PHI without IRB approvals or waivers.	Remedial Actions: Research activities suspended; other actions pending.
287	16	Oklahoma City	H	12/11/2013	RCO Audit found PI did not obtain a CRADO Waiver to enroll pregnant women into his study. Eight pregnant women were enrolled. Study is now closed.	Remedial Actions: None required. Facility withdrew event as it was not apparent serious non-compliance. CRADO waiver was not required. CASE CLOSED
288	09	Louisville	H	12/12/2013	RCO regulatory audit found 1 research member with expired CITI training.	Remedial Actions: Pending
289	15	Columbia	A	12/17/2013	RCO Audit found a lapse in annual review of an animal protocol.	Remedial Actions: The Subcommittee on Animal Studies will monitor annual reviews; prevent animal ordering should a lapse occur; and require the PI to stop research until the review is completed. CASE CLOSED.
290	21	San Francisco VAMC	H	12/18/2013	RCO audit found programmatic failure to identify deficiencies in HIPAA authorizations for multiple protocols. The deficiencies consisted of the absence of an expiration date or event.	Remedial Actions: Re-review of all HIPAA authorizations approved during past year; responsible person relieved of responsibility pending trainer and refresher education; HIPAA authorization template review; other actions pending.
291	09	VA Tennessee Valley HCS	H	12/20/2013	RCO audit found that HIPAAs for 21 subjects in a lung cancer study did not completely document permissions for use and disclosure of 38 USC 7332 data to a non-VA entity.	Remedial Actions: Pending
292	21	VA Pacific Islands HCS	H	12/20/2013	NSOC reported use of ICD forms without the IRB approval stamp and HIPAA authorizations without local requirement for affirmation of PO review.	Remedial Actions: Pending

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
293	16	Houston	I	12/23/2013	RCO audit found and NSOC reported discovery of one missing ICD.	Remedial Actions: Pending
294	21	San Francisco VAMC	H	12/23/2013	RCO Audit of a PTSD study found an outdated ICD version was used for enrollment of 43 of 192 subjects.	Remedial Actions: Pending
295	09	VA Tennessee Valley HCS	I	12/30/2013	RCO audit found one subject's case report form (including dates and subject initials) was missing.	Pending
296	15	Columbia	A	12/31/2013	RCO audit discovered one animal protocol with a lapse in annual review and use of eight mice during the lapse.	Remedial Actions: The investigator submitted an annual review to the Subcommittee on Animal Studies; other actions pending.
297	15	Columbia	H	12/31/2013	RCO audit found that an expired cardiac stent had been placed in a patient for the VA CSP #571 device study.	Remedial Actions: Pending
298	15	Columbia	R	12/31/2013	RCO audit found that the R&DC approved an ACORP involving mice prior to all subcommittee final approvals.	Remedial Actions: Pending
299	18	Phoenix VA HCS	H	12/31/2013	RCO audit of research records for 9 of 76 enrolled subjects in a blood pressure intervention trial found multiple concerns including missing source documentation, discrepancies between source documents and CPRS entries, failure to obtain ICD for DNA sampling, and 1 subject running out of study med.	Remedial Actions: Sponsor notified; employment of one CRC terminated; other actions pending.

TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT

The director of each VHA research facility must lead an annual program-wide self-assessment of research compliance and provide ORO with a certification of research oversight based on this self-assessment in July of each year. The program requires that the facility director's certification include an action plan to remediate any deficiencies identified by the self-assessment. ORO monitors implementation of these remedial actions.

Summary

- 21 = Cases Continuing from Calendar Year 2012
- 83 = New Cases in Calendar Year 2013
- 104 = Total Cases (Continuing Plus New) in Calendar Year

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
1	07	Atlanta	H	2012	Remedial Actions: Research Service review of systemic issues; one time process/software programming tracking failure corrected. Staff asst. retraining to track projects properly; identified protocols processed for Continuing Review. All actions completed. CASE CLOSED.
2	07	Birmingham	A	2012	Remedial Actions: None required. CASE CLOSED.
3	16	Central Arkansas VHS (Little Rock)	A	2012	Remedial Actions: Each subcommittee will appoint individuals to track training; develop new SOP to ensure timeliness of annual reviews; audit staff records to ensure correct scopes of practice are present. CASE CLOSED.
4	16	Central Arkansas VHS (Little Rock)	P	2012	Remedial Actions: Appoint all R&DC members to R&DC; ensure investigators have scopes of practice; ensure training tracking system is complete; ensure training complete. CASE CLOSED.
5	05	DC VAMC	A	2012	Remedial Actions: Scopes of practice for research personnel; ensure SRS review of protocols; hire a SRS coordinator; correct HVAC deficiencies. CASE CLOSED.
6	16	Fayetteville	P	2012	Remedial Actions: Complete the MOU and update SOPs. CASE CLOSED.
7	12 NE	Hines	H	2012	Remedial Actions: CRADO Waiver required for participation in a children's study.
8	16	Houston	A	2012	Remedial Actions: Ensure SRS approval of protocols; ensure personnel training is current; complete annual reviews of IACUC protocols; ensure HVAC enhancements are completed.
9	11	Indianapolis	A	2012	Remedial Actions: Implement a new occupational health and safety program to encompass all personnel by fall/winter 2012. CASE CLOSED.
10	16	Jackson	P	2012	Remedial Actions: Update SOPs and policies. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
11	12 NE	James A. Lovell Federal Health Care Center	S	2012	Remedial Actions: SRS review to prevent lapses in continuing review. CASE CLOSED.
12	01	Manchester	P	2012	Remedial Actions: R&DC must provide oversight of research programs and subcommittees; conduct reviews of same; conduct reviews of budget. CASE CLOSED
13	09	Memphis	A	2012	Remedial Actions: Complete scopes of practice for all personnel; complete training; renovations to VMU biocontainment area; ensure SRS continuing reviews are conducted at appropriate intervals. CASE CLOSED.
14	08	Miami	A	2012	Remedial Actions: Weekly meetings between the Research Service and Engineering; repairs to the Heating Ventilation and Air Conditioning (HVAC) system. CASE CLOSED.
15	18	New Mexico VA HCS	A	2012	Remedial Actions: Ensure that individuals complete all training; ensure continuing reviews are conducted at appropriate intervals. CASE CLOSED.
16	08	Tampa	A	2012	Remedial Actions: Develop standard operating procedures for RSSP and ACUP; complete SRS review of protocols; complete SRS annual review of protocols.
17	08	Tampa	P	2012	Remedial Actions: Revise IRB MOU; develop a system for alerting expiration of WOC appointments prior to renewal. CASE CLOSED.
18	01	VA Connecticut HCS	H	2012	Remedial Actions: Personnel to complete refresher Human Subjects Protection and Good Clinical Practice training. CASE CLOSED.
19	03	VA New York Harbor HCS	A	2012	Remedial Actions: Update on Heating, Ventilation and Air Conditioning in animal facility. CASE CLOSED
20	09	VA Tennessee Valley HCS	A	2012	Remedial Actions: Complete annual review of IACUC protocol; complete continuing review of SRS; ensure all training is complete. CASE CLOSED.
21	02	VA Western New York HCS	P	2012	Remedial Actions: Process Action Team formed to ensure appointment, credentialing and privileging for research personnel, revision of SOPs and local policies, 2011 annual reviews. CASE CLOSED.
22	01	VA Connecticut HCS	S	2013	Remedial Actions: Memorandum of Understanding with affiliate Institutional Biosafety Committee finalized; protocols reviewed and approved by IBC. CASE CLOSED.
23	11	Ann Arbor HCS	I	2013	Remedial Actions: One laptop identified as not having VA-approved encryption is now encrypted. CASE CLOSED
24	11	Ann Arbor HCS	H-R	2013	Remedial Actions: Clarification needed on following items: if ICD template is being fixed to address missing element; if facility reported to ORO lack of subject signatures on ICDs; if protocols terminated by the IRB were reported to ORO. CASE CLOSED.
25	07	Atlanta	S	2013	Remedial Actions: IBC review of protocols; SRS annual review. CASE CLOSED.
26	07	Augusta	S	2013	Remedial Actions: Facility must develop a plan for conducting annual drills to test the Safety, Security and Emergency Response/Preparedness Plans. CASE CLOSED.
27	08	Bay Pines	A	2013	Remedial Actions: Training program to be reviewed; SRS to review lapse in SRS annual review at next convened meeting. CASE CLOSED.
28	20	Boise VAMC	A	2013	Remedial Actions: Ensure IACUC annual review of protocols; review and update policies for SRS/RSSP and noncompliance reporting; ensure adequate resources and personnel.
29	20	Boise VAMC	H-R	2013	Remedial Actions: Revise reporting SOP. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
30	07	Charleston	S	2013	Remedial Actions: Perform reviews on protocols with lapses in SRS annual reviews. CASE CLOSED.
31	12	Chicago HCS	H-R	2013	Remedial Actions: Facility to provide clarification on study terminated by IRB; facility to clarify if all RDC only protocols required a continuing review. CASE CLOSED.
32	04	Clarksburg	H-R	2013	Remedial Actions: Error in data entry for item #s 21 and 22 revised by Facility with follow up by AD/RCEP; no additional RDC/HRPP action required. CASE CLOSED.
33	10	Cleveland	H-R	2013	Remedial Actions: All remedial actions to be addressed during 10/21/13-10/25/13 R&DC program routine review, CASE CLOSED.
34	07	Columbia	H-R	2013	Remedial Actions: No IRB review will occur until PO summary review and PO signature has been obtained. CASE CLOSED
35	15	Columbia	S	2013	Remedial Actions: Complete scopes of practices and required training; ensure SRS annual reviews of protocols. CASE CLOSED.
36	15	Columbia	H-R	2013	Remedial Actions: ORO to follow up on revised SOPs during the November 2013 R&DC Program and HRPP routine reviews. CASE CLOSED.
37	10	Dayton	H-R	2013	Remedial Actions: ORO to require facility RDC to conduct a complete review of the HRPP. CASE CLOSED
38	05	DC VAMC	A	2013	Remedial Actions: Fill administrative positions; complete MOU.
39	05	DC VAMC	H-R	2013	Remedial Actions: ICDs revised adding sponsor info, injury text PRN, staff training completed (one team member removed, two left VAMC). CASE CLOSED.
40	11	Detroit	H-R	2013	Remedial actions: RDC to complete annual review of HRPP that includes all required elements; facility to provide clarification on missing signatures from ICDs and why all RDC only protocols did not receive an annual continuing review. CASE CLOSED.
41	23	Fargo	H-R	2013	Remedial Actions: Facility provided R&DC summary report of the SRS committee. CASE CLOSED.
42	12 NE	Hines	E	2013	Remedial Actions: RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
43	16	Houston	H-R	2013	Remedial Actions: education; development of a single pdf document containing ICD and HIPAA; change language in renewal emails to PIs; adding a link to ISO/PO guidance and hired an analyst to assist with VA Board 4 workload. CASE CLOSED.
44	09	Huntington	H-R	2013	Remedial Actions: Facility RDC to provide clarification on why not all RDC only protocols required an annual continuing review; clarification provided that an error in reporting caused the discrepancy, all RDC only protocols did receive a CR; remedial actions complete, CASE CLOSED.
45	11	Indianapolis	S	2013	Remedial Actions: SRS continuing review documents must be completed by July 30, 2013 and will be reviewed at the August SRS meeting; Chemical Hygiene Officer position to be filled by mid-August and chemical inventories completed by November 30, 2013. CASE CLOSED.
46	11	Indianapolis	H-R	2013	Remedial Actions: Facility RDC to be reminded to complete the annual review of subcommittees in its entirety in 2014; facility to provide clarification if RCO audit findings were reported to ORO. RCO audits reported as required. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
47	16	Jackson	S	2013	Remedial Actions: Continue efforts to recruit SRS union representative. CASE CLOSED.
48	16	Jackson	H-R	2013	Remedial Actions: Recruit additional personnel to help with research service workload. CASE CLOSED.
49	09	Lexington	H-R	2013	Remedial Actions: Facility to provide clarification if RDC is following IRB exempt protocols; remedial actions complete, CASE CLOSED.
50	16	Central Arkansas VHS (Little Rock)	A	2013	Remedial Actions: Use IRBNet to facilitate notifications of annual reviews for IACUC and SRS protocols. CASE CLOSED.
51	16	Central Arkansas VHS (Little Rock)	H-R	2013	Remedial Actions: Revise SOPs and Medical Center Memorandums. CASE CLOSED.
52	09	Louisville	H-R	2013	Remedial Actions: ACOS/R to be sent reminder to complete respective annual review, CASE CLOSED.
53	12	Madison	H-R	2013	Remedial Actions: Facility to be reminded that ACOS/R annual reviews need to be completed; facility to be reminded that exempt protocols should be categorized as RDC only protocols. CASE CLOSED.
54	06	McGuire Veterans Affairs Medical Center	H-R	2013	Remedial Actions: All addressed in recent SRO onsite review report. CASE CLOSED
55	09	Memphis	A	2013	Remedial Actions: Complete scopes of practice for all personnel; complete training; renovations to VMU biocontainment area; ensure SRS continuing reviews are conducted at appropriate intervals. CASE CLOSED.
56	09	Memphis	A	2013	Remedial Actions: Review and document training; complete MOU signatures; complete occupational health and safety risk assessments for applicable personnel; update SOPs.
57	09	Memphis	I	2013	Remedial Actions: SOP revisions; referred to MWRO for follow-up. CASE CLOSED
58	09	Memphis	H-R	2013	Remedial Actions: All deficiencies identified will be addressed in the routine review report from the ORO onsite visit conducted in August 2013, CASE CLOSED.
59	12	Milwaukee	H-R	2013	Remedial Actions: ORO to provide facility with copy of Veterans Affairs CIRB annual review so facility's RDC can review it at a meeting. CASE CLOSED.
60	23	Minneapolis	S	2013	Remedial Actions: Update training records; ensure research safety activities reviewed prior to commencement. CASE CLOSED.
61	23	Minneapolis	I	2013	Remedial Actions: A risk based assessment for each laptop has been prepared and was provided to the CIO for review; attempts to encrypt the laptop are still underway; other actions pending.
62	09	Mountain Home	H-R	2013	Remedial Actions: None, RDC annual review deficiency was included as a RAP item in the July 2013 R&DC program routine review report. CASE CLOSED
63	16	Muskogee	H-R	2013	Remedial Actions: Clarify Program Status Hold; Clarify that a study requiring the USH authorization is being conducted at JCMVAMC; and Update MOUs.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
64	16	Muskogee	I	2013	Remedial Actions: Clarify Program Status Hold; clarify that a study requiring the USH authorization is being conducted at facility; and update MOUs. Due to non-response, ORO restricted human subject research until a functional and effective HRPP is in place.
65	03	Northport	A	2013	Remedial Actions: Due to facility non-response with SRO-identified issues, ORO restricted human subject research until a functional and effective HRPP is in place. ORO RISP granted an extension for response to this case to assist facility to work on their HRPP. CASE CLOSED.
66	16	Oklahoma City	H-R	2013	Remedial Actions: Assess Research Program at JCMVAMC and update Muskogee FWA. CASE CLOSED.
67	08	Orlando VAMC	E	2013	Remedial Actions: RCO support of program including coaching and educational needs assessment and resources. CASE CLOSED.
68	18	Phoenix VA HCS	S	2013	Remedial Actions: Both studies with a lapse in SRS annual review were closed. CASE CLOSED.
69	20	Portland VAMC	S	2013	Remedial Actions: Perform reviews on protocols with lapses in SRS annual reviews. CASE CLOSED.
70	20	Portland VAMC	H-R	2013	Remedial Actions: Provide clarification regarding 3 reported SAEs; ensure staff completes required research related training. CASE CLOSED.
71	11	Saginaw	H-R	2013	Remedial Actions: The R&DC is to provide a summary of the RSSP annual review to the MCD; summary was provided to the MCD; remedial actions complete. CASE CLOSED.
72	21	San Francisco VAMC	H-R	2013	Remedial Actions: Continue monitoring separation of VA from non-VA research under separate case. CASE CLOSED.
73	18	Southern Arizona VA HCS	S	2013	Remedial Actions: Lapsed or suspended SRS protocols and lapsed IACUC protocols were closed. CASE CLOSED.
74	15	St Louis	H-R	2013	Remedial Actions: ORO to provide copy of VA CIRB HRPP Annual Report so the facility's RDC can review it a meeting; CASE CLOSED.
75	08	Tampa	H-R	2013	Remedial Actions: The Research Service is tracking staff who are delinquent in CITI training. All members of the R&DC have fulfilled their research-specific training requirements. CASE CLOSED.
76	23	VA Black Hills HCS	H-R	2013	Remedial Actions: R&DC must conduct an annual review of the IRB.
77	17	VA Central Texas HCS	H-R	2013	Remedial Actions: Facility to monitor completion of refresher HRPP training. CASE CLOSED
78	01	VA Connecticut HCS	H	2013	Remedial Actions: Personnel to complete refresher Human Subjects Protection and Good Clinical Practice training. CASE CLOSED
79	01	VA Connecticut HCS	S	2013	Remedial Actions: Memorandum of Understanding with affiliate Institutional Biosafety Committee finalized; protocols reviewed and approved by IBC. CASE CLOSED.
80	19	VA Eastern Colorado HCS	H-R	2013	Remedial Actions: Minor deficiencies regarding training and scopes of practice were identified and are being managed locally. CASE CLOSED.
81	22	VA Greater Los Angeles HS	H-R	2013	Remedial Actions: R&DC conducted all required reviews. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
82	15	VA Kansas City Medical Center	A	2013	Remedial Actions: Update training requirements; ensure all staff are current with mandatory training. CASE CLOSED.
83	15	VA Kansas City Medical Center	H-R	2013	Remedial Actions: Facility to clarify if all SAEs and Serious Unanticipated Problems have been reported to ORO; facility to clarify if ICD deficiencies identified in RCO audits have been addressed. CASE CLOSED.
84	22	VA Loma Linda HS	S	2013	Remedial Actions: Update policies and plans. CASE CLOSED.
85	22	VA Loma Linda HS	H-R	2013	Remedial Actions: ORO to provide facility with copy of VA CIRB Annual Report for review by the RDC; ORO to provide reminder to facility that RDC must include review of subcommittee training as part of its annual review process. CASE CLOSED.
86	05	VA Maryland HCS	A	2013	Remedial Actions: Update scopes of practice; ensure SRS review at appropriate intervals; ensure adequate ACUP and RSSP resources; update SOPs. CASE CLOSED.
87	05	VA Maryland HCS	H-R	2013	Remedial Actions: Re-audit of 13 protocols due to audit discrepancy; re-audit completed, IRB reviewed two protocols with open findings re: missing ICD (N=1) and HIPAA (N=1), found non-serious, not continuing, approved using the data. CASE CLOSED.
88	03	VA New Jersey HCS	A	2013	Remedial Actions: Update training requirements. CASE CLOSED.
89	03	VA New Jersey HCS	H	2013	Remedial Action: Follow-up to an RCO Audit of a closed VA nurses electronic survey study received PI attestation that consent was obtained prior to participation; no action required. CASE CLOSED
90	17	VA North Texas HCS	S	2013	Remedial Actions: Ensure initial and continuing SRS, IBC and R&DC approvals as necessary; assess ACUP and RSSP program needs; ensure risk assessment and offer of participation in Occupational and Health and Safety Program. CASE CLOSED.
91	17	VA North Texas HCS	H-R	2013	Remedial Actions: Continue monitoring lack of research resources, training, and scopes of practice deficiencies. CASE CLOSED.
92	21	VA Northern California HCS	I	2013	FDC component closed. Unable to adequately assess RISP remotely. Will schedule future site review.
93	21	VA Northern California HCS	H-R	2013	Remedial Actions: IRB members must complete required refresher training. CASE CLOSED.
94	21	VA Palo Alto HCS	S	2013	Remedial Actions: Update personnel training records & SOPs. CASE CLOSED.
95	21	VA Palo Alto HCS	H-R	2013	Remedial Actions: Minor deficiencies with training, scopes of practice, and appointments are being corrected. CASE CLOSED
96	04	VA Pittsburgh HCS	A	2013	Remedial Actions: Revise SOPs; complete chemical inventories. CASE CLOSED.
97	20	VA Puget Sound HCS	H-R	2013	Remedial Actions: R&DC must submit summary reports of the annual reviews and evaluations of their subcommittees and research programs to the MCD. CASE CLOSED.
98	19	VA Salt Lake City HCS	H-R	2013	Remedial Actions: Under review.
99	17	VA South Texas HCS	S	2013	Remedial Actions: Update scopes of practice; ensure SRS continuing reviews are conducted at appropriate intervals. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
100	09	VA Tennessee Valley HCS	A	2013	Remedial Actions: Update procedure for reporting events to ORO. CASE CLOSED.
101	09	VA Tennessee Valley HCS	I	2013	Remedial Actions: SOP revisions; referred to MWRO for follow-up. CASE CLOSED
102	02	VA Western New York HCS	I	2013	Remedial Actions: The MCD concurred with the IRB software contract risk assessment completed by the CIO, ISO, and PO; the IRB software contract was modified to include security language. CASE CLOSED
103	02	VA Western New York HCS	H-R	2013	Remedial Actions: RDC complete annual evaluations of all RDC subcommittees, document submission to the MCD. CASE CLOSED.
104	01	White River Junction	S	2013	Remedial Actions: Conduct annual drills to test effectiveness of Research Safety, Security and Emergency Preparedness Plans; conduct annual multi-disciplinary vulnerability assessment. CASE CLOSED.

TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS

ORO remote technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Remote technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Summary

- 20 = Cases Continuing from Previous Calendar Year
- 64 = New Cases – January 1 through March 31
- 72 = New Cases – April 1 through June 30
- 162 = New Cases – July 1 through September 30
- 109 = New Cases – October 1 through December 31
- 407 = Total New Cases in Calendar Year
- 427 = Total Cases (Continuing Plus New) in Calendar Year

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
1	11	Battle Creek	E	07/05/2011	Technical Assistance: New RCO support program including coaching and education needs assessment and resources. CASE CLOSED.
2	11	Indianapolis	E	01/19/2012	MOU consultation and review. CASE CLOSED
3	22	VA Southern Nevada HS	E	02/03/2012	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
4	05	VA Maryland HCS	E	02/28/2012	MOU between facility and affiliate; consultation and review. Facility discussing MOU with its affiliate. CASE CLOSED.
5	07	Columbia	E	05/08/2012	New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
6	17	VA Central Texas HCS	E	05/25/2012	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
7	08	Orlando VAMC	E	06/06/2012	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
8	21	VA Sierra Nevada HCS	E	08/06/2012	Technical assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
9	17	VA South Texas HCS	E	09/24/2012	Technical Assistance: Evaluated and addressed auditing plan and progress on 2013 triennial human subjects' auditing requirements. CASE CLOSED.
10	05	DC VAMC	E	10/09/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, and RCO office. CASE CLOSED.
11	23	VA Black Hills HCS	E	10/17/2012	Technical Assistance: Evaluated and addressed auditing plan and progress on 2013 triennial human subjects' auditing requirements.
12	23	Fargo	E	10/22/2012	Technical assistance. New RCO support program including coaching and education through first 12 months.
13	23	Minneapolis	H	11/07/2012	VA-NSOC incident (PSET82059) transferred from RIPP to WRO. Unauthorized disclosure of III identified by IRB as neither serious nor continuing noncompliance; remedial actions - internal QA of IRB review process and additional training to study coordinators. CASE CLOSED
14	21	San Francisco VAMC	E	11/19/2012	Technical assistance. New RCO support program including coaching and educational needs assessment and resources.
15	01	Northampton	E	11/28/2012	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office.
16	02	Albany	E	12/06/2012	Technical Assistance: Reviewed audit plan, interpersonal communications with research program, decision support systems in research program, and progress towards audit goals. CASE CLOSED.
17	03	VA New York Harbor HCS	A	12/13/2012	Technical Assistance: Post hurricane Sandy operations. CASE CLOSED
18	18	New Mexico VA HCS	E	12/15/2012	MOU consultation and review. CASE CLOSED.
19	16	Gulf Coast HCS	E	12/27/2012	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
20	19	VA Salt Lake City HCS	E	12/28/2012	FWA modification approved, return of Director from detail. CASE CLOSED.
21	21	San Francisco VAMC	E	01/02/2013	Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
22	21	VA Pacific Islands HCS	E	01/03/2013	Technical Assistance: Reviewed audit plan, interpersonal communications and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
23	22	VA Loma Linda HS	E	01/03/2013	MOU consultation and review. CASE CLOSED.
24	12 NE	Hines	E	01/08/2013	IRB SOP Consultation. CASE CLOSED.
25	16	Gulf Coast HCS	E	01/08/2013	FWA modification approved. New Director. CASE CLOSED.
26	22	VA Loma Linda HS	E	01/10/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
27	01	White River Junction	E	01/14/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
28	04	Wilkes-Barre	E	01/14/2013	Notification of change in RCO. CASE CLOSED.
29	04	Wilkes-Barre	E	01/14/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
30	22	VA Southern Nevada HS	E	01/14/2013	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
31	07	Charleston	E	01/15/2013	Technical assistance; Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit plans. CASE CLOSED.
32	12 NE	James A. Lovell Federal Health Care Center	E	01/18/2013	Consultation and review for MOU between DOD and VA Boston, Palo Alto, and JALFHCC for a multi-site research protocol. CASE CLOSED.
33	15	Wichita	E	01/18/2013	FWA Modification approved. Interim Director. CASE CLOSED.
34	21	VA Pacific Islands HCS	E	01/18/2013	FWA modification approved. Acting Director. CASE CLOSED.
35	21	VA Pacific Islands HCS	E	01/18/2013	FWA modification approved. Acting Director. CASE CLOSED
36	02	Bath	E	01/23/2013	MOU Consultation and review. CASE CLOSED
37	02	Canandaigua	E	01/23/2013	MOU Consultation and review. CASE CLOSED
38	01	Togus	E	01/24/2013	Technical assistance: New RCO support program including coaching and educational needs assessment and resources (case reopened).
39	21	San Francisco VAMC	E	01/24/2013	FWA modification approved. Acting Medical Center Director. CASE CLOSED
40	23	Fargo	E	01/24/2013	New RCO. CASE CLOSED
41	16	Muskogee	E	01/30/2013	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
42	22	VA San Diego HS	I	01/30/2013	Facility RCO requested advise on two questions regarding disclosure of PHI to Sponsor's contract research office as authorized agent and whether this specific HIPAA Authorization for the study was valid for that purpose. CASE CLOSED.
43	01	Togus	E	01/31/2013	New part time RCO. CASE CLOSED
44	19	VA Eastern Colorado HCS	A	01/31/2013	Reviewed MOU for IACUC oversight at affiliate institution. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
45	01	White River Junction	E	02/01/2013	FWA modification approved. New Institutional Official. CASE CLOSED.
46	12	Chicago HCS	E	02/04/2013	MOU consultation and review. CASE CLOSED.
47	11	Saginaw	E	02/05/2013	FWA modification approved. Acting Director. CASE CLOSED.
48	03	Northport	A	02/06/2013	Technical Assistance: Reviewed MOU for IACUC oversight at affiliate institution. CASE CLOSED.
49	07	Birmingham	E	02/12/2013	FWA modification approved. Acting Director. CASE CLOSED
50	07	Tuscaloosa	E	02/12/2013	FWA modification approved. Acting Director. CASE CLOSED
51	12	Chicago HCS	E	02/12/2013	Technical Assistance: Reviewed audit plan, interpersonal communication, dynamics with research program, decision support systems in the research program and RCO office, and progress towards audit goals CASE CLOSED.
52	03	VA New York Harbor HCS	R	02/13/2013	Key issues addressed: R&DC meeting organization; SOP revisions; R&DC Agenda development; review of contingencies for study approvals. CASE CLOSED.
53	09	Huntington	A	02/13/2013	Reviewed MOU for IACUC oversight at affiliate institution. CASE CLOSED
54	16	Shreveport	E	02/13/2013	MOU consultation and review. CASE CLOSED
55	03	Bronx	A	02/15/2013	Reviewed MOU for IACUC oversight at affiliate institution. CASE CLOSED.
56	01	White River Junction	E	02/19/2013	Consultation and review for MOU between VA White River Junction and Dartmouth college. CASE CLOSED.
57	01	Togus	E	02/25/2013	FWA modification approved. Addition of Dartmouth College IRB. CASE CLOSED
58	04	Coatesville	H	02/25/2013	Requirements for use of VA Form 3203 for audio/video recording of research subjects in local site study (main site at collaborating VAMC). CASE CLOSED
59	09	Huntington	E	02/25/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals.
60	04	Coatesville	H	02/27/2013	RCO inquiry on requirements for VA study data collected at VA by local PI and removed from VA for analysis by a WOC appointed University researcher. Further PO and ISO review at site. CASE CLOSED.
61	01	Manchester	E	02/28/2013	Technical Assistance: Review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
62	07	Birmingham	E	02/28/2013	Technical Assistance: Review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
63	18	Southern Arizona VA HCS	E	02/28/2013	Technical Assistance: Review interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
64	01	White River Junction	E	03/01/2013	MOU consultation and review. CASE CLOSED.
65	07	Atlanta	E	03/01/2013	MOU consultation and review. CASE CLOSED.
66	03	VA New York Harbor HCS	H	03/05/2013	Recommendations: Increased efficiencies in expedited reviews for IR and CR; IRB administrative staff functions; documentation of controverted issues; status of students conducting research; management of lapsed CRs. CASE CLOSED.
67	05	VA Maryland HCS	E	03/05/2013	Technical Assistance: Reviewed audit plan, interpersonal communication, dynamics with research program, decision support systems in research program and RCO office, and progress towards goals. CASE CLOSED
68	16	Oklahoma City	E	03/07/2013	Consultation and review for MOU between VA and Oklahoma University. CASE CLOSED.
69	21	VA Sierra Nevada HCS	E	03/11/2013	IRB SOP consultation on local procedures for use of VHA Central Office IRB. CASE CLOSED.
70	12 NE	Hines	E	03/12/2013	IRB SOP consultation and review for Hines VAMC and James A Lovell FHCC. CASE CLOSED
71	12	Chicago HCS	E	03/13/2013	Standard Operating Procedures consultation and review for VAMC Jesse Brown. Local SOP for submission and conduct of VA research overseen by the VHA Central Office IRB. CASE CLOSED
72	06	McGuire Veterans Affairs Medical Center	E	03/19/2013	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
73	15	Wichita	E	03/19/2013	Technical assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
74	01	White River Junction	R	03/20/2013	Facility requested guidance in planning an off-site retreat. CASE CLOSED.
75	01	Manchester	E	03/21/2013	FWA modification approved. Acting Director. CASE CLOSED.
76	03	VA New York Harbor HCS	E	03/21/2013	FWA Renewal approved. CASE CLOSED.
77	06	Hampton	E	03/21/2013	FWA Renewal approved. CASE CLOSED.
78	07	Tuscaloosa	E	03/21/2013	FWA modification approved. Acting Director. CASE CLOSED.
79	10	Chillicothe	E	03/21/2013	FWA modification approved. New Director. CASE CLOSED.
80	23	Iowa City	E	03/21/2013	FWA modification approved. New Director. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
81	03	VA New York Harbor HCS	R	03/27/2013	Technical Assistance: Key issues addressed were enhancing information security and privacy; improved documentation in meeting minutes; avoiding potential conflict of interest in committee meetings. CASE CLOSED.
82	18	New Mexico VA HCS	E	03/27/2013	MOU consultation and review for VA New Mexico HCS and University New Mexico six-month amendment. CASE CLOSED.
83	01	Manchester	E	03/29/2013	FWA modification approved. New HRPP Administrator. CASE CLOSED.
84	07	Tuscaloosa	E	03/29/2013	FWA modification approved. New Director. CASE CLOSED.
85	22	VA San Diego HS	H	04/01/2013	Facility queried as to why study results have not been entered into the NIH www.clinicaltrials.gov. database as required by FDA. Investigator will enter study results. CASE CLOSED.
86	23	Minneapolis	H	04/01/2013	Facility queried as to why study results have not been entered into the NIH www.clinicaltrials.gov. database as required by FDA. Study results will be entered when the paper is published. CASE CLOSED.
87	16	New Orleans	E	04/09/2013	FWA modification approved to remove Jackson, MS as IRB of Record. CASE CLOSED
88	18	Southern Arizona VA HCS	E	04/09/2013	MOU consultation and review. CASE CLOSED
89	20	Portland VAMC	E	04/09/2013	FWA modification approved new signatory official. CASE CLOSED.
90	20	VA Puget Sound HCS	E	04/12/2013	FWA modification approved new signatory official. CASE CLOSED.
91	21	VA Central California HCS	E	04/15/2013	Technical assistance: New RCO support program including coaching and educational needs assessment and resources.
92	01	White River Junction	E	04/23/2013	MOU consultation and review. CASE CLOSED.
93	03	VA New York Harbor HCS	R	04/24/2013	Technical Assistance: Key issues addressed include annual assessments of R&DC and its subcommittees; management of expiring ICDs; protocol submission turnaround time and other quality metrics; attendance requirements for committee members; management of clinical trials with sponsors. CASE CLOSED.
94	09	Louisville	E	04/24/2013	MOU consultation and review. CASE CLOSED
95	09	Mountain Home	E	04/25/2013	RCEP Technical assistance: reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
96	05	Martinsburg VA Medical Center	E	04/29/2013	RCEP Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
97	01	Togus	E	04/30/2013	FWA modification approved new human protections administrator. CASE CLOSED.
98	02	Canandaigua	E	04/30/2013	MOU consultation and review. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
99	07	Birmingham	E	04/30/2013	FWA modification approved. CASE CLOSED.
100	06	W.G. (Bill) Hefner VA Medical Center	E	05/07/2013	RCEP Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
101	18	Southern Arizona VA HCS	S	05/07/2013	RSAW Technical Assistance: Advise facility IBC on proper constitution and operation in accordance with NIH Guidelines. CASE CLOSED.
102	12	Madison	E	05/09/2013	RCEP Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
103	01	Providence	A	05/17/2013	RSAW Technical Assistance: IACUC protocol review processes. CASE CLOSED.
104	03	Northport	E	05/17/2013	RCEP Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
105	03	VA New Jersey HCS	A	05/17/2013	RSAW Technical Assistance: IACUC protocol review processes. CASE CLOSED.
106	03	VA New Jersey HCS	A	05/17/2013	RSAW Technical Assistance: IACUC Annual Protocol Review Processes. CASE CLOSED.
107	08	Bay Pines	S	05/17/2013	RSAW Technical Assistance: RCO safety audit reporting requirements. CASE CLOSED.
108	01	White River Junction	S	05/20/2013	RSAW Technical Assistance: SRS Composition. CASE CLOSED.
109	03	VA New York Harbor HCS	R	05/20/2013	RDC Technical Assistance: RDC Agenda and assignments improved in comparison to prior meetings; some inattention to detail continues, new review templates in compliance with current requirements are in use. CASE CLOSED
110	04	Philadelphia	S	05/20/2013	RSAW Technical Assistance: Facility Security & Access Records. CASE CLOSED
111	04	VA Pittsburgh HCS	A	05/20/2013	RSAW Technical Assistance: ACORP Requirements. CASE CLOSED.
112	06	McGuire Veterans Affairs Medical Center	S	05/20/2013	RSAW Technical Assistance: Hazardous Chemicals. CASE CLOSED.
113	08	San Juan	S	05/20/2013	RSAW Technical Assistance: Safety Officer Qualifications & Responsibilities. CASE CLOSED.
114	06	McGuire Veterans Affairs Medical Center	A	05/23/2013	RSAE Technical Assistance: Controlled substances documentation. CASE CLOSED.
115	08	VA North Florida/ South Georgia HCS	S	05/23/2013	RSAW Technical Assistance: Reporting requirements. CLOSE CASE.
116	09	Mountain Home	S	05/23/2013	RSAW Technical Assistance: Nomination process for new and re-appointment of SRS members. CLOSE CASE.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
117	15	St Louis	S	05/23/2013	RSAW Technical Assistance: Select Agents and Toxins. CASE CLOSED.
118	15	VA Kansas City Medical Center	S	05/23/2013	RSAW Technical Assistance: Research exempt from SRS oversight; requirements and applicability of semiannual chemical inventories. CASE CLOSED.
119	11	Indianapolis	S	05/24/2013	RSAW Technical Assistance: IBC MOU. CASE CLOSED.
120	12	Madison	A	05/24/2013	RSAW Technical Assistance: IACUC composition. CASE CLOSED.
121	06	McGuire Veterans Affairs Medical Center	S	05/29/2013	RSAW Technical Assistance: Use of VA Form 10-0398 (Research Protocol Safety Survey). CASE CLOSED.
122	23	VA Nebraska/West Iowa HCS	E	05/29/2013	RCEP Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
123	04	VA Pittsburgh HCS	A	05/30/2013	RSAW Technical Assistance: IACUC review of ACORP. CASE CLOSED.
124	03	VA New Jersey HCS	S	06/03/2013	RSAW Technical Assistance: Chemical Inventory requirements. CASE CLOSED.
125	21	VA Pacific Islands HCS	E	06/03/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.
126	01	White River Junction	S	06/07/2013	RSAW Technical Assistance: Reporting requirements for external IBC. CASE CLOSED
127	01	Northampton	R	06/10/2013	Remote Technical Assistance provided to assist the R&DC with its oversight responsibilities for this new research program. CASE CLOSED
128	03	Northport	S	06/10/2013	RSAW Technical Assistance: Biosecurity training requirements. CASE CLOSED.
129	10	Cincinnati	A	06/10/2013	RSAW Technical Assistance: Reporting requirements for VA funded study at affiliate university. CASE CLOSED.
130	17	VA Central Texas HCS	S	06/10/2013	RSAW Technical Assistance: Reporting requirements. CASE CLOSED.
131	17	VA South Texas HCS	S	06/10/2013	Technical Assistance: SRS review of closed studies. CASE CLOSED.
132	08	Tampa	S	06/11/2013	RSAW Technical Assistance: Semiannual chemical inventory requirements. CASE CLOSED
133	09	Memphis	A	06/18/2013	RSAW Technical Assistance: Signatory on inter-institutional agreements. CASE CLOSED
134	10	Cincinnati	A	06/18/2013	RSAW Technical Assistance: OLAW reporting requirements. CASE CLOSED
135	11	Detroit	S	06/18/2013	RSAW Technical Assistance: IBC responsibilities. CASE CLOSED.
136	11	Indianapolis	A	06/20/2013	RSAW Technical Assistance: (OLAW) Reporting requirements for noncompliance involving an animal study at affiliate institution. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
137	06	McGuire Veterans Affairs Medical Center	S	06/21/2013	RSAW Technical Assistance: SRS and IBC Composition. CASE CLOSED.
138	01	White River Junction	S	06/24/2013	RSAW Technical Assistance: Reviewed draft IBC MOU for facility. CASE CLOSED.
139	03	Bronx	A	06/24/2013	RSAW Technical Assistance: Reviewed MOU for the affiliate IACUC. CASE CLOSED.
140	05	VA Maryland HCS	A	06/24/2013	RSAW Technical Assistance: Reviewed draft MOU for the affiliate IACUC. CASE CLOSED.
141	06	McGuire Veterans Affairs Medical Center	S	06/24/2013	RSAW Technical Assistance: SRS and IBC Composition. CASE CLOSED.
142	01	Bedford	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
143	01	Providence	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
144	04	VA Pittsburgh HCS	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
145	07	Charleston	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
146	08	Bay Pines	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
147	09	VA Tennessee Valley HCS	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
148	11	Ann Arbor HCS	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
149	17	VA North Texas HCS	A	06/25/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
150	05	DC VAMC	A	06/27/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
151	18	Southern Arizona VA HCS	A	06/27/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
152	22	VA San Diego HS	A	06/27/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
153	23	Minneapolis	A	06/27/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
154	23	VA Nebraska/West Iowa HCS	A	06/27/2013	RSAW Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED
155	03	VA New York Harbor HCS	S	06/28/2013	RSAW Technical Assistance: SRS Reporting, annual safety reviews and laboratory practices. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
156	15	St Louis	A	06/28/2013	RSAW Technical Assistance: Semi-annual program review/facility inspections. CASE CLOSED.
157	03	Bronx	A	07/01/2013	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
158	08	Miami	A	07/01/2013	Technical Assistance: Non-affiliated member of an IACUC. CASE CLOSED.
159	01	VA Boston Healthcare System	A	07/01/2013	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
160	04	Coatesville	E	07/02/2013	MOU consultation and review. CASE CLOSED
161	12	Milwaukee	S	07/02/2013	Technical Assistance: Information on chemical safety. CASE CLOSED.
162	11	Saginaw	S	07/02/2013	Technical Assistance: Information on chemical safety. CASE CLOSED.
163	06	Salem	S	07/02/2013	Technical Assistance: Information on chemical safety. CASE CLOSED.
164	23	Sioux Falls	S	07/02/2013	Technical Assistance: Information on chemical safety. CASE CLOSED.
165	01	VA Connecticut HCS	S	07/02/2013	Technical Assistance: Information on chemical safety. CASE CLOSED.
166	23	VA Nebraska/West Iowa HCS	E	07/02/2013	MOU consultation and review. CASE CLOSED
167	07	Columbia	S	07/03/2013	Technical Assistance: Template provided for drafting a research-specific Security Plan. CASE CLOSED
168	02	Canandaigua	S	07/05/2013	Technical Assistance: SRS Reporting. CASE CLOSED.
169	07	Columbia	S	07/05/2013	Technical Assistance: Information on chemical safety. CASE CLOSED
170	04	Philadelphia	A	07/05/2013	Technical Assistance: Reporting an unanticipated loss of animal life. CASE CLOSED.
171	02	Bath	E	07/08/2013	RCO Part Time Waiver Program: Follow-Up Survey. CASE CLOSED.
172	16	Shreveport	S	07/08/2013	Technical Assistance: Information on chemical safety. CASE CLOSED.
173	01	Togus	E	07/08/2013	RCO Part Time Waiver Program: Follow-Up Survey.
174	01	Manchester	E	07/08/2013	RCO Part Time Waiver Program: Follow-Up Survey. CASE CLOSED.
175	10	Columbus	E	07/09/2013	FWA modification approved - interim director. CASE CLOSED

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
176	04	Philadelphia	S	07/11/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
177	11	Indianapolis	E	07/15/2013	MOU consultation and review. CASE CLOSED.
178	03	VA New York Harbor HCS	A	07/15/2013	Technical Assistance: Animal Component of Research Protocol. CASE CLOSED
179	01	White River Junction	S	07/15/2013	Technical Assistance: Assisted with question regarding SRS Membership. CASE CLOSED
180	16	Central Arkansas VHS (Little Rock)	E	07/16/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.
181	04	VA Pittsburgh HCS	A	07/17/2013	Technical Assistance: Use of anesthetics. CASE CLOSED
182	04	VA Pittsburgh HCS	S	07/17/2013	Technical Assistance: Annual drills to test the effectiveness of various research specific plans. CASE CLOSED
183	20	VA Puget Sound HCS	A	07/17/2013	Technical Assistance: Reporting requirements. CASE CLOSED
184	06	Asheville	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
185	07	Augusta	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
186	12 NE	Hines	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
187	11	Indianapolis	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
188	08	Tampa	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
189	23	VA Nebraska/West Iowa HCS	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
190	01	White River Junction	S	07/19/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
191	07	Atlanta	S	07/22/2013	Technical Assistance: Assisted with question regarding FDC Reporting. CASE CLOSED
192	16	Jackson	S	07/22/2013	Technical Assistance: Assisted with question regarding expedited protocol reviews. CASE CLOSED
193	09	Memphis	E	07/24/2013	MOU consultation and review. CASE CLOSED
194	07	Charleston	A	07/25/2013	Technical Assistance: Reporting requirements to ORO related to IACUC oversight. CASE CLOSED.
195	15	Columbia	A	07/25/2013	Technical Assistance: Status of OLAW documentation. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
196	09	Mountain Home	S	07/25/2013	Technical Assistance: SRS membership related to appointment letters. CASE CLOSED.
197	18	New Mexico VA HCS	A	07/25/2013	Technical Assistance: Breeding protocol. CASE CLOSED.
198	07	Atlanta	S	07/26/2013	Technical Assistance: Reporting to ORO and ORD. CASE CLOSED.
199	09	Huntington	A	07/26/2013	Technical Assistance: Whistleblower Policy. CASE CLOSED.
200	03	VA New Jersey HCS	S	07/26/2013	Technical Assistance: Reporting noncompliance's pertaining to semi-annual chemical inventories. CASE CLOSED.
201	11	Detroit	E	07/30/2013	MOU consultation and review. CASE CLOSED.
202	07	Birmingham	S	08/06/2013	Technical Assistance: Use of an IBC. CASE CLOSED
203	07	Columbia	A	08/06/2013	Technical Assistance: IBC composition. CASE CLOSED.
204	09	Huntington	S	08/06/2013	Technical Assistance: Physical security of research labs. CASE CLOSED.
205	11	Indianapolis	S	08/06/2013	Technical Assistance: SRS annual reviews. CASE CLOSED
206	10	Cincinnati	A	08/09/2013	Technical Assistance: Animal study reviews. CASE CLOSED
207	04	Clarksburg	A	08/09/2013	Technical Assistance: MOU with affiliate. CASE CLOSED.
208	11	Detroit	A	08/09/2013	Technical Assistance: Animal study reviews. CASE CLOSED
209	03	VA New York Harbor HCS	H	08/12/2013	Recommendations: Alter local submission forms to ensure complete submissions, IRB Office timely preparation of minutes must improve, education for IRB and PIs regarding inclusion of non-Veterans. CASE CLOSED
210	05	Martinsburg VA Medical Center	E	08/13/2013	MOU consultation and review. CASE CLOSED.
211	15	Columbia	E	08/15/2013	FWA modification approved new institutional official. CASE CLOSED.
212	10	Columbus	E	08/15/2013	FWA modification approved new institutional official. CASE CLOSED.
213	23	Fargo	E	08/15/2013	FWA modification approved - new institutional official. CASE CLOSED.
214	16	Muskogee	E	08/15/2013	FWA modification approved new institutional official. CASE CLOSED.
215	17	VA Central Texas HCS	S	08/15/2013	Technical Assistance: Nanoparticles. CASE CLOSED .

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
216	03	VA New York Harbor HCS	M	08/16/2013	Technical Assistance: Applicable sections of VHA Handbook 1058.02 ("Research Misconduct"). CASE CLOSED.
217	07	Charleston	E	08/19/2013	Technical Assistance: Part Time RCO Waiver request.
218	16	Oklahoma City	E	08/19/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
219	16	Oklahoma City	M	08/21/2013	Technical Assistance: VHA Handbook 1058.02 - "Research Misconduct" (with an emphasis on the requirements pertaining to research misconduct Inquiries) and witness interviews. CASE CLOSED
220	11	Ann Arbor HCS	A	08/26/2013	Technical Assistance: Assisted with question regarding review and approval dates for one year continuation reviews. CASE CLOSED
221	15	St Louis	S	08/26/2013	Technical Assistance: Assisted with question regarding MOUs with affiliate institutions. CASE CLOSED
222	21	VA Sierra Nevada HCS	E	08/26/2013	FWA modification approved, new institutional official. CASE CLOSED.
223	11	Ann Arbor HCS	S	08/27/2013	Technical Assistance: Assisted with question regarding occupational health and safety programs. CASE CLOSED
224	06	Durham	S	08/27/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
225	16	Jackson	E	08/27/2013	MOU consultation and review. CASE CLOSED
226	06	McGuire Veterans Affairs Medical Center	A	08/27/2013	Technical Assistance: Assisted with question regarding IACUC composition. CASE CLOSED
227	15	St Louis	A	08/27/2013	Technical Assistance: Assisted with question regarding holding protocols. CASE CLOSED
228	22	VA San Diego HS	S	08/27/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
229	07	Charleston	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
230	12	Chicago HCS	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
231	07	Columbia	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
232	09	Mountain Home	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
233	02	Syracuse	E	08/28/2013	Technical Assistance: Review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
234	08	Tampa	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
235	17	VA Central Texas HCS	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
236	15	VA Kansas City Medical Center	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
237	06	W.G. (Bill) Hefner VA Medical Center	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study.
238	01	White River Junction	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study.
239	15	Columbia	E	08/30/2013	FWA modification approved, new human protections administrator. CASE CLOSED
240	10	Columbus	E	08/30/2013	FWA modification approved, new institutional official. CASE CLOSED.
241	12 NE	Hines	E	08/30/2013	FWA modification approved. CASE CLOSED
242	21	VA Central California HCS	E	09/02/2013	Technical Assistance: Review audit plan, interpersonal communication and dynamics withe research program, decision support systems in research program office, and progress towards audit goals. CASE CLOSED.
243	02	Albany	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
244	11	Ann Arbor HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
245	07	Atlanta	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
246	08	Bay Pines	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
247	01	Bedford	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
248	07	Birmingham	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
249	20	Boise VAMC	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
250	07	Charleston	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
251	12	Chicago HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
252	10	Cincinnati	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
253	11	Detroit	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
254	06	Durham	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
255	16	Houston	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
256	09	Huntington	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
257	23	Iowa City	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
258	09	Louisville	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
259	12	Madison	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
260	06	McGuire Veterans Affairs Medical Center	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
261	09	Mountain Home	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
262	18	New Mexico VA HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
263	16	Oklahoma City	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
264	20	Portland VAMC	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
265	01	Providence	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
266	21	San Francisco VAMC	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
267	01	VA Boston Healthcare System	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
268	19	VA Eastern Colorado HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
269	22	VA Long Beach HS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
270	05	VA Maryland HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
271	08	VA North Florida/ South Georgia HCS	E	09/03/2013	FWA modification approved. CASE CLOSED.
272	21	VA Palo Alto HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
273	19	VA Salt Lake City HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
274	09	VA Tennessee Valley HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
275	02	VA Western New York HCS	S	09/03/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
276	05	DC VAMC	S	09/04/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
277	16	Jackson	E	09/04/2013	MOU consultation and review. CASE CLOSED
278	18	Southern Arizona VA HCS	S	09/04/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
279	15	St Louis	S	09/04/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
280	17	VA Central Texas HCS	S	09/04/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
281	20	VA Puget Sound HCS	S	09/04/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
282	09	Louisville	A	09/05/2013	Technical Assistance: Assisted with question regarding pharmaceutical grade compounds. CASE CLOSED
283	22	VA Loma Linda HS	E	09/05/2013	FWA modification approved, new institutional official. CASE CLOSED
284	23	Iowa City	A	09/11/2013	Technical Assistance: ORO has requested that the facility continue to provide updates and information regarding the documentation for release. CASE CLOSED.
285	01	Togus	E	09/11/2013	MOU consultation and review. CASE CLOSED.
286	01	Manchester	E	09/11/2013	MOU consultation and review. CASE CLOSED.
287	18	Phoenix VA HCS	S	09/12/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
288	21	San Francisco VAMC	S	09/12/2013	Technical Assistance: Assisted with question regarding doxorubicin. CASE CLOSED
289	18	Southern Arizona VA HCS	S	09/12/2013	Reviewed draft MOU for the academic affiliate institution. CASE CLOSED.
290	15	VA Eastern Kansas HCS	E	09/12/2013	FWA modification approved, new institutional official. CASE CLOSED.
291	04	Coatesville	S	09/13/2013	Technical Assistance: Assisted with question regarding SRS annual reviews. CASE CLOSED
292	18	New Mexico VA HCS	A	09/13/2013	Technical Assistance: Assisted with question regarding triennial expiration date of an ACORP. CASE CLOSED.
293	07	Columbia	E	09/17/2013	FWA modification approved. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
294	09	Lexington	A	09/17/2013	Technical Assistance: IACUC Reporting. CASE CLOSED
295	22	VA Long Beach HS	E	09/17/2013	FWA modification approved. CASE CLOSED.
296	15	Columbia	E	09/18/2013	Technical Assistance: Review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
297	22	VA Long Beach HS	E	09/18/2013	FWA modification approved, new Institutional Official. CASE CLOSED.
298	01	Manchester	E	09/18/2013	FWA modification approved, new Institutional Official. CASE CLOSED.
299	08	Bay Pines	S	09/19/2013	Technical Assistance: SRS protocol review process. CASE CLOSED
300	15	Columbia	S	09/19/2013	Technical Assistance: SRS annual reviews and reporting requirements. CASE CLOSED
301	10	Cleveland	E	09/25/2013	MOU, FWA, IRB Registration Consultation and review. CASE CLOSED.
302	03	Bronx	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
303	15	Columbia	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
304	09	Lexington	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
305	16	Central Arkansas VHS (Little Rock)	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
306	09	Memphis	S	09/26/2013	Technical Assistance: Assisted with question regarding safety and health hazards of animal handling. CASE CLOSED
307	08	Miami	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
308	23	Minneapolis	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
309	15	St Louis	A	09/26/2013	Technical Assistance: Assisted with question regarding triennial reviews. CASE CLOSED
310	22	VA Greater Los Angeles HS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
311	15	VA Kansas City Medical Center	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
312	22	VA Loma Linda HS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
313	03	VA New Jersey HCS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
314	08	VA North Florida/ South Georgia HCS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
315	04	VA Pittsburgh HCS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
316	22	VA San Diego HS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
317	17	VA South Texas HCS	S	09/26/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
318	02	Syracuse	E	09/27/2013	FWA modification approved, new institutional official. CASE CLOSED
319	02	Syracuse	E	10/01/2013	MOU consultation and review. CASE CLOSED
320	03	VA New York Harbor HCS	H	10/07/2013	Recommendations: IRB review enrollment figures and targets for accuracy; expedited review category checklist; IRB staff ensure final draft minutes available for review for IRB approval. CASE CLOSED
321	03	Bronx	E	10/11/2013	Technical Assistance will review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office, and progress towards audit goals.
322	21	VA Central California HCS	E	10/15/2013	MOU consultation and review. CASE CLOSED
323	19	VA Eastern Colorado HCS	E	10/15/2013	MOU consultation and review. CASE CLOSED
324	03	Bronx	E	10/18/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office, and progress towards audit goals. CASE CLOSED
325	05	DC VAMC	H	10/20/2013	Technical Assistance: Observed DCVAMC IRB convened board meetings (via teleconference). Recommended re-reviewing minimal risk determination of clinical trial involving sham surgery, requested copy of root cause analysis for TempTrak "excursion." Case closed 11.4.13
326	08	Bay Pines	A	10/21/2013	Technical Assistance: Management of conflicts of interest. CASE CLOSED
327	11	Indianapolis	S	10/21/2013	Technical Assistance: Question related to lab security. CASE CLOSED
328	16	Jackson	S	10/21/2013	Technical Assistance: NIH guide on the use of recombinant and synthetic nucleic acids. CASE CLOSED
329	17	VA Central Texas HCS	A	10/21/2013	Technical Assistance: VA applications vs. Animal Use Protocol/Proposal and ACORPs. CASE CLOSED
330	03	VA New Jersey HCS	A	10/21/2013	Technical Assistance: FOIA Requests for IACUC Minutes. CASE CLOSED
331	03	VA New Jersey HCS	A	10/21/2013	Technical Assistance: Research scope of practice. CASE CLOSED

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
332	09	VA Tennessee Valley HCS	S	10/21/2013	Technical Assistance: Lapse in approval. CASE CLOSED
333	12	Chicago HCS	S	10/22/2013	Technical Assistance: Review cycle for safety protocols. CASE CLOSED
334	01	Providence	S	10/22/2013	Technical Assistance: Enforcing local policies at another institution. CASE CLOSED
335	17	VA Central Texas HCS	A	10/22/2013	Technical Assistance: Correct timing for a PI to close an animal or science study. CASE CLOSED
336	17	VA Central Texas HCS	S	10/22/2013	Technical Assistance: Lab decommissioning. CASE CLOSED
337	15	Columbia	E	10/23/2013	MOU consultation and review. CASE CLOSED
338	09	Lexington	E	10/24/2013	FWA modification approved, new signatory official. CASE CLOSED
339	04	Philadelphia	E	10/24/2013	FWA modification approved, interim signatory official. CASE CLOSED
340	00	VA Central Office	E	10/24/2013	FWA modification approved, change of Human Protections Administrator. CASE CLOSED
341	17	VA Central Texas HCS	E	10/24/2013	FWA modification approved, new signatory official. CASE CLOSED
342	19	VA Eastern Colorado HCS	E	10/24/2013	FWA renewal approved. CASE CLOSED
343	15	Columbia	E	10/28/2013	MOU consultation and review. CASE CLOSED
344	01	Togus VA Medical and Regional Office Center	E	10/29/2013	IRB SOP Review. CASE CLOSED
345	16	Gulf Coast HCS	E	11/01/2013	FWA modification approved, remove Jackson, MS IRB from FWA. CASE CLOSED
346	11	Indianapolis	A	11/01/2013	Technical Assistance: Transfer of electronic data. CASE CLOSED.
347	09	Lexington	A	11/01/2013	Technical Assistance: Training requirements. CASE CLOSED
348	09	Lexington	E	11/01/2013	FWA modification approved, new signatory official. CASE CLOSED
349	16	Little Rock	S	11/01/2013	Technical Assistance - Reporting requirements. CASE CLOSED.
350	09	Memphis	E	11/01/2013	FWA modification approved, new signatory official. CASE CLOSED
351	18	New Mexico VA HCS	S	11/01/2013	Technical Assistance: RCO audit reporting. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
352	18	Phoenix VA HCS	S	11/01/2013	Technical Assistance: 10-0398 Protocol signatures and approval dates. CASE CLOSED.
353	15	St Louis	S	11/01/2013	Technical Assistance: Laboratory inspections. CASE CLOSED.
354	15	St Louis	S	11/01/2013	Technical Assistance: registration of affiliate IBC. CASE CLOSED.
355	01	VA Connecticut HCS	E	11/01/2013	FWA modification approved, new signatory official. CASE CLOSED
356	21	VA Pacific Islands HCS	E	11/01/2013	FWA modification approved, new signatory official. CASE CLOSED
357	22	VA San Diego HS	E	11/01/2013	FWA modification approved, remove UCSD IRB from FWA. CASE CLOSED
358	16	Jackson	S	11/04/2013	Technical Assistance: NIH Guidelines for use recombinant and synthetic nucleic acids. CASE CLOSED
359	08	Tampa	A	11/04/2013	Technical Assistance: Training requirements. CASE CLOSED
360	03	VA New York Harbor HCS	H	11/04/2013	Recommendations: IRB review of data repositories with guidance from HB 1200.15; Initial Reviews of international review CRADO approvals; IRB determinations of protocol deviations involving over enrollment; IRB education re: special protections for populations covered by 7332 USC. CASE CLOSED
361	10	Cleveland	S	11/05/2013	Technical Assistance: Organization of the IBC as an advisory committee to the SRS. CASE CLOSED
362	08	VA North Florida/ South Georgia HCS	E	11/05/2013	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
363	21	San Francisco VAMC	E	11/06/2013	FWA modification approved. New signatory official. CASE CLOSED
364	17	VA Central Texas HCS	E	11/06/2013	MOU review and consultation CASE CLOSED
365	15	Wichita	E	11/06/2013	MOU consultation and review CASE CLOSED
366	04	Coatesville	S	11/08/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
367	10	Dayton	S	11/08/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
368	23	Fargo	S	11/08/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
369	21	VA Central California HCS	S	11/08/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
370	21	VA Northern California HCS	S	11/08/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
371	01	Manchester	S	11/08/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
372	16	New Orleans	S	11/12/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
373	03	VA New York Harbor HCS	S	11/12/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
374	21	VA Sierra Nevada HCS	S	11/12/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
375	01	Togus VA Medical and Regional Office Center	S	11/13/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
376	08	VA North Florida/ South Georgia HCS	E	11/13/2013	MOU consultation and review. CASE CLOSED
377	06	W.G. (Bill) Hefner VA Medical Center	S	11/13/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
378	04	Coatesville	E	11/15/2013	FWA modification approved. New signatory official. CASE CLOSED
379	08	Orlando VAMC	S	11/15/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
380	08	San Juan	S	11/15/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
381	15	St Louis	E	11/15/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
382	22	VA Long Beach HS	E	11/15/2013	FWA modification approved. New signatory official. CASE CLOSED
383	04	Wilkes-Barre	S	11/15/2013	Technical Assistance: Provided information on chemical safety. CASE CLOSED
384	23	VA Nebraska/West Iowa HCS	E	11/18/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.
385	04	Philadelphia	E	11/19/2013	FWA modification approved. New signatory official. CASE CLOSED
386	23	VA Nebraska/West Iowa HCS	E	11/19/2013	CASE CLOSED
387	16	Gulf Coast HCS	E	11/20/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.
388	16	New Orleans	E	11/20/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
389	16	Oklahoma City	E	11/20/2013	MOU consultation and review. CASE CLOSED
390	19	VA Eastern Colorado HCS	E	11/20/2013	MOU consultation and review. CASE CLOSED
391	03	Bronx	E	11/21/2013	MOU consultation and review. CASE CLOSED
392	16	New Orleans	E	11/21/2013	CASE CLOSED
393	03	Bronx	E	11/22/2013	MOU consultation and review. CASE CLOSED
394	01	VA Connecticut HCS	E	11/22/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
395	16	Shreveport	E	11/26/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals.
396	07	Augusta	E	12/03/2013	FWA modification approved. New signatory official. CASE CLOSED
397	06	Salem	E	12/03/2013	Technical assistance: New RCO support program including coaching and educational needs assessment and resources.
398	03	VA New York Harbor HCS	H	12/04/2013	Technical Assistance: IRB reviewer education; consenting of subjects for blood draws and analysis. CASE CLOSED
399	15	Columbia	E	12/05/2013	MOU consultation and review. CASE CLOSED
400	11	Detroit	M	12/05/2013	Technical Assistance: VHA Handbook 1058.02 - "Research Misconduct" (with an emphasis on the requirements pertaining to research misconduct Inquiries); and conducting witness interviews. CASE CLOSED.
401	09	Memphis	H	12/08/2013	Monitor additional IRB meetings; QA of lapsed studies; process to ensure data collected during lapse is not used; increased support for IRB Chair. Case may remain open until Follow-up Onsite Review April 2014.
402	16	Muskogee	E	12/10/2013	MOU consultation and review. CASE CLOSED
403	23	VA Black Hills HCS	H	12/10/2013	Provided information concerning required Central Office notifications, and the establishment of documents reflecting closure of the research program.
404	04	VA Pittsburgh HCS	A	12/11/2013	Technical Assistance: Provided information regarding expiration dates for compounded drugs. CASE CLOSED.
405	07	Atlanta	S	12/13/2013	Technical Assistance: Question regarding dispensing controlled drugs. CASE CLOSED.
406	09	Lexington	A	12/13/2013	Technical Assistance: Question regarding dispensing controlled drugs. CASE CLOSED.
407	08	Miami	A	12/13/2013	Technical Assistance: Assisted facility with question regarding protocol continuing review requirements. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
408	23	Minneapolis	A	12/13/2013	Technical Assistance: Question regarding research oversight. CASE CLOSED.
409	08	San Juan	S	12/13/2013	Technical Assistance: Question regarding SRS oversight. CASE CLOSED.
410	23	Sioux Falls	A	12/13/2013	Technical Assistance: Assisted facility with question regarding storage of animal research data. CASE CLOSED.
411	15	VA Kansas City Medical Center	S	12/13/2013	Technical Assistance: Question regarding weekly access records review. CASE CLOSED.
412	05	VA Maryland HCS	A	12/13/2013	Technical Assistance: Question regarding submission of noncompliance reports. CASE CLOSED.
413	04	VA Pittsburgh HCS	S	12/13/2013	Technical Assistance: Question regarding reporting requirements. CASE CLOSED.
414	21	VA Sierra Nevada HCS	S	12/13/2013	Technical Assistance: Assisted facility with question regarding IBC composition and appointments. CASE CLOSED.
415	21	VA Sierra Nevada HCS	S	12/13/2013	Technical Assistance: SRS and IBC meeting and training requirements. CASE CLOSED.
416	16	Oklahoma City	E	12/16/2013	MOU consultation and review. CASE CLOSED
417	18	New Mexico VA HCS	H	12/18/2013	Technical Assistance: Facility planning creation of a local IRB; provided information concerning timelines and required steps before implementation.
418	03	Bronx	S	12/19/2013	Technical Assistance: Provided information on training requirements. CASE CLOSED
419	07	Columbia	E	12/19/2013	FWA modification approved. New signatory official. CASE CLOSED
420	01	Providence	E	12/19/2013	FWA modification approved. New signatory official. CASE CLOSED
421	04	Wilkes-Barre	E	12/19/2013	FWA modification approved. New signatory official. CASE CLOSED
422	15	St Louis	E	12/23/2013	MOU consultation and review. CASE CLOSED
423	09	Memphis	A	12/24/2013	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
424	18	New Mexico VA HCS	A	12/24/2013	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
425	02	Syracuse	A	12/24/2013	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
426	22	VA Greater Los Angeles HS	A	12/24/2013	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
427	08	Miami	S	12/30/2013	Technical Assistance: Question regarding reporting lapses for studies overseen by SRS. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

VA requires that unanticipated serious adverse events (SAEs) in research be reported to, and rapidly reviewed by, the responsible the Institutional Review Board (IRB). Reporting to ORO is required for unanticipated deaths and other unanticipated SAEs that the IRB judges to be caused by, or probably caused by, the research. ORO uses these reports to review local SAE management and assist facilities in improving their research programs.

Summary

- 4 = Cases Continuing from Previous Calendar Year
- 5 = New Cases – January 1 through March 31
- 8 = New Cases – April 1 through June 30
- 2 = New Cases – July 1 through September 30
- 6 = New Cases – October 1 through December 31
- 21 = Total New Cases in Calendar Year
- 25 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
1	17	VA North Texas HCS	04/13/2012	A subject in an industry sponsored drug study for acute coronary syndrome who did not meet enrollment criteria was administered study drug, and developed hemorrhagic shock, cardiac arrest and renal failure.	Required Actions: Suspension of enrollment; Development of action plan to prevent recurrence and procedure for review of high-risk studies; IRB re-review of PI's studies completed; resolution pending PI acceptance of IRB oversight plan. CASE CLOSED.
2	08	Tampa	08/19/2012	A subject enrolled in the Service Dogs for Veterans with PTSD study reported that the dog he was paired with was sick at time of pairing and has remained sick. This may increase the risk to subject.	Remedial Actions: VA has suspended additional pairings of Veterans with service dogs from this vendor. IRB determined the event was serious, related, unanticipated, and increased risk to subject. The study is still under administrative hold for new pairings and active in follow-up of the current pairings, so that the pairings to date (N=16) will be followed according to protocol. The study is being re-designed using a CSP model. The Principal Investigator (PI) will become the study main PI and a new local site investigator will be named for the Tampa study. CASE CLOSED
3	20	Portland VAMC	10/29/2012	Preliminary report to ORO of a reportable Adverse Event (anxiety and PTSD symptoms) in a PTSD and mindful meditation study.	AE determined to have been serious, unanticipated, and study related. ICD was revised. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
4	15	VA Kansas City Medical Center	12/03/2012	Subject in study of combined donepezil and selegiline effects on cocaine reinforced behavior passed out for 5 minutes following IV dose of donepezil and cocaine. PI waiting results of cardiac echo and chest CT.	Remedial actions: Study placed on full clinical hold by FDA due to safety concerns; PI submitted proposed study changes to FDA; FDA approved changes and lifted clinical hold; CASE CLOSED
5	03	Bronx	02/01/2013	SAE (dizziness, lethargy, and sinus bradycardia) reported on CSP-sponsored randomized clinical trial of Mifepristone for PTSD.	IRB and DMC required further medical evaluation, revised protocol to add ECG screening and 48 hour follow-up monitoring, intense monitoring & analysis of subsequent events, and revised ICD to clarify risks and new procedures. CASE CLOSED.
6	15	VA Kansas City Medical Center	02/06/2013	Adverse event oversight of a human subjects protocol in which there may have been an IRB member with a conflict of interest who did not recuse during the discussion and vote on a reported serious event. Re-review by IRB determined it to be a serious, unanticipated, related problem.	Remedial actions: Education of IRB on conflict of interest. Also, whenever a research subject is admitted to the hospital, a pharmacist will do an initial assessment to determine if additional steps are required. Performance and Patient Care Improvement committee will then review the event. CASE CLOSED.
7	11	Indianapolis	03/01/2013	Adverse event in a study of Chlorthalidone Among Patients with Resistant Hypertension and CKD Event. Subject hospitalization for mild syncope and hypotension.	Subject hospitalization for mild syncope and hypotension. Determined by reviewer to be Serious, Unanticipated, and possibly related. Study drug discontinued. CASE CLOSED.
8	00	VA Central Office	03/15/2013	A participant in CSP 577, a study of colorectal screening methods, fainted and was hospitalized and treated for dehydration after taking a bowel-cleansing prep for colonoscopy. The subject recovered and was discharged.	The VA Central IRB determined that the adverse event was serious, unanticipated and probably related to the research. The IRB did not require any remedial actions. CASE CLOSED.
9	18	New Mexico VA HCS	03/15/2013	External SAE report of a new risk involving slowness of heart rate in schizophrenia study.	An initial expedited review determined that the information was serious, unanticipated, and related to the research. Review by convened IRB determined serious, unanticipated, but unrelated. CASE CLOSED.
10	17	VA South Texas HCS	04/02/2013	Facility reported that based on the Data Safety Monitoring Program the Sponsor modified the protocol involving lymphoma to exclude subjects over 65 years of age; all local subjects are less than 65 years of age and are still living.	Remedial Actions: Investigator excluded enrolling subjects over 65 years of age immediately; protocol was modified; local reporting policies revised. CASE CLOSED.
11	23	Minneapolis	04/02/2013	A participant in a study of colorectal screening methods, fainted and was hospitalized and treated for dehydration after taking a bowel-cleansing prep. The subject recovered and was discharged.	The IRB determined that the adverse event was serious, unanticipated, and probably research related. CASE CLOSED.
12	20	VA Puget Sound HCS	04/19/2013	48 hour notification of an SAE (not a subject death)	The IRB determined that the SAE was not related to the investigational part of the protocol. CASE CLOSED.
13	00	VA Central Office	05/02/2013	A participant in a study on reducing colorectal cancer mortality developed an incarcerated hernia during colonoscopy, requiring immediate surgery. The patient recovered.	Remedial actions: The VA Central IRB determined that this was a rare event and that no changes are required in the informed consent document for the study. There was no further action required by the VA Central IRB. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
14	11	Ann Arbor HCS	05/12/2013	Study participant with previously diagnosed inguinal hernia that was exacerbated during the study colonoscopy procedure resulting in participant having surgery for hernia repair.	VA Central IRB Primary Reviewer determined that the event was unanticipated, serious, and related to the research. In consultation with experts in this field, it was determined that no changes to the informed consent or modification to the inclusion criteria are required based on this event due to the rarity of its occurrence. CASE CLOSED.
15	00	VA Central Office	05/29/2013	A participant in a study of treatment for depression took twice the prescribed dose of an antidepressant and developed flailing behavior requiring hospitalization. Subsequently he had no memory of the events leading to hospitalization.	Remedial Actions: Study medication was discontinued. The incident was determined by the IRB to be possibly related to the research. CASE CLOSED.
16	22	VA Greater Los Angeles HS	05/29/2013	Serious Adverse Event -- not local. The Sponsor made the determination to discontinue study drug, subject participation, and suspend the study.	Remedial Actions: Local PI notified IRB; notified subjects; all information noted in subjects' electronic medical record. CASE CLOSED.
17	**07**	**Charleston**	**06/07/2013**	**Subject death on a treatment study for drug relapse prevention in patients with substance use disorder and PTSD.**	**Cause of death was cardiovascular collapse, metabolic acidosis and bowel ischemia. Subject had hypertension and strong family history of cardiac events prior to joining the study; IRB determined that the death was serious and unanticipated but NOT RELATED TO OR CAUSED BY the research. Study exclusion criteria revised as a future precaution. CASE CLOSED.**
18	05	VA Maryland HCS	08/13/2013	Participant was injured (bruised scrotum) by harness used in balance enhancement/falls prevention study.	Remedial Actions: Team met to discuss event and corrective actions; Reported to DSMB; participant withdrew from the study; notified OHRP and NIA; IRB requested a revised ICD to reflect new risk, documentation of report to DSMB, and urologist's note from the participant. CASE CLOSED.
19	**15**	**VA Kansas City Medical Center**	**09/17/2013**	**Adverse event report from CSP regarding a suicide death in a subject enrolled in CSP 576.**	**IRB review determined that the death was serious and unanticipated but NOT RELATED TO OR CAUSED BY the research. CASE CLOSED.**
20	21	VA Palo Alto HCS	10/02/2013	Vascular surgical patient (at another study site) who received a research surgery adhesive developed an inflammation of pus in the liver area requiring hospitalization.	FDA identified possible relationship to the research but did not recommend protocol changes. CASE CLOSED
21	**11**	**Indianapolis**	**10/22/2013**	**SAE death (cardiovascular) in an unfunded kidney disease study reported by the IRB. IRB reviewer determined death was serious, unanticipated, and possibly related to the research. IRB reviewer did not see an immediate harm to other subjects.**	**Convened IRB determined that the death was not caused by the research. CASE CLOSED.**
22	**16**	**Central Arkansas VHS (Little Rock)**	10/25/2013	Facility reported subject death in a phase IIIb study on peripheral artery disease. Cause of death unknown at this time.	IRB determination pending receipt of additional information including the autopsy report or the death certificate.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
23	15	VA Kansas City Medical Center	11/24/2013	Subject admitted to VAMC with hypotension after beginning study treatment on the lowest dose of treatment in this diabetes and acute coronary syndrome event study.	IRB determined SAE was not related to the study. CASE CLOSED.
24	**22**	**VA Loma Linda HS**	**12/06/2013**	**Subject died in an industry sponsored diabetes study. Cause of death was ischemic cardiomyopathy and atherosclerotic heart disease. IRB determined event is serious, possibly anticipated, and possibly related.**	**IRB determination pending receipt of additional information.**
25	15	VA Kansas City Medical Center	12/20/2013	Subject on study drug developed hemolytic anemia requiring hospitalization. The SAE reviewer assessed as possibly related to the study treatment.	IRB determination pending receipt of additional information.

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

ORO monitors all reported cases of alleged research misconduct (i.e., fabrication, falsification, or plagiarism) that involve VA research. ORO ensures that correct procedures are used by each facility's Inquiry and Investigation Committees and provides guidance as needed. ORO determines when notification of various VA offices and federal agencies must be given and facilitates coordination. In certain cases, ORO may perform onsite technical visits to provide assistance.

* NOTE: Because of the need to follow strict federal Inquiry, Investigation, and Adjudication procedures for research misconduct, and because of the range of consequences for research misconduct and debarment, such cases may take months or years to resolve. In addition, the resolution of some cases is delayed because they are also under the jurisdiction of the VA Office of Inspector General (OIG), the Department of Health and Human Services (HHS) Office of Research Integrity, the Food and Drug Administration (FDA), and/or a university affiliate.

Summary

- 6 = Cases Continuing from Previous Calendar Year
- 0 = New Cases – January 1 through March 31
- 2 = New Cases – April 1 through June 30
- 4 = New Cases – July 1 through September 30
- 1 = New Cases – October 1 through December 31
- 7 = Total Cases (Continuing Plus New) in Calendar Year
- 13 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
1	03	VA New York Harbor HCS	04/13/2010	Research misconduct allegations involving fabrication and falsification.	Status: The VISN Director's adjudication of the case was completed, and resulted in findings of research misconduct and recommendations for corrective actions; the Respondent was notified of the outcome of the adjudication and did not file an appeal. CASE CLOSED.
2	02	Syracuse	04/29/2010	Research misconduct allegation involving fabrication and falsification.	Status: VISN adjudication resulted in findings of research misconduct; an appeal was submitted and the USH's decision on the appeal is pending.
3	11	Detroit	03/30/2012	Research misconduct allegations involving falsification.	Status: The acting VISN Director adjudicated the case and made findings of research misconduct; an appeal was submitted and the USH's decision on the appeal is pending.
4	18	Phoenix VA HCS	06/15/2012	Research misconduct allegation involving fabrication.	Status: The VISN Director adjudicated the case and made findings of research misconduct; an appeal was not filed and the case was closed with the findings and corrective actions standing. CASE CLOSED.

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
5	22	VA Greater Los Angeles HS	11/07/2012	Research misconduct allegation involving fabrication and/or falsification.	Status: An Inquiry determined that there was insufficient evidence to proceed with an Investigation, and the MCD concurred with the determination. CASE CLOSED.
6	07	Birmingham	11/09/2012	Research misconduct allegation involving falsification.	Status: Inquiry convened.
7	03	VA New York Harbor HCS	05/31/2013	Research misconduct allegation involving falsification.	Status: Investigation pending.
8	16	Oklahoma City	06/11/2013	Research misconduct allegation involving falsification.	Status: Threshold assessment of allegations completed; Inquiry pending.
9	01	VA Boston Healthcare System	08/01/2013	Research misconduct allegation involving fabrication and/or falsification.	Status: Inquiry convened.
10	05	VA Maryland HCS	08/19/2013	Research misconduct allegation involving falsification.	Status: The RIO determined that the minimal threshold requirements for opening a research misconduct Inquiry were not met. CASE CLOSED.
11	11	Detroit	08/29/2013	Research misconduct allegations involving fabrication and falsification.	Status: Inquiry convened.
12	02	Albany	09/27/2013	Research misconduct allegations involving falsification.	Status: An Inquiry Committee determined that there was insufficient evidence to warrant opening a research misconduct Investigation. CASE CLOSED.
13	19	VA Eastern Colorado HCS	11/18/2013	Allegation involving an authorship dispute.	Status: The RIO determined that the allegation involved an authorship dispute and did not involve plagiarism. CASE CLOSED

TABLE 3. ACRONYMS

A = Animal Care and Use Program Focus
AAALAC = Association for Assessment and Accreditation of Laboratory Animal Care International
AAHRPP = Association for Accreditation of Human Research Protection Programs
ACORP = Animal Component of Research Protocol
ACOS/R = Associate Chief of Staff for Research
ACUP = Animal Care and Use Program
AIB = Administrative Investigation Board
ANSI = American National Standards Institute
AO/R = Administrative Officer for Research
ARF = Animal Research Facility
AWA = Animal Welfare Act
AWR = Animal Welfare Regulations

BSC = Biosafety Cabinet
BSL-3 = Biosafety Level 3

CAP = Corrective Action Plan
CC = Case Closed
CIO = Chief Information Officer
CIRB = Central Institutional Review Board (ORD)
CITI = Collaborative Institutional Training Initiative
CO = ORO Central Office
COI = Conflict of Interest
CoPI = Co-Principal Investigator
COS = Chief of Staff
CPRS = VHA Computerized Patient Record System
CR = Continuing Review
CRADA = Cooperative Research & Development Agreement
CRADO = VHA Chief Research & Development Officer
CRC = Clinical Research Coordinator
CSP = VHA Cooperative Studies Program
CT = Computerized Tomography (Scan)
CVMO = ORD Chief Veterinary Medical Officer

DMC / DSMB = Data Monitoring Committee / Data and Safety Monitoring Board
DMR = Designated Member Review
DoD = Department of Defense
DTA = Data Transfer Agreement
DUA = Data Use Agreement

E = Research Compliance Officer Education Focus
ECOG = Eastern Cooperative Oncology Group
EIL = Equipment Inventory List
EOC – Environment of Care
ESCCB = Enterprise Security Change Control Board

FCD = Facility Center Director
FCR = Full Committee Review
FDA = Food and Drug Administration
FDC = Facility Director Certification
FIPS = Federal Information Processing Standards
FISMA = Federal Information Security Management Act
FOIA = Freedom of Information Act
FTE/FTEE = Full Time Employee/Equivalent

GFE = Government Furnished Equipment
GFI = Ground Fault Interrupter

H = Human Research Protection Focus
HCS = Health Care System
HHS = Department of Health and Human Services
HIPAA = Health Insurance Portability & Accountability Act
HRPP = Human Research Protection Program
HSR&D = Health Services Research and Development
HVAC = Heating, Ventilation and Air Conditioning

I = Information Security Focus
IACUC = Institutional Animal Care and Use Committee
IBC = Institutional Biosafety Committee
ICD / ICF = Informed Consent Document / Form
IDE = FDA Investigational Device Exemption
III = Individually Identifiable Information
IND = FDA Investigational New Drug
IRB = Institutional Review Board
IRM = Information Resource Management
ISA/SIA = Interconnection Security Agreement
ISO = Information Security Officer
IT = Information Technology
ITOC = VA OI&T Oversight and Compliance Office

LAN = Local Area Network
LAR = Legally Authorized Representative
LSI = Local Site Investigator

M = Research Misconduct Focus
MCD = Medical Center Director
MOU = Memorandum of Understanding
MRI = Magnetic Resonance Imaging
MVP = VA Million Veteran Program Research Study

NARA = National Archives and Records Administration
NIH = National Institutes of Health
NIOSH = National Institute for Occupational Safety & Health

(continued on next page)

TABLE 3. ACRONYMS

(continued from previous page)

NIST = National Institute of Standards and Technology
NOK = Next of Kin
NPC = Nonprofit Research and Education Corporation
NSOC = VA Network & Security Operations Center

OBA = NIH Office of Biotechnology Activities
OE = Other Equipment (Non-GFE)
OEF-OIF = Operation Enduring Freedom / Iraqi Freedom
OGC = Office of General Counsel
OHRP = HHS Office for Human Research Protections
OHSP = Occupational Health and Safety Program
OIG = Office of Inspector General
OI&T / OIT = VA Office of Information and Technology
OLAW = PHS Office of Laboratory Animal Welfare
ORD = VHA Office of Research and Development
OPC = Outpatient Clinic
ORI = HHS Office of Research Integrity
OSHA = Occupational Safety and Health Administration
OSHP = Occupational Safety and Health Program
OTA = On-Site Technical Assistance

P = Multiple Concerns Focus
PBM = VHA Pharmacy Benefits Management
PET = Positron Emission Tomography (Scan)
PHI = Protected Health Information under HIPAA
PHS = Public Health Service
PI = Principal Investigator
PII = Personally Identifiable Information
PKI = Public Infrastructure Key
PO = Privacy Officer
POC = Person Obtaining Consent
PSETS = Privacy Security Event Tracking System (NSOC)
PTSD = Post-Traumatic Stress Disorder

QA = Quality Assurance
QI = Quality Improvement

R = Research & Development Committee Program Focus
R&DC(P) / RDC(P) = Research and Development Committee (Program)
RAP = Remedial Action Plan
RCEP = Research Compliance Officer Education Program
RCO = Research Compliance Officer
RCS = Record Control Schedule
RCT = Randomized Control Clinical Trial
rDNA = Recombinant Deoxyribonucleic Acid
REAP = VHA Research Enhancement Award Program
REDCaP = Research Electronic Data Capture
RIA = Research Integrity Assurance RIO = Research Integrity Officer
RIPP = Research Information Protection Program
RISP = Research Information Security Program
RO = ORO Regional Office
ROI = Release of Information
RPSS = Research Protocol Safety Survey
RSSP = Research Safety and Security Program

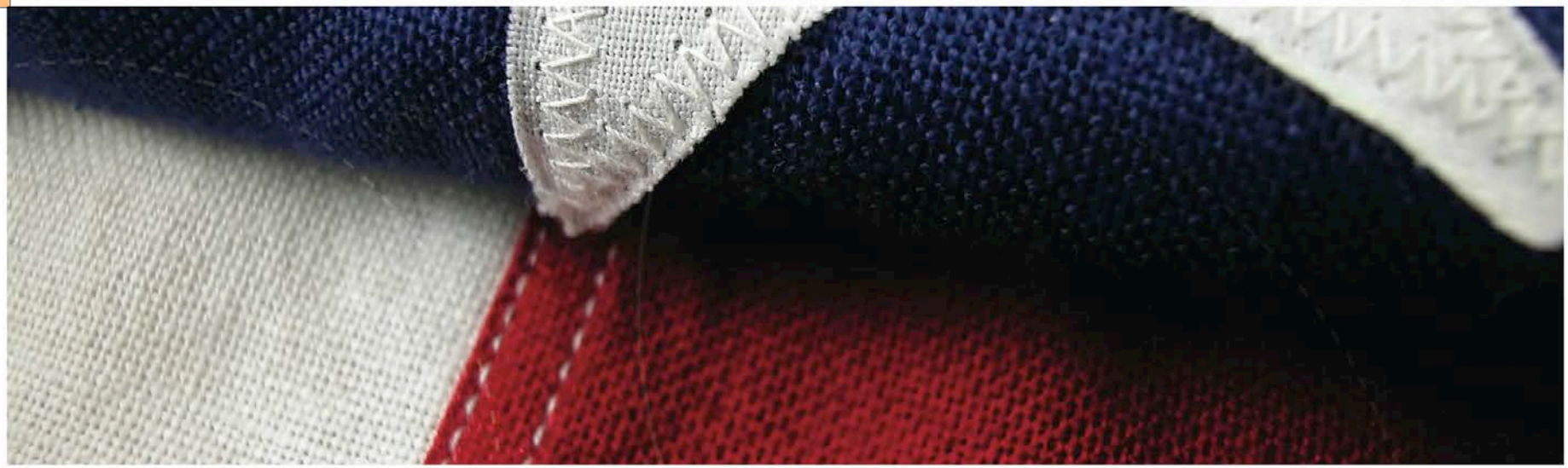
S = Research Safety Focus
SAE = Serious Adverse Event
SAT = Select Agent and Toxin
SECVA = Secretary of Veterans Affairs
SIA/ISA = Interconnection Security Agreement
SMART = Site Monitoring Auditing & Review Team
SNC = Serious Noncompliance
SOP = Standard Operating Procedure
SOR = System of Records
SORP = Scope of Research Practice
SRS = R&DC Subcommittee on Research Safety
SSN = Social Security Number
SWOG = Southwest Oncology Group

T = BSL-3 Program Focus
TAV = Technical Assistance Visit (ORO)
TBI = Traumatic Brain Injury

UPR = Unanticipated Problem(s) involving Risk(s)
USDA = United States Department of Agriculture
USH = VA Under Secretary for Health

VA = Department of Veterans Affairs
VAMC = VA Medical Center
VASI = VA Sensitive Information
VHA = Veterans Health Administration
VHACO = VHA Central Office
VINCI = Veterans Informatics Computing Infrastructure
VIREC = VA Information Resource Center
VISN = Veterans Integrated Service Network
VMO = Veterinary Medical Officer
VMU = Veterinary Medical Unit
VPN = Virtual Private Network

WOC = VA Appointment Without Compensation



Department of Veterans Affairs
Veterans Health Administration

Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2013

Appendix B: National Research Protection Quality Measures

ORO Annual System-wide National Quality Metrics

- 108 Facilities submitted Facility Director Certification Data
- 75 Facilities with Animal Care and Use Programs
- **16,568** active Human Subjects Protocols
  - (range 1 – 741)
- **3,203** active Animal Protocols
  - (range 0 – 224)
- **8,111** active Safety Protocols
  - (range 0 – 411)

ORO Annual System-wide Metrics: Informed Consent Audits

	2011	2012	**2013**
Total number of protocols audited	15,978	16,546	**16,522**
Number of protocols with ICDs	3,813 (23.86%)	3,859 (23.32%)	**4,282 (25.92%)**
Total number of ICDs audited	100,832	99,013	**102,085**
• Incorrect ICDs used	1,478 (1.47%)	1,806 (1.82%)	**1,727 (1.69%)**
• Missing ICDs		157	**36**
• Not signed by subjects	284 (0.28%)	201 (0.20%)	**80 (0.08%)**
• Not dated by subjects		349 (0.35%)	**300 (0.29%)**

ORO Annual System-wide Metrics: Million Veteran Program

- 46 Facilities enrolling subjects in MVP as of May 31, 2013
  - **105,733** Veterans enrolled from June 2012 – May 2013
  - **13,814** Informed Consent Documents (ICD) audited
  - **13.06%** of ICD's audited
    - Requirement is 10% monthly per facility
  - **132** Deficiencies found (0.96% deficiency rate)
  - **73** Deficiencies NOT corrected after 2 weeks upon re-audit

ORO Annual System-wide Metrics: HIPAA

	2011	2012	**2013**
Total number of protocols audited	15,978	16,546	**16,522**
• Subjects Requiring HIPAA Authorization	95,916	96,290	**97,458**
• Subjects Without Required HIPAA Authorization	1,383 (1.44%)	827 (0.86%)	**1,397 (1.43%)**

ORO Annual System-wide Metrics: Regulatory Audits - IRB and R&DC Approval (Human)

	2011	2012	**2013**
Total number of human research protocols audited	3,558	4,249	**3,834**
• Initiated prior to IRB approval	2 (0.06%)	4 (0.09%)	**1 (0.03%)**
• Completed without IRB approval	2 (0.06%)	1 (0.02%)	**0 (0.00%)**
• Initiated prior to R&DC approval	8 (0.22%)	16 (0.38%)	**4 (0.10%)**
• Completed without R&DC approval	5 (0.14%)	9 (0.21%)	**0 (0.00%)**

ORO Annual System-wide Metrics: Regulatory Audits – For-Cause Suspensions/Terminations (Human)

	2011	2012	**2013**
Total number of human research protocols audited	3,558	4,249	**3,834**
Protocols suspended/terminated	47 (1.32%)	63 (1.48%)	**45 (1.17%)**
• Due to human subject concerns	16 (0.45%)	31 (0.73%)	**12 (0.31%)**
• Due to investigator-related concerns	31 (0.87%)	32 (0.75%)	**33 (0.86%)**

ORO Annual System-wide Metrics: Regulatory Audits – Local SAEs & Unanticipated Problems (Human)

	2011	2012	**2013**
Total number of human research protocols audited	3,558	4,249	**3,834**
Local AEs determined to be serious, unanticipated, and related to research	43	17	**30**
• Resulted in hospitalization	10	5	**2**
• Resulted in death	0	0	**3**

ORO Annual System-wide Metrics: Regulatory Audits – Lapse in Continuing Review (Human)

	2011	2012	**2013**
Total number of human research protocols requiring continuing reviews	2,942	3,411	**3,112**
• Lapsed in IRB continuing reviews	208 (7.07%)	208 (6.10%)	**189 (6.07%)**
• Continued research activities during lapse	6 (0.20%)	4 (0.12%)	**3 (0.10%)**

ORO Annual System-wide Metrics: Regulatory Audits – Subject Case History Review (Human)

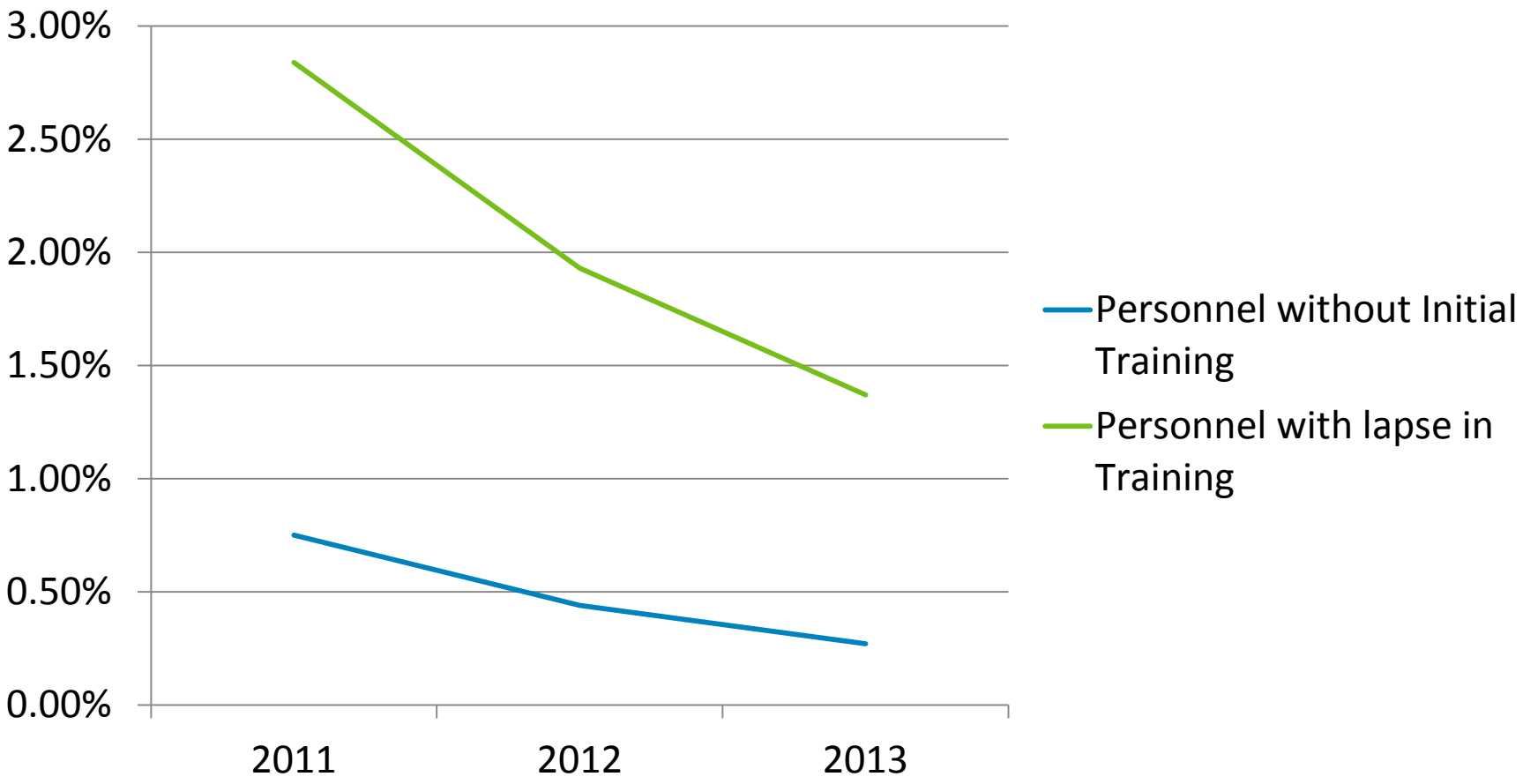
	2011	2012	**2013**
Total number of case histories reviewed	23,657	26,291	**22,306**
• No documentation of informed consent obtained prior to initiation of study procedure	39 (0.16%)	91 (0.35%)	**176 (0.79%)**
• No documentation that inclusion criteria was met	226 (0.96%)	657* (2.5%)	**192 (0.86%)**
• No documentation that exclusion criteria was NOT met	167 (0.71%)	189 (0.72%)	**148 (0.66%)**
• Subjects included in research with documentation that inclusion/exclusion criteria not satisfied		553* (2.10%)	**108 (0.48%)**

*467 were from one facility and from a chart review study

ORO Annual System-wide Metrics: Regulatory Audits – Personnel Training (Human)

	2011	2012	**2013**
Total number of research personnel in human protocols audited	12,328	16,598	**17,330**
• Without initial training	92 (0.75%)	73 (0.44%)	**46 (0.27%)**
• Lapse in continuing training	350 (2.84%)	320 (1.93%)	**238 (1.37%)**

ORO Annual System-wide Metrics: Regulatory Audits – Personnel Training (Human)



ORO Annual System-wide Metrics: Regulatory Audits – Personnel Scopes of Practice (Human)

	2011	2012	**2013**
Total number of research personnel in human protocols audited	12,328	16,598	**17,330**
• Without Scope of Practice (SOP)	294 (2.38%)	92 (0.55%)	**112 (0.65%)**
• Working outside SOP	9 (0.07%)	7 (0.04%)	**2 (0.01%)**

ORO Annual System-wide Metrics: Research Overseen by the R&DC Only

	2012	**2013**
Total number of protocols followed only by the R&DC	1,430	**1,730**
• Protocols NOT initially approved by the R&DC before entering into research	0 (0.00%)	**14 (0.81%)**
• Protocols requiring at least one continuing review	1,057	**1,266**
• Protocols NOT receiving required continuing review	118 (11.16%)	**40 (3.16%)**

ORO Annual System-wide Metrics: Regulatory Audits – IACUC, R&DC and other Required Approvals (Animal)

	2011	2012	**2013**
Total number of animal protocols audited	1,347	1,286	**1,147**
• Initiated prior to IACUC approval	2 (0.15%)	1 (0.08%)	**2 (0.17%)**
• Completed without IACUC approval	0 (0.00%)	1 (0.08%)	**0 (0.00%)**
• Initiated prior to R&DC approval	1 (0.07%)	2 (0.16%)	**4 (0.35%)**
• Completed without R&DC approval	12 (0.89%)	1 (0.08%)	**0 (0.00%)**
• Initiated prior to other required approval (SRS, IBC)	Not obtained	Not obtained	**8 (0.70%)**
• Completed prior to other required approval (SRS, IBC)	Not obtained	Not obtained	**3 (0.26%)**

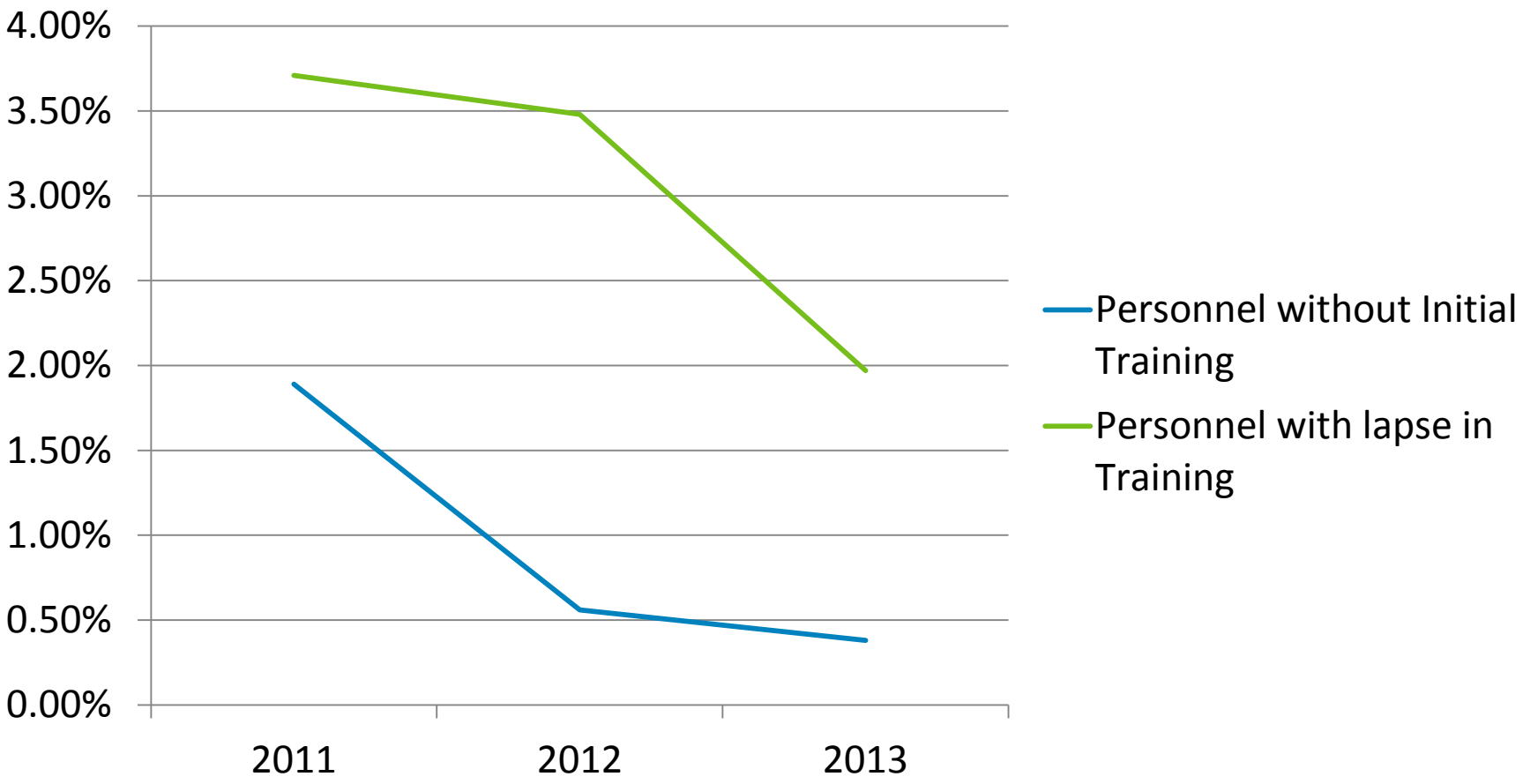
ORO Annual System-wide Metrics: Regulatory Audits – Lapse in Annual or Triennial Review (Animal)

	2011	2012	**2013**
Total number of animal protocols requiring at least one annual review	Not obtained	1,159	**1,125**
• Lapsed in annual or triennial review	75	53 (4.57%)	**23 (2.04%)**
• Continued research activities during lapse	Not obtained	25 (2.16%)	**6 (0.53%)**

ORO Annual System-wide Metrics: Regulatory Audits – Personnel Training (Animal)

	2011	2012	**2013**
Total number of research personnel in animal protocols audited	4,926	4,604	**5,064**
• Without initial training	93 (1.89%)	26 (0.56%)	**19 (0.38%)**
• Lapse in continuing training	183 (3.71%)	160 (3.48%)	**100 (1.97%)**

ORO Annual System-wide Metrics: Regulatory Audits – Personnel Training (Animal)



ORO Annual System-wide Metrics: Regulatory Audits – Personnel Scopes of Practice (Animal)

	2011	2012	**2013**
Total number of research personnel in animal protocols audited	4,926	4,604	**5,064**
• Without Scope of Practice (SOP)	170 (3.45%)	276 (5.99%)	**64 (1.20%)**
• Working outside SOP	1 (0.02%)	1 (0.02%)	**1 (0.02%)**

ORO Annual System-wide Metrics: For-Cause Suspensions/Terminations (Animal)*

	2013
Total number of Active Animal Protocols	3,079
Protocols suspended/terminated	41 (1.28%)
• Due to animal welfare concerns	7 (0.22%)
• Due to administrative issues	34 (1.06%)

* Based on total number of active animal protocols

ORO Annual System-wide Metrics: Regulatory Audits – SRS, R&DC, IBC Approval (Safety)

	2011	2012	**2013**
Total number of safety protocols audited	2,264	2,722	**2,362**
• Initiated prior to SRS approval	64 (2.83%)	26 (0.96%)	**12 (0.51%)**
• Completed without SRS approval	15 (0.66%)	2 (0.07%)	**1 (0.04%)**
• Initiated prior to R&DC approval	64 (2.83%)	6 (0.22%)	**8 (0.34%)**
• Completed without R&DC approval	12 (0.53%)	3 (0.11%)	**1 (0.04%)**
Total number of safety protocols requiring IBC Approval	Not obtained	Not obtained	**317**
• Initiated prior to IBC approval	Not obtained	Not obtained	**22 (6.94%)**
• Completed prior to IBC approval	Not obtained	Not obtained	**0 (0.00%)**

ORO Annual System-wide Metrics: Regulatory Audits – Lapse in SRS Annual Review (Safety)

	2011	2012	**2013**
Total number of safety protocols audited	2,264	2,722	**2,362**
Total number of safety protocols requiring at least one SRS annual review	Not obtained	Not obtained	**1,946**
• Lapsed in SRS annual review	120	156	**141 (7.25%)**
• Continued research activities during lapse	Not obtained	Not obtained	**58 (2.98%)**

ORO Annual System-wide Metrics: For-Cause Suspensions/Terminations (Safety)*

	2013
Total number of active safety protocols	**8,111**
Protocols suspended/terminated	**14 (0.17%)**
• Due to safety concerns	**1 (0.01%)**
• Due to administrative issues	**13 (0.16%)**

* Based on total number of active safety protocols

ORO Annual System-wide Metrics: Conclusions

- **Unchanged or Negative Trends**
  - Documentation of subject consent prior to research
  - Lapse in IRB continuing review
- **Possible Improvements**
  - R&DC Continuing Review
  - Lapse in IACUC annual or triennial review
- **Positive Trends**
  - Human protocols completed without IRB approval
  - Animal protocols completed without R&DC approval
  - Safety protocols initiated prior to SRS approval
  - Safety protocols completed without SRS or R&DC approval
  - Research Personnel training requirements (human and animal)
  - Scopes of Practice (animal)

Department of Veterans Affairs
Veterans Health Administration

Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2014

OFFICE OF RESEARCH OVERSIGHT

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

This report summarizes the activities of the Veterans Health Administration Office of Research Oversight (ORO) from January 1 through December 31, 2014, and describes all suspected lapses in protecting human subjects and others in VA research as required under Title 38 United States Code (38 U.S.C.), section 7307 (d)(4).

The report was prepared for the Committees on Veterans' Affairs of the Senate and the House of Representatives of the United States pursuant to 38 U.S.C., section 7307(f).

ORO reports directly to the Under Secretary for Health in monitoring, reviewing, and investigating compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Federal-wide debarment for research impropriety, and the activities of facility-level research compliance officers.

J. Thomas Puglisi, PhD
Executive Director
Office of Research Oversight

CONTENTS

A. INTRODUCTION

The Department of Veterans Affairs (VA), through the Veterans Health Administration (VHA) Office of Research Oversight (ORO), conducts one of the most comprehensive programs of research compliance oversight in the Federal Government.

Creation of ORO within VA was mandated under legislation signed by the President of the United States on December 6, 2003, as Public Law 108-170. Section 401 of this statute stipulates ORO's functions as follows:

> *(a) Requirement for Office. – (1) There is in the Veterans Health Administration an Office of Research Oversight (hereinafter in this section referred to as the 'Office'). The Office shall advise the Under Secretary for Health on matters of compliance and assurance in human subjects' protections, research safety, and research impropriety and misconduct. The Office shall function independently of entities within the Veterans Health Administration with responsibility for the conduct of medical research programs. (2) The Office shall -- (A) monitor, review, and investigate matters of medical research compliance and assurance in the Department with respect to human subjects' protections; and (B) monitor, review, and investigate matters relating to the protection and safety of human subjects and Department employees participating in medical research in Department programs.*

This report summarizes ORO's activities for the period from January 1 through December 31, 2014. The summary includes oversight activities carried out by ORO in advising the Under Secretary for Health (USH) on matters of regulatory compliance related to the protection of human research subjects, research safety, research laboratory security, and research misconduct, as required under Title 38 United States Code (38 U.S.C.) section 7307.

These activities reflect ORO's responsibilities to monitor, review, and investigate matters of regulatory compliance in each of these aspects of VA research. The report addresses suspected lapses from all causes in protecting human subjects and others in VA research as required under 38 U.S.C. section 7307(d)(4).

The report also includes ORO's activities in providing oversight of laboratory animal welfare, research safety, research laboratory security, research information security and privacy, Government-wide non-procurement suspensions and debarments for research impropriety, facility research compliance officer (RCO) audits, and RCO education, as directed by the USH.

A total of 108 VHA facilities operated research programs in calendar year (CY) 2014. All 108 of these facilities operated human research programs, 80 of these facilities operated

laboratory research programs, and 77 of these facilities operated animal research programs.

In addition, the VHA Central Office Human Research Protection Program (HRPP) operates an Institutional Review Board (IRB) for oversight of multi-center clinical trials sponsored by VA, such as trials conducted under the VA Cooperative Studies Program (CSP).

Appendix A provides summaries of all ORO compliance cases for the calendar year.

Because this report contains sensitive information related to open investigations, distribution of the report should be limited to those persons engaged in authorized Congressional oversight and to other required Congressional entities.

B. BACKGROUND

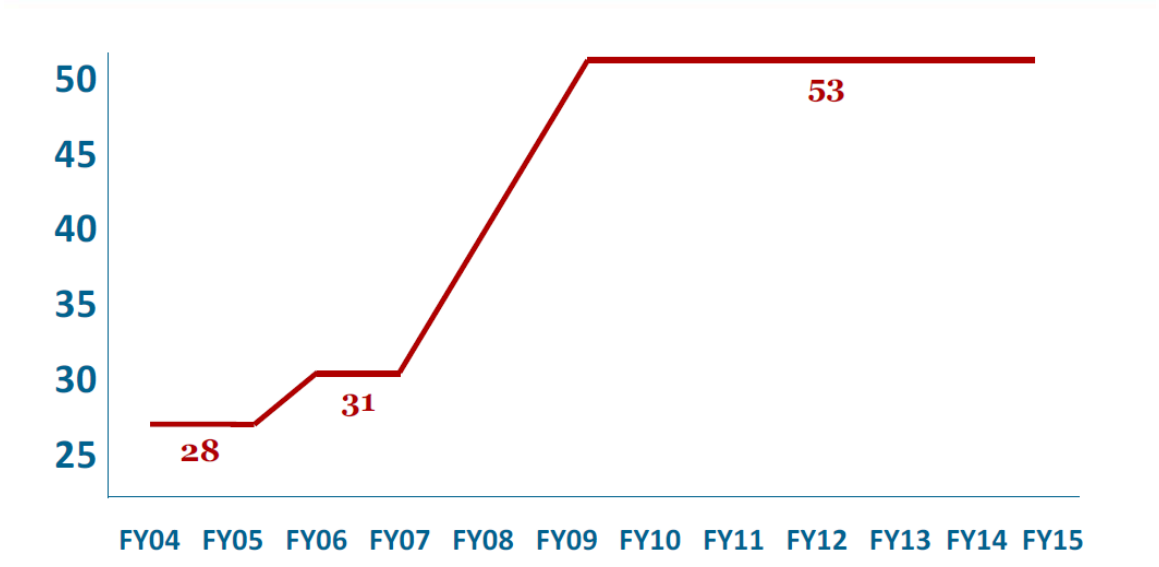
ORO Central Office (CO) develops and manages ORO's programs and provides direct oversight of the VHA Central Office Human Research Protection Program (HRPP). CO professionals also provide direct oversight of all VA research activities related to laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Government-wide suspension and debarment for research impropriety, RCO audits, and RCO education.

ORO Regional Offices (ROs) provide direct oversight of VA research activities related to the protection of human subjects and facility research program administration and oversight. ORO's ROs are located within VA space in four geographic regions to provide prompt access and response to issues that may require onsite review and assistance. Each RO has oversight responsibility for approximately 25-30 VA research facilities:

- Midwestern RO (Edward Hines, Jr. VA Hospital, Chicago, IL)
- Northeastern RO (Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA)
- Southern RO (Veterans Integrated Service Network 7 Headquarters, Duluth, GA)
- Western RO (VA Loma Linda Health Care System, Loma Linda, CA)

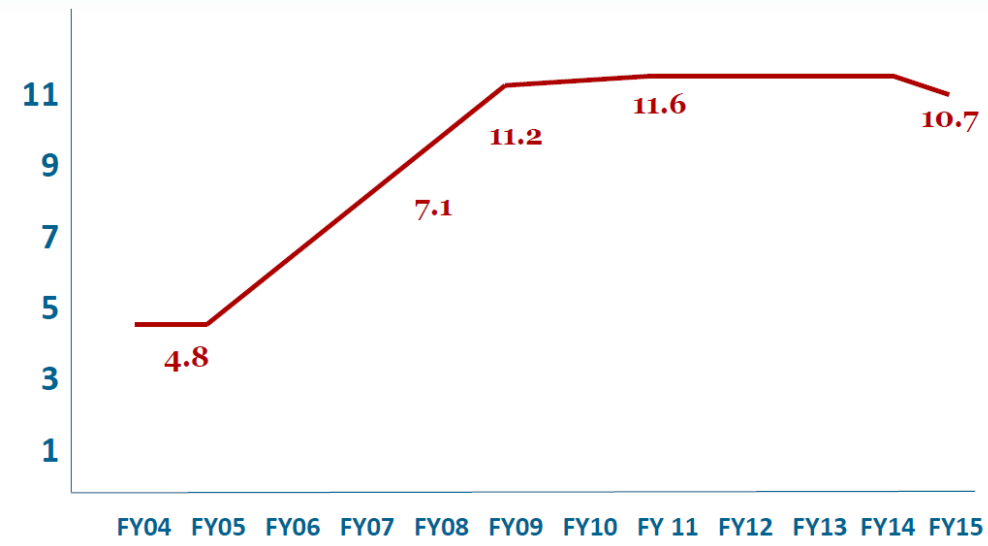
A full ORO staff includes 53 individuals (28 in ORO's CO, and 25 in ORO's ROs). The Figure below illustrates the staffing levels for ORO since its creation in December 2003.

Figure 1. ORO Staffing (FTEs)



ORO's current fiscal year budget is approximately $10.7 million. The Figure below illustrates the funding provided to ORO since its creation in December 2003.

Figure 2. ORO Funding ($ Millions)



ORO solicits advice and feedback from the research community through the ORO Field Advisory Committee. Committee members are encouraged to raise any and all matters of concern related to ORO's activities and to recommend strategies to enhance efficiency and effectiveness in the fulfillment of ORO's mission. The Committee convenes three times per year, either in person or by video conference. Members also participate in ad hoc work groups pertinent to ORO's mission.

As previously indicated, 108 VHA facilities operated research programs during this reporting period. All 108 of these facilities operated human research programs, 80 of these facilities operated laboratory research programs, and 77 of these facilities operated animal research programs. In addition, the VHA Central Office HRPP operates an Institutional Review Board (IRB) for oversight of multi-center clinical trials sponsored by VA, such as trials conducted under the VA Cooperative Studies Program (CSP).

ORO fulfills its review and oversight responsibilities for regulatory compliance and assurance through three types of programs:

- Onsite research compliance reviews
- Remote compliance reviews
- Oversight of VA facilities' Federalwide Assurances (FWAs), research compliance education, and quality assurance

C. Onsite Research Compliance Reviews

ORO conducts three types of onsite compliance reviews:

- For-cause onsite reviews
- Proactive routine onsite reviews
- Proactive technical assistance onsite reviews

Most onsite reviews are announced to the facility in advance, but ORO also may conduct unannounced onsite reviews as warranted. Summaries of ORO's onsite compliance reviews are provided in Appendix A of this report. Complete reports of these reviews are available upon request.

C1. For-Cause Onsite Reviews

ORO receives reports of possible noncompliance from a variety of sources, including other VA offices, other government agencies, VA employees, Veterans, family members of Veterans, ORO's anonymous complaint line, and the media.

In cases where there may be serious, systemic concerns about a facility's research protection programs, ORO may conduct for-cause onsite compliance reviews to establish the nature and severity of the possible noncompliance, and to assess the effectiveness of the facility's research protection programs. These reviews involve in-depth evaluations of potentially serious noncompliance with the laws, regulations, and policies governing VA research.

ORO requires remedial actions to resolve any serious or continuing noncompliance that is identified. All facilities that are required to develop and execute remedial action plans are carefully monitored, and cases are held open until ORO confirms that remedial actions have been implemented satisfactorily to ensure compliance.

C2. Proactive Routine Onsite Reviews

Routine onsite reviews are systematic proactive inspections of regulatory compliance to assist VA facilities in conducting research with appropriate human subject protections, care and use of laboratory animals, research safety, research laboratory security, and research information security and privacy. Where applicable, these reviews include inspections of VA's Biological Safety Level Three (BSL-3) research laboratories.

Routine onsite reviews include thorough onsite inspections, assessment, and follow-up of regulatory compliance in VA research programs. Reviews are performed on a rotating schedule by ORO subject matter experts appropriate to the programs under review.

C3. Proactive Technical Assistance Onsite Reviews

ORO onsite technical assistance reviews constitute an additional proactive approach to assist VA facilities in conducting research with appropriate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protection, and the responsible conduct of research. Onsite technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

C4. Summary: Onsite Research Compliance Reviews

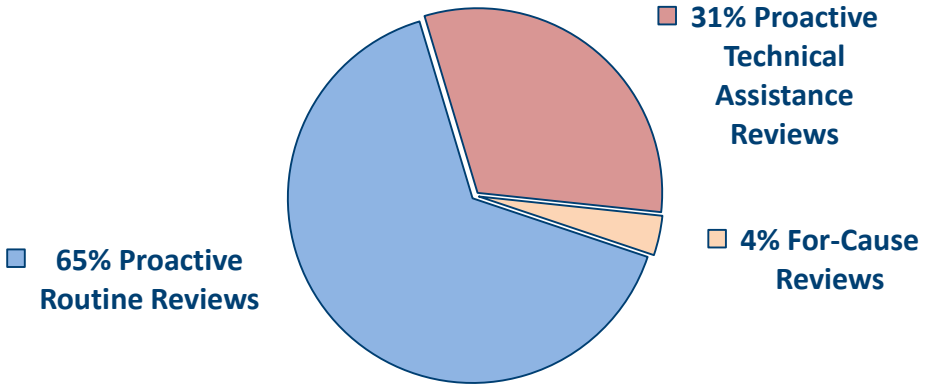
Table 1 of Appendix A provides case summaries of ORO's onsite compliance reviews.

Summary: Number of Onsite Research Compliance Reviews:

- 73 = Cases Continuing from Previous Calendar Year
- 36 = New Cases – January 1 through March 31
- 56 = New Cases – April 1 through June 30
- 30 = New Cases – July 1 through September 30
- 35 = New Cases – October1 through December 31
- 157 = Total New Cases in Calendar Year
- 230 = Total Cases (Continuing Plus New) in Calendar Year

The Figure below illustrates ORO's onsite compliance review cases for CY 2014.

Figure 3. Calendar Year Onsite Research Compliance Reviews (n=230)



D. Remote Research Compliance Reviews

Certain compliance cases can be evaluated and managed remotely through written communications with facility leadership and facility compliance personnel. ORO conducts seven types of remote reviews to ensure compliance with VA research requirements:

- Reviews of externally identified noncompliance
- Reviews of facility self-identified noncompliance
- Reviews of Research Compliance Officer (RCO) audits
- Reviews of annual facility director certifications of research oversight
- Remote technical assistance reviews
- Reviews of unanticipated serious adverse events related to research
- Reviews of research misconduct and debarment proceedings

Each review includes monitoring by ORO to verify that remedial actions have been implemented as warranted.

D1. Remote Reviews of Externally Identified Noncompliance

ORO's remote compliance reviews include cases of apparent noncompliance that have been identified by sources external to the facility's research program. Such sources include, but are not limited to, apparent noncompliance identified by ORO, by other VA offices, by other government regulatory agencies, and by industry sponsors.

D2. Remote Reviews of Facility Self-Identified Noncompliance

ORO and the VHA Office of Research and Development (ORD) require VA research facilities to accept responsibility and accountability for maintaining a compliant research program and fostering a culture that values adherence to the required protections for Veterans and other human research subjects, research personnel, and research animals. Building a culture of local accountability is a continuing focus of ORO's compliance and technical programs and of ORD's education program.

VA facilities are required to report to ORO any events that might reasonably indicate serious or continuing noncompliance in research. As the focal point for fulfilling VA's research mission and a responsible steward of VA resources, each VA research facility has an obligation to serve as the primary watchdog for identifying and correcting noncompliance problems in its own research programs. ORO works cooperatively with VA research facilities by assisting them in developing remedial action plans and monitoring resolution of all identified noncompliance.

D3. Remote Reviews of Research Compliance Officer (RCO) Audits

Facility RCOs must conduct audits of all informed consents obtained for VA research throughout the year. Regulatory audits of all VA research must be conducted at least every 3 years. Facilities are required to report to ORO any serious or continuing noncompliance identified in these audits.

D4. Reviews of Annual Facility Director Certifications of Research Oversight

ORO requires that the director of each VA facility conducting research lead an annual program-wide self-assessment of research compliance and provide ORO with an annual certification of research oversight based on this self-assessment. Certifications must be completed and forwarded to ORO by July 31 each year. ORO evaluates all deficiencies identified by the facility and requires remedial actions where needed. ORO monitors the case until appropriate remedial actions have been implemented satisfactorily.

D5. Remote Technical Assistance Reviews

ORO remote technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Remote technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

D6. Remote Reviews of Unanticipated Serious Adverse Events

VA requires that unanticipated serious adverse events (SAEs) in research be reported to, and rapidly reviewed by, the responsible IRB. Reporting to ORO is required for any unanticipated deaths and other unanticipated SAEs that the IRB determines to be caused by, or probably caused by, the research. ORO uses these reports to review local SAE management and assist facilities in improving their research programs.

D7. Research Misconduct and Debarment Procedural Reviews

All Federal agencies that conduct or support research have adopted the following uniform definition of research misconduct: *fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.*

VA has established precise processes for responding to allegations of misconduct involving VA research and for sanctioning with Government-wide debarment VA

investigators who commit serious improprieties in the conduct of research. The severity and potentially grave consequences of research misconduct and of Government-wide debarment necessitate detailed procedural mechanisms for adjudication.

D8. Summary: Remote Research Compliance Reviews

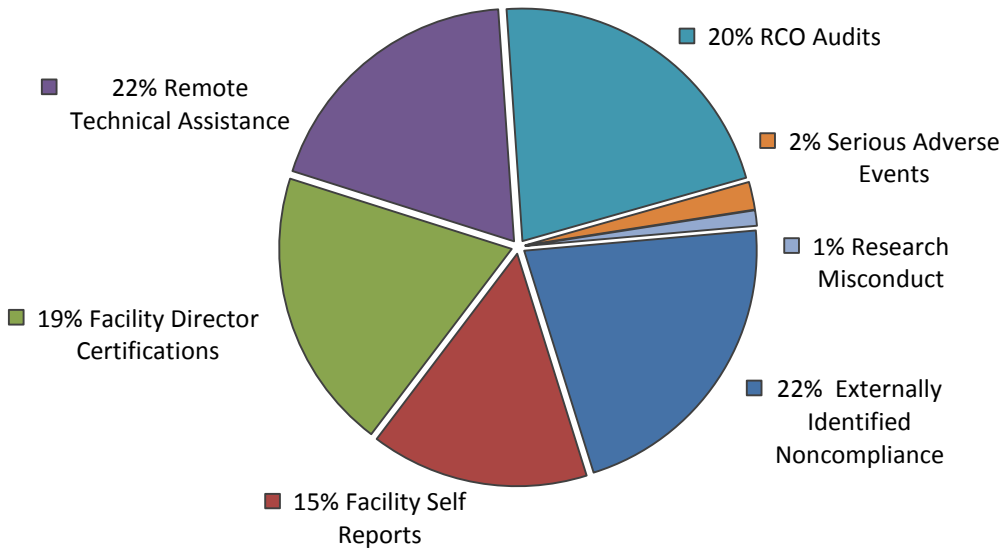
Table 2 of Appendix A provides case summaries of ORO's remote compliance reviews.

Summary: Number of Remote Research Compliance Reviews:

- 158 = Cases Continuing from Previous Calendar Year
- 246 = New Cases – January 1 through March 31
- 247 = New Cases – April 1 through June 30
- 658 = New Cases – July 1 through September 30
- 189 = New Cases – October 1 through December 31
- 1340 = Total New Cases in Calendar Year
- 1498 = Total Cases (Continuing Plus New) in Calendar Year

The Figure below illustrates ORO's remote compliance review cases for CY 2014.

Figure 4. Calendar Year Remote Research Compliance Reviews (n=1498)



E. Research Assurance, Compliance Education, and Quality Assurance

E1. Research Assurance Program

ORO administers the VA human research assurance program. Assurances are formal agreements required by regulation and signed by VA facility directors and network directors assuring compliance with VA and other Federal requirements, including provision of adequate training and resources, for the protection of human research subjects. The Federalwide Assurance (FWA) for any VA research facility requires the approval of both ORO and the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (HHS).

ORO has the authority to restrict or suspend a VA facility's FWA for failure to meet its responsibilities for protecting human subjects.

All 108 VA research facilities and the VHA Central Office HRPP hold current, approved FWAs.

Although FWAs are typically approved for 5 years, the facility must modify its FWA whenever certain changes occur (e.g., a change in the designation of an IRB or a change in responsible facility officials). ORO's participation in the approval, renewal, and modification of FWAs during this calendar year is reflected among the cases in Table 2E. ORO also tracks membership and membership changes in all IRBs used by VA research facilities to ensure regulatory compliance.

Each VA research facility that uses an IRB operated by another VA facility (19 facilities), operated by the VHA Central Office HRPP (94 facilities), or operated by the facility's academic affiliate (40 facilities) must effect a memorandum of understanding (MOU) indicating how the entities will work together to support the IRB and collaborate in the protection of human research subjects. MOUs documenting these IRB arrangements are reviewed by ORO whenever substantive modifications occur, at the time of FWA renewal, and in conjunction with ORO's onsite compliance reviews.

The MOU can also be used to document other related organizational arrangements used in human research protection programs, such as using the Research and Development Committee (R&DC) of one VA facility to oversee the research program of another VA facility. ORO regularly reviews MOUs and provides guidance to facilities on developing appropriate MOUs, as reflected among the cases in Table 2E.

E2. Research Compliance Education Program

Every VA facility conducting research is required to support at least one RCO to provide facility-level oversight of its research program. The lead RCO at each facility must report directly to the facility director, and each facility director has a responsibility to ensure the functional independence of the facility's RCO(s) relative to the Research Service.

ORO conducts an RCO education program to strengthen oversight of research at the facility level and monitors RCO activities to ensure compliance with VA requirements.

The primary function of RCOs is to conduct mandatory informed consent and regulatory compliance audits of VA research. Every VA research study must receive a 100 percent audit of informed consent documentation each year, as well as a full regulatory compliance audit approximately every 3 years. ORO provides audit tools for this purpose on its Research Compliance and Technical Assistance SharePoint site and trains RCOs in their use. This SharePoint site is available to all VHA employees at http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx.

RCOs also serve as local resources on research compliance requirements and consultants to the R&DC, IRB(s), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), and other facility research oversight committees. ORO has developed a variety of informational materials, and conducts monthly video teleconferences, for RCO education.

ORO regularly develops updated policy, guidance materials, and oversight tools to assist the wider VA research community in implementing optimal protections for human research subjects, laboratory animals, and research investigators. These materials are provided on the ORO Web site at http://www.va.gov/oro/ and the ORO Research Compliance and Technical Assistance SharePoint site referenced above. ORO also maintains several large ListServs for rapid distribution of guidance materials and important announcements.

ORO holds nationwide research compliance video teleconferences at 2-month intervals and contributes extensively to educational activities sponsored by ORD and national professional associations where possible.

ORO has been instrumental in convening and continues to participate vigorously in collaborative workgroups with the VHA ORD, the VHA Privacy Office, the VA Office of General Counsel, the VA Office of Information and Technology (OI&T), and the Association of American Medical Colleges (AAMC) to address common areas of concern, including data ownership and data security issues in research with VA's university affiliates.

ORO also participates actively in several interagency workgroups, including the HHS Secretary's Advisory Committee on Human Research Protections (SACRHP), the Federal Research Integrity Workgroup, and Office of Science and Technology (OSTP) Common Rule Modernization Working Group, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight.

E3. Research Quality Assurance Program

ORO has developed a set of indicators for assessing the quality of VA research protection programs. These quality indicators have been incorporated into RCO informed consent and regulatory audits and the annual facility director certifications of research oversight.

Quality indicators for human research include documentation of informed consent, Health Insurance Portability and Accountability Act (HIPAA) authorization for use and disclosure of protected health information, IRB approval, protocol documentation, and investigator qualifications and training.

Quality indicators for animal research include Institutional Animal Care and Use Committee (IACUC) approval and investigator qualifications and training. Quality indicators for research safety include Subcommittee on Research Safety (SRS) approval.

ORO compiles the data for these indicators to identify areas for system-wide quality improvement and provides these data to each VA research facility and Veterans Integrated Service Network (VISN) for quality improvement purposes at the facility and VISN level. ORO's National Research Oversight Metrics Report (Appendix B) includes a longitudinal summary of data for these indicators going back, in most cases, to CY2011.

Highlights for the 2014 reporting period (June 1, 2013 through May 31, 2014) include:

- 16,244 human research studies, 3119 animal research studies, and 7948 basic science laboratory studies were active during reporting period (slide 2).
- Facility Research Compliance Officers (RCOs) audited 100% of the 93,206 informed consent documents (ICDs) obtained in VA research other than the Million Veteran Program (MVP). Deficiencies were identified in fewer than 4% of these ICDs (slide 3).
- The MVP audited 14,881 (13.5%) of the 109,604 ICDs obtained during the reporting period. Deficiencies were identified in fewer than 0.2% of these ICDs (slide 8).
- Of 15,824 human studies audited since 2011, fewer than 0.1% were initiated without required Institutional Review Board (IRB) approval (slide 20).
- Fewer than 0.1% of 12,241 human studies continuing beyond the initial IRB approval period during the 2014 reporting period conducted research activity without the required continuing IRB review and approval (slide 18).

Department of Veterans Affairs
Veterans Health Administration

Office of Research Oversight
Annual Report of Activities
January 1 – December 31, 2014

Appendix A: Research Compliance Case Summaries
(Includes all compliance cases for 1st, 2nd, 3rd, and 4th Quarters of CY2014)

OFFICE OF RESEARCH OVERSIGHT

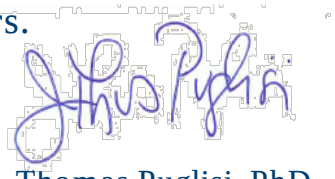
VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

000391

This report summarizes the activities of the Veterans Health Administration Office of Research Oversight (ORO) from January 1 through December 31, 2014, and describes all suspected lapses in protecting human subjects and others in VA research as required under title 38 United States Code (38 U.S.C.) §7307(d)(4).

The report was prepared for the Committees on Veterans' Affairs of the Senate and the House of Representatives of the United States pursuant to 38 U.S.C. §7307(f).

ORO reports directly to the Under Secretary for Health in monitoring, reviewing, and investigating compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security and privacy, research misconduct, Federalwide debarment for research impropriety, and the activities of facility-level research compliance officers.



J. Thomas Puglisi, PhD
Executive Director
Office of Research Oversight

CONTENTS

TABLE 1. ON-SITE RESEARCH COMPLIANCE REVIEWS

TABLE 1A. FOR-CAUSE ON-SITE REVIEWS

ORO for-cause onsite reviews involve in-depth evaluations of suspected serious systemic non-compliance with VA or other federal research requirements. ORO review teams typically spend 4 to 5 days at the facility examining records and interviewing key personnel involved in the issues under review. Remediation involves development by the facility of an action plan acceptable to ORO, and oversight of corrective actions by ORO until remediation is complete. NOTE: Cases under the jurisdiction of additional offices (for example, OIG or FDA) or involving physical infrastructure improvements may remain open for extended periods.

SUMMARY

- 4 = Cases Continuing from Previous Calendar Year
- **0 = New Cases – January 1 through March 31**
- **2 = New Cases – April 1 through June 30**
- **2 = New Cases – July 1 through September 30**
- **0 = New Cases – October 1 through December 31**
- 4 = Total New Cases in Calendar Year
- 8 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 1A. FOR-CAUSE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	Issue of Noncompliance	Remedial Actions
1	21	San Francisco	S	05/14/2012	Facility reported employee death; presumptive diagnosis is disseminated meningococcemia with suspect occupational exposure.	Remedial Actions: Provide prophylactic vaccination as available; revise biosafety manual; develop lab-specific SOPs; staff education and training; revise protocols with safety enhancements as needed; orientation, training and evaluation of worker competencies. CASE CLOSED.
2	00	VA Central Office	P	04/16/2013	ORO review of allegations against the VA Office of Public Health (OPH) by a former OPH employee	Remedial Actions: Ensure approval of all manuscript authors; research data retained per federal requirements; OPH PIs empowered to fulfill all PI responsibilities; OPH leadership training. VHA to designate specific IRB for VHA Program Office research. Separate VHA administrative action. CASE CLOSED.

TABLE 1A. FOR-CAUSE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	Issue of Noncompliance	Remedial Actions
3	01	Providence	P	06/27/2013	ORD Non-profit Program Office reported that a PI was possibly conducting genotyping on children specimens without CRADO waiver and staff conducting the work unsupervised.	Remedial Actions: ACOS/R must ensure effective system is in place to orient VA researchers with dual appointment on VHA requirements in the conduct of multisite research; consult OGC STAR team when complex multisite research activities are planned to be conducted at the VA; R&DC education on VA research. CASE CLOSED.
4	23	Minneapolis	R	09/25/2013	OIG Hotline referral reported possible R&DC approval of non-VA research and the possible conduct of research by an individual lacking appropriate VA appointment and research scope of practice. This is a total knee arthroplasty study.	Remedial Actions: Facility must remediate deficiencies regarding individuals who conducted research without an appropriate appointment; multiple violations regarding informed consent and HIPAA; lack of adequate oversight of human subjects research by the PI, IRB, and R&DC; and financial COI.
5	10	Cincinnati	H	**06/04/2014**	HRPP onsite follow-up review to re-access procedures for off-site oncology research, pharmacy deficiencies, and IRB electronic documentation issues.	Remedial Actions: Ensure that investigational drug orders are signed by an authorized provider and that signed ICDs are viewed by the pharmacist; establish letter of understanding with affiliate investigational drug pharmacy; and include all required elements in investigational drug logs. CASE CLOSED.
6	09	Memphis	H	**06/18/2014**	Privacy reviews and HIPAA documentation problems identified in previous ORO review.	Remedial Actions: Complete PO reviews prior to IRB review; correctly document HIPAA waivers; update OHRP IRB Registration in a timely manner; revise verbal consent scripts to include all required elements; revise IRB approval letters for expedited review to include the required expedited category documentation; ensure IRB members complete CITI training. CASE CLOSED.
7	01	White River Junction	R	**09/09/2014**	Follow-up review of systemic noncompliance in which the R&DC did not conduct continuing reviews of research not overseen by its subcommittees, and the affiliate IRB failed to maintain oversight of requirements specific to VA.	Remedial Actions: Facility and affiliate have revised local policies and procedures to address the compliance issues adequately. Initial expedited IRB approval letters are now being signed by the IRB Chair or the experienced member who reviewed the research. The R&DC has developed a thorough process to track studies that require annual review by R&DC. CASE CLOSED.
8	16	Houston (Michael DeBakey)	S	**09/10/2014**	Targeted review following identification of unregistered Biological Select Agents (BSATs) during an agency-wide laboratory survey.	Remedial Actions: Destruction of unregistered BSATs; reporting to relevant external oversight agencies.

TABLE 1B. PROACTIVE ROUTINE ON-SITE REVIEWS

ORO routine onsite inspections provide a proactive, systematic approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite reviews involve a two stage process of assessment and remediation. The assessment stage includes a review of compliance with current federal laws, regulations, and VA policies governing research. Remediation involves development by the facility of an action plan acceptable to ORO, and oversight of corrective actions by ORO until remediation is complete.

SUMMARY

- 61 = Cases Continuing from Previous Calendar Year *
- **25 = New Cases – January 1 through March 31**
- **33 = New Cases – April 1 through June 30**
- **14 = New Cases – July 1 through September 30**
- **17 = New Cases – October 1 through December 31**
- 89 = Total New Cases in Calendar Year
- 150 = Total Cases (Continuing Plus New) in Calendar Year

***** Case #2 was inadvertently omitted from the 1st Quarter report.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
1	22	VA Greater Los Angeles HS	A	06/07/2010	Remedial Actions: VMU HVAC monitoring, testing, temperature, pressure regulation, routine maintenance; security of outside canine exercise area; VMU supervision; pest control; cage standards; veterinary access to animals and records; canine husbandry; protocol adherence; SOPs; offsite oversight. CASE CLOSED.
2	20	Boise*	S	04/11/2011	Remedial Actions: Ensure risk assessment results of proposals are adequately documented; adhere to MOU with collaborating VA for the establishment of shared rDNA subcommittee; ensure annual assessment security plans; R&DC annual review of SRS and RSSP; correct lab inspection findings. ORO continues to work with the facility on systematic review of plans and drills. CASE CLOSED.
3	20	Boise	H	09/10/2012	Remedial Actions: Revise and update HRPP SOPs; ensure required representation to IRB of record; require use of photographs or video/voice recordings consent form; PO conduct required reviews. CASE CLOSED.
4	20	Boise	R	09/10/2012	Remedial Actions: Conduct annual review of subcommittees, programs, of IRB exempt research; establish and implement SOPs for all recurring and required processes; review and approve subcommittee minutes; remove ineligible voting members from the R&DC; and ensure individuals have VA appointments. CASE CLOSED.
5	12	Madison (William Middleton)	S	10/23/2012	Remedial Actions: Establish MOU with affiliate; conduct and document semi-annual chemical inventory; review access records weekly; review status of personnel with access to labs semi-annually; document SRS procedures consistently; establish SOP for reporting. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
6	17	South Texas HCS	S	12/04/2012	Remedial Actions: Review of weekly access records; establish procedures for reporting; semiannual inventory of hazardous chemicals; document the multidisciplinary vulnerability assessment; SRS membership; review the research security plan; establish an MOU for the use of the IBC
7	21	VA Pacific Islands HCS	R	02/05/2013	Remedial Actions: Establish R&DC processes to distinguish VA from non-VA research, re-review collaborative research protocols, and ensure negotiated agreements are reviewed by OGC; establish SRS or seek policy waiver; and review CIRB minutes. MOU developed in collaboration with the OGC STAR group. CASE CLOSED.
8	21	VA Palo Alto HCS	I	03/18/2013	Remedial Actions: MOU/ISA; System Security Plan; IT system backups; undocumented research IT systems; EILs; unencrypted VASI on CDs; ICF and HIPAA Authorization template; incomplete waiver of HIPAA Authorization; ISO and PO review roles and process; SOPs; undocumented research data repositories.
9	07	Columbia SC (WJB Dorn)	A	03/26/2013	Remedial Actions: Include all risk personnel in the Occupational Health and Safety Program; establish SOP for reporting noncompliance. CASE CLOSED.
10	07	Columbia SC (WJB Dorn)	S	03/26/2013	Remedial Actions: IBC review of rDNA; annual review of Safety Plan and Chemical Hygiene Plan; review of Emergency Preparedness Plan and Security Plan; annual drills; SRS review of the multidisciplinary vulnerability assessment; review of access records; MOU for offsite research; SOP for reporting. CASE CLOSED.
11	16	Muskogee	H	03/26/2013	Remedial Actions: Ensure SOP of IRB of record is available and HRPP, SOPs, and MCMs are current & consistent with VHA policies; appoint 2 VA employees as representatives to the IRBs at affiliate OR obtain waiver from CRADO; IRB must document waivers of ICD & HIPAA authorization in minutes or in IRB protocol file. CASE CLOSED.
12	16	Muskogee	R	03/26/2013	Remedial Actions: R&DC ensures annual evaluations of research programs & subcommittees are conducted; business conducted only at convened meetings, approval letter not issued prior to review & approval by the convened R&DC; projects which are not VA research are not voted on for approval. CASE CLOSED.
13	17	VA North Texas HCS	H	03/26/2013	Remedial Actions: PO/ISO to provide summary reports; adhere to VHA SAE policy; update reporting policies; separate VA from affiliate research; update research pharmacy procedures; update and educate PIs on revised administrative procedures; SOP developed for data repositories. CASE CLOSED.
14	17	VA North Texas HCS	R	03/26/2013	Remedial Actions: Assess resource needs and advise MCD; ACOS notification to PI when research can begin; ACOS quality assurance reviews of publications, CRADAS, scopes of practice; R&DC program reviews; reviews of IRB-exempt research; compliance meeting minutes and rosters; research training. CASE CLOSED.
15	05	VA Maryland HCS	H	04/15/2013	Remedial Actions: Revise IRB SOP on suspension termination; review training on HIPAA waiver; VA member present for VA research review; revise SOP and training on non-Veteran research subjects; revise SOP and train on SAE, UPR, reconciling protocol, ICD, and HIPAA authorization; revise COI policy. CASE CLOSED.
16	05	VA Maryland HCS	R	04/15/2013	Remedial Actions: Restriction on use of expedited review; complete all subcommittee and program reviews; R&DC & IRB members complete HRP training, R&DC roster must link members and alternates; subcommittee membership must be properly constituted; SRS minutes must use prescribed format; MCD should assess RCO duties; revise SOPs. CASE CLOSED.
17	05	Martinsburg	I	05/06/2013	Remedial Actions: Facility CIO approval of personally owned IT equipment, background checks for study monitor direct access to VA network, revise release of data procedures for extramural research, SOPs, retention of electronic research data upon staff departure, waivers of HIPAA Authorization. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
18	01	Togus	H	05/13/2013	Remedial Actions: Ensure only an officially designated and properly convened IRB reviews and approves human subject research; ensure human subject protocols, ICDs, and HIPAA authorizations are consistent with one another; ensure IRB approval before subjects contact occurs; and establish SOPs. CASE CLOSED.
19	01	Togus	R	05/13/2013	Remedial Actions: Harmonize program documents to reflect authorized committees of record; develop and maintain updated R&DC membership listing; implement SOPs for all recurring processes to include protocol reviews; discontinue expedited review processes; and approve final subcommittee minutes. CASE CLOSED.
20	01	Manchester	H	05/15/2013	Remedial Actions: Appoint representatives to each IRB of record; ensure IRB composition meets regulatory and policy requirements; develop SOPs for all required processes and agreements; comply with prohibited recruitment practices; and re-assess HIPAA authorization waivers. CASE CLOSED.
21	01	Manchester	R	05/15/2013	Remedial Actions: Base resource recommendations on program evaluations; conduct QA reviews; remove ineligible R&DC members; ensure representation to affiliate IRBs; develop and implement SOPs; discontinue expedited review processes; improve & approve minutes. CASE CLOSED.
22	05	Washington DC	H	05/20/2013	Remedial Actions: Educate on HIPAA Waivers and Authorizations, including non-Veterans in VA research, and VA vs. non-VA research; re-review and approve minutes not approved by convened IRB; revise SOP for recurring processes; revise HIPAA and ICD templates; review specimens collected from deceased Veterans. CASE CLOSED.
23	05	Washington DC	R	05/20/2013	Revise R&DC subcommittees' rosters; R&DC conduct annual evaluations of its subcommittees; reconcile appointment terms of primary and alternate members on R&DC; members complete mandatory training; R&DC suspend activity on protocols lacking subcommittee approvals; revise organization chart. CASE CLOSED.
24	20	VA Puget Sound HCS	I	06/10/2013	Put air-gapped network terms in SSP; correct unapproved use of personal laptop; DAS OIS approval of unencrypted laptops; properly dispose VASI; account for non-VA IT; fix HIPAA authorizations; correct "prep to research", PO, reporting, and record retention policies and practices. CASE CLOSED.
25	12	Madison (William Middleton)	H	06/11/2013	ISO/PO reports to IRB prior to approval; data repositories must be compliant with 1200.12; ICD template-research injury statements and access for Federal agencies; current research pharmacy files; compliant HIPAA template language; signed ICDs into CPRS; current investigator files. CASE CLOSED.
26	15	St Louis	S	06/18/2013	Remedial Actions: Review the Chemical Hygiene Plan annually; conduct annual drills; register IBC; review local policies. CASE CLOSED.
27	05	Martinsburg	H	06/19/2013	Remedial Actions: ISO and PO to provide summary reports to the IRB and ISO and PO must attend IRB meetings and complete human subjects protection training, revise SOPs accordingly. CASE CLOSED.
28	05	Martinsburg	R	06/19/2013	Remedial Actions: Update R&DC approval process; update MOU; update organizational chart and FRC reporting lines; follow presentation approval processes; and evaluate auditing program, revise SOPs accordingly. CASE CLOSED.
29	12	Hines IL (Edward Hines)	S	07/15/2013	Remedial Actions: Revise security plan; weekly review of access records; review required plans annually; conduct and review drills annually; review multi-disciplinary vulnerability assessments; ensure proper emergency safety showers maintained and inspected properly. CASE CLOSED.
30	23	VA Nebraska/West Iowa HCS	R	07/16/2013	Remedial Actions: R&DC must approve all subcommittee final minutes; must not use expedited review process; must conduct all required annual reviews; ACOS must document QA reviews of other agreements; clinicians must have an approved Scope of Practice; all staff must complete all required training. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
31	03	Northport	R	07/22/2013	Remedial Actions: Review of all existing agreements; revise subcommittee composition, revise rosters; human subjects protection training by R&DC members; signatures on written notifications. CASE CLOSED.
32	03	Bronx	S	08/06/2013	Remedial Actions: Conduct an annual multidisciplinary vulnerability assessment; ensure drills to test safety and security plans; establish a research-specific security plan. CASE CLOSED.
33	21	VA Sierra Nevada HCS	H	08/12/2013	Remedial Actions: Revise SOPs; ensure ICDs include all required information and statements; document and communicate IRB decisions; provide list of approved studies investigational drugs to pharmacy; and update FWA. CASE CLOSED.
34	21	VA Sierra Nevada HCS	R	08/12/2013	Remedial Actions: Request RAP to address deficiencies involving the review of programs/committees, MOUs, CRADAs; ACOS must conduct QA reviews; improve time to complete subcommittee minutes; maintain committee membership lists; review internal policies; review committee business practices. CASE CLOSED.
35	09	Memphis	H	08/19/2013	Remedial Actions: Conduct IRB meetings with at least one non-scientific member present; review all lapsed protocols to determine if work continued during lapse and assess non-compliance; ISO/PO timely review of all protocols; update IRB roster; revise RCO audit structure; revise forms. CASE CLOSED.
36	09	Memphis	R	08/19/2013	Remedial Actions: R&DC must review VA CIRB meeting minutes; R&DC must do an annual review of the VA CIRB; R&DC must not allow contingent approvals; the R&DC must give the ACOS/R a written list of protocols approved; the ISO/PO must provide timely reviews. CASE CLOSED.
37	01	VA Boston Healthcare System	I	08/19/2013	Remedial Actions: System Security Plan update; overly permissive logical electronic access to PHI; CD/DVD encryption; IT system backups; EILs; HIPAA Authorization missing required statements; incomplete documentation of waivers of HIPAA Authorization; SOPs; undocumented research data repositories.
38	23	Fargo	I	09/09/2013	Remedial Actions: Ensure use of e-mail encryption; remove VASI from affiliate systems; revise HIPAA authorizations and Waiver of HIPAA authorization; revise SOPs; require the use of standalone HIPAA authorization; ensure ISO/PO reviews are submitted to IRB; ensure mandatory trainings are complete. CASE CLOSED.
39	23	Sioux Falls	I	09/09/2013	Remedial Actions: Document VASI on OE in VA agreement; remove VASI from shared drive; sanitize palm pilots; encrypt laptop; secure passwords; logs for IT closets; list OE in inventory; revise HIPAA template and study authorizations; revise SOPs; revise HIPAA waivers; ensure ISO/PO reviews CASE CLOSED.
40	16	Jackson MS (Sonny Montgomery)	H	09/24/2013	Remedial Actions: SOP; HIPAA authorization for exempt protocols; ICD on treatment for injury; documentation for consent waiver; IND log, separate storage, and label for specific studies; HIPAA waiver while requesting written ICD; and missing info in ICD on specimens for future research. CASE CLOSED.
41	16	Jackson (Sonny Montgomery)	R	09/24/2013	Remedial Actions: SOP and policies; organizational chart; chair election; annual review of VA CIRB; and review of publications. CASE CLOSED.
42	10	Dayton	I	10/07/2013	Remedial Actions: Systemic absences of documentation for waivers of HIPAA Authorization approvals; ISO and PO review process; IRB SOPs on waivers of HIPAA Authorization; RCS; unapproved use of personal IT equipment for VA use; electronic folder permissions with PHI open to all staff. CASE CLOSED.
43	15	Kansas City	A	10/15/2013	Remedial Actions: Establish MOU with affiliate for shared oversight of animal research; ensure presentation of semi-annual IACUC self-assessments to MCD includes all required participants. CASE CLOSED.
44	15	Kansas City	S	10/15/2013	Remedial Actions: Ensure conduct of annual drills; ensure weekly review and documentation of access records. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
45	02	Syracuse	H	10/21/2013	Remedial Actions: Revise HIPAA and Informed Consent Document templates; document processes are in place for reviewing and reporting of non-compliances; provide justification for inclusion of non-Veterans in VA research; conduct evaluations of facility's outreach program. CASE CLOSED.
46	02	Syracuse	R	10/21/2013	Remedial Actions: Update CIRB MOU; conduct adequate annual quality assurance reviews; ensure use of VA e-mail for conducting VA business; ensure approvals from all subcommittees are in place prior to R&DC approval; protocols/amendment approved by electronic voting must be reviewed. CASE CLOSED.
47	10	Cleveland (Louis Stokes)	R	10/22/2013	Remedial Actions: Develop procedure for publication review; submit all RCO audit reports to the RDC; update all appointment letters; refine ACOS annual QA reviews; ensure RDC conducts annual review of exempt protocol. CASE CLOSED.
48	10	Cleveland (Louis Stokes)	H	10/22/2013	Remedial Actions: Correct use of Category #4 exemptions; follow local SOP for expired protocols; correct injury statement in ICD template; ensure Pharmacy receives all required study documents; correct member designations on IRB roster. CASE CLOSED.
49	16	Oklahoma City	H	10/22/2013	Remedial Actions: SOPs; event reporting; PO and ISO review summaries to IRB; alternate member assignments, presence of VA representative at convened meetings; timely meeting minutes; expedited review procedures; VA appointment letters. CASE CLOSED.
50	16	Oklahoma City	R	10/22/2013	Remedial Actions: Update SOPs; update organizational chart; review publications; R&DC review of exempt protocols; recusal recording. CASE CLOSED.
51	21	VA Central California HCS	R	10/28/2013	Remedial Actions: Request RAP to address deficiencies involving the review of SRS business practices; review laboratory practices; harmonize "in lieu of" subcommittee documentation; maintain committee membership lists; and maintain written procedures for all recurring processes. CASE CLOSED.
52	15	Columbia MO (Harry Truman)	H	11/19/2013	Remedial Actions: Revise HIPAA authorization template; inform ORO within 30 days of IRB membership changes. CASE CLOSED.
53	15	Columbia MO (Harry Truman)	R	11/19/2013	Remedial Actions: The R&DC must approve complete, un-redacted sets of final HSIRB meeting minutes; the R&DC must establish a process to receive written notification of projects approvals from the subcommittees signed by a voting member. CASE CLOSED.
54	17	VA Central Texas HCS	H	11/19/2013	Remedial Actions: Implement procedures to ensure minutes are completed and approved in a timely manner; correct procedural deficiencies in research pharmacies; establish processes to correct administrative procedural deficiencies (exemptions, waivers, and modifications). CASE CLOSED.
55	17	VA Central Texas HCS	R	11/19/2013	Remedial Actions: RDC must ensure it only approves VA research; RDC must maintain SOPs for all recurring processes; RDC meeting minutes must document activities of convened meetings; and Scopes of Practice must be in place for all research staff. CASE CLOSED.
56	03	Bronx	H	12/02/2013	Remedial Actions: Separate VA and non-VA in collaborative studies; conduct IRB business only with quorum; ensure non-affiliated member obtain WOC; update IRB SOP; ensure all human research is reviewed by VA IRB. CASE CLOSED.
57	03	Bronx	R	12/02/2013	Remedial Actions: R&DC to perform annual evaluations of all subcommittees and programs; ACOS/R conduct adequate annual QA reviews; update R&DC SOPs; R&DC committee members complete all required training. CASE CLOSED.
58	22	VA Long Beach HS	A	12/09/2013	Remedial Actions: Ensure participation of the VMO/VMC in MCD meetings; update whistleblower policy. CASE CLOSED.
59	22	VA Long Beach HS	S	12/09/2013	Remedial Actions: Ensure consistency of chemical labeling; verify appropriate signage on microwave equipment. CASE CLOSED.
60	08	VA North Florida/South Georgia HCS	H	12/10/2013	Remedial Actions: SOP; reporting roster changes; recusal documentation; protocol change without IRB approval; required consent form for photos; approved cold call; and inconsistency between ICD and HIPAA authorization. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
61	08	VA North Florida/South Georgia HCS	R	12/10/2013	Remedial Actions: Chair's appointment and voting status; approving action without voting; review and approval of exempt protocols; annual QA reviews; and approval of non-VA research. CASE CLOSED.
62	01	VA Connecticut HCS	H	**01/13/2014**	Remedial Actions: Conduct on-going education; ensure ISO and PO reviews completed; review use of exemption categories; ensure justifications for including non-Veterans in research is discussed in IRB minutes; update SOPs; update IRB voting membership; update HIPAA authorization template. CASE CLOSED.
63	01	VA Connecticut HCS	I	**01/13/2014**	Remedial Actions: Air-gap MOU; update SSP; VASI on OE agreement; limit research folders; IT closet logs; compliant shredders; list ICF risks; list affiliate equipment; approve elevated privileges; report incidents from ACOS to Director. CASE CLOSED.
64	01	VA Connecticut HCS	R	**01/13/2014**	Remedial Actions: Conduct on-going education; update SOPs, organizational chart, and exempt procedures; perform subcommittee and quality assurance reviews; develop objectives; establish process to review publications prior to submission; ISO and PO reviews on exempt studies and properly report. CASE CLOSED.
65	15	St Louis	H	**01/14/2014**	Remedial Actions: IRB to only approve the VA form 10-1086 (informed consent); PI to provide justification for enrolling non-Veterans and IRB to document approval for their inclusion; include ICDs in CPRS; amend HIPAA authorization template; implement administrative oversight of data repositories.
66	15	St Louis	R	**01/14/2014**	Remedial Actions: MCD/PI ensure publication review prior to submission; ACOS must notify PI of continuing review approvals; RCO must complete all required audits; RCO must report all audits to RDC/IRB; RDC minutes must include recused member documentation; RDC member must complete CITI training. CASE CLOSED.
67	21	VA Palo Alto HCS	A	**01/21/2014**	Remedial Actions: IACUC promptly initiated corrective actions including risk assessment of semi-annual facility inspection participation by IACUC members; IACUC reviewed most recent annual overheat test which was recorded in the January 2014 minutes. CASE CLOSED.
68	21	VA Palo Alto HCS	S	**01/21/2014**	Remedial Actions: Facility must conduct weekly review of access records; facility must conduct semi-annual review of personnel with lab access; facility must conduct annual review of personnel with VISA and/or WOC status. CASE CLOSED.
69	22	VA Greater Los Angeles HS	H	**01/27/2014**	Remedial Actions: Revise IRB rosters; update SOPs; document risk determinations; improve expedited review procedures; re-review all determinations involving waivers of documentation of informed consent and waivers of informed consent; revise HIPAA authorization template; establish necessary waivers of HIPAA authorization; and fully implement HIPAA and Privacy statutes and regulations in the conduct research.
70	22	VA Greater Los Angeles HS	I	**01/27/2014**	Remedial Actions: Correct all identified deficiencies, including VASI on non-VA systems; Undocumented air-gapped networks; unapproved devices on the VA network; non-VA IT equipment used for research not inventoried; inadequate ISO review of protocols. CASE CLOSED.
71	22	VA Greater Los Angeles HS	R	**01/27/2014**	Remedial Actions: Revise organizational charts; revise SOPs; revise membership roster; discontinue R&DC expedited review processes; conduct annual reviews of all subcommittees; ensure that review and approval periods to not exceed 365 days; report results of all RCO audits to R&DC and subcommittees; and establish and implement procedures for the ACOS/R&D to communicate approvals to PIs.
72	16	Shreveport (Overton Brooks)	H	**01/28/2014**	Remedial Actions: Correct deficiencies in consent compensation language; including expedited review in minutes; and required documents in investigational pharmacy. CASE CLOSED.
73	16	Shreveport (Overton Brooks)	R	**01/28/2014**	Remedial Actions: Deficiencies in vote documentation; voting by emails; and ACOS/R notification. CASE CLOSED.
74	01	Providence	H	**02/24/2014**	Remedial Actions: Develop IRB roster; review approved protocols to ensure inclusion of non-Veterans in VA research is adequately justified; review and revise HRPP SOPs to be consistent with VHA policies. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
75	01	Providence	R	**02/24/2014**	Remedial Actions: MOUs and agreements to be updated for change in signatory official; R&DC develop goals and objectives for the program; re-review conditionally approved protocols and amendments at fully convened R&DC meeting; revise local R&DC SOP to be consistent with VHA policies. CASE CLOSED.
76	08	VA Caribbean HCS (San Juan)	H	**02/25/2014**	Remedial Actions: SOPs. CASE CLOSED.
77	08	VA Caribbean HCS (San Juan)	R	**02/25/2014**	Remedial Actions: None required. CASE CLOSED.
78	04	Coatesville	I	**03/10/2014**	Remedial Actions: Ensure logical permissions for electronic storage; retain research data in accordance with RCS 10-1; revise HIPAA authorization (HA); require the IRB to not stamp HAs; revise and appropriately document waivers of HA; and PO re-review of identified protocols. CASE CLOSED.
79	20	VA Puget Sound HCS	H	**03/10/2014**	Remedial Actions: Use of identifiable information to recruit subjects must involve informed consent or an approved waiver; establish complete IRB membership records; amend IRB SOP; and deliver all investigational drugs directly to pharmacy. CASE CLOSED.
80	20	VA Puget Sound HCS	R	**03/10/2014**	Remedial Actions: Appoint an ACOS/R, implement definition "VA Research", discontinue enrollment only studies; separate VA from non-VA research; provide oversight of off-site VA research; provide VA appointments to all staff; R&DC must review science only studies and conduct QA reviews.
81	07	Augusta	A	**03/11/2014**	Remedial Actions: None required; ORO did not identify any programmatic regulatory concerns associated with the facility ACUP. CASE CLOSED.
82	07	Augusta	S	**03/11/2014**	Remedial Actions: Establish an IBC; ensure oversight of off-site research; review status of personnel granted access to laboratories. CASE CLOSED.
83	06	Hampton	R	**03/14/2014**	Remedial Actions: SOP, reporting RCO audit results to IRB; reporting apparent serious or continuing noncompliance identified in RCO audits; retaining scope of practice in Research Office; ACOS/R&D notifying investigators to initiate research before R&DC approval; and IRB review and documentation of involving non-Veterans in research. CASE CLOSED.
84	06	Hampton	H	**03/24/2014**	Remedial Actions: SOP. CASE CLOSED.
85	09	Huntington	H	**03/25/2014**	Required Actions: IRB Closure Letters must be revised; expedited approvals must be in next IRB meeting minutes; Investigator must justify and IRB must review and document the review of non-Veterans in VA research; IC template must be revised; investigation drugs must be correctly labeled. CASE CLOSED.
86	09	Huntington	R	**03/25/2014**	Required Actions: R&DC must provide the ACOS/R a signed written communication regarding approved projects; review and approve the VA CIRB minutes; perform an annual review and evaluation of the VA CIRB; develop and implement SOPs for the VA CIRB. CASE CLOSED.
87	15	St. Louis	I	**04/7/2014**	Remedial Actions: Obtain approvals for VASI stored on non-VA information systems; ISO will assess unauthorized thumb drive; -non-VA IT equipment used for research will be inventoried; copies of case report forms will be retained at the VA; develop SOP for research data repository.
88	10	Cincinnati	I	**04/14/2014**	Remedial Actions: VASI on non-VA systems without approvals; MOU/ISA not accurate; unencrypted VA laptop without waiver; Inventory; ISO review; logical access controls; mobile devices in use were not approved for issuance; hard copy record storage at affiliate not consistent with facility approvals.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
89	12	Hines IL (Edward Hines)	H	**04/14/2014**	Remedial Actions: Education; submit CRADO Waiver request; ensure research activities do not start prior to receiving IRB approved amendments; train research staff on use of VA Form 10-3203 (photo/audio consent) and develop process to ensure studies requiring the use of this form have required IRB approval prior to initiation of study; develop system to review and ensure all current and future protocols, ICD and HIPAA authorizations are consistent; update procedures for the monitoring of lapse studies; and update SOP.
90	12	Hines IL (Edward Hines)	R	**04/14/2014**	Remedial Actions: Education; establish research goals and objectives; develop process to ensure subcommittee approvals are completed prior to RDC approval of studies; conduct subcommittee and program reviews; establish process to review and send subcommittee minutes to Director; update local SOPs and policies; and train all research staff on collaborative research processes. CASE CLOSED.
91	10	Cincinnati	R	**04/15/2014**	Remedial Actions: Modify ACOS notification memo; perform annual review of the CIRB; provide SOPs for the CIRB; remove expedited review procedure from the R&DC SOP. CASE CLOSED.
92	10	Cincinnati	H	**04/15/2014**	Remedial Actions: Research Pharmacy must control investigational drug receipt, storage, and dispensation; PI must prescribe investigational drugs for each subject; Research Pharmacist must verify ICDs before dispensing drug; IRB must review ICD, HIPAA, and protocol for consistency; update IRB roster.
93	22	VA Loma Linda Healthcare System	A	**04/15/2014**	Remedial Actions: Conduct the annual overheat test; offer the occupational health and safety program to individuals accessing the animal facility.
94	22	VA Loma Linda Healthcare System	S	**04/15/2014**	Remedial Actions: Conduct drills; review status of personnel access to labs semiannually. CASE CLOSED.
95	23	Fargo	R	**04/22/2014**	Remedial Actions: IRB provide signed documentation or project approvals; R&DC notifies the ACOS of project approvals via signed communication; SRS review and approve research prior to initiation, approve scopes of practice for all research staff; R&DC approve all subcommittee minutes R&DC perform annual reviews for all subcommittees; non-voting members must not be permitted to vote; all R&DC members to complete required training; SOPs. CLOSED.
96	23	Fargo	H	**04/22/2014**	Remedial Actions: Develop agreement with affiliate IRB; SOPs for use of VA CIRB; document all required information in IRB minutes; approved scopes of practice or functional statements for all research staff; RCO audit results reported to R&DC and all relevant committees in timely manner; ensure IRB correspondence with PI clearly indicates ICD version approval; ensure alternate members qualifications comparable to primary member.
97	08	Miami VA Healthcare System	H	**05/6/2014**	Remedial Actions: SOP; IRB review of protocols and amendments; initiating research procedure prior to obtaining consent; documentation of expedited review; altering IRB final minutes; ISO review after IRB; and unsecured VASI. CASE CLOSED.
98	08	Miami VA Healthcare System	R	**05/6/2014**	Remedial Actions: Correct deficiencies in R&DC reporting on Organizational Chart and review of publications. CASE CLOSED.
99	02	VA Western New York Healthcare System	R	**05/12/2014**	Remedial Actions: RDC conduct adequate annual reviews; RDC to develop objectives and evaluate; follow local policy for evaluation of the Research Subject Outreach Program; ACOS to forward CIRB minutes to MCD and COS; ACOS to review abstracts/presentations prior to publication; ACOS and RDC to conduct annual quality assurance review of CRADAs and other agreements. CASE CLOSED.
100	02	VA Western New York Healthcare System	H	**05/12/2014**	Remedial Actions: Ensure no inconsistencies between protocol, ICD and HIPAA Authorization; utilize revised HIPAA Authorization; review studies with data sets described as 'de-identified' that contained HIPAA identifiers; ensure necessary waivers are in place before PIs use identifiable information to recruit subjects. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
101	01	Bedford (Edith Rogers)	R	**05/13/2014**	Remedial Actions: Correct all identified deficiencies, including administrative staff serving as voting members on research review subcommittees; subcommittees not providing R&DC with documentation of project approvals; the R&DC failing to notify the ACOS of project approvals; and the R&DC not approving all subcommittee minutes. CASE CLOSED.
102	01	Bedford (Edith Rogers)	H	**05/13/2014**	Remedial Actions: Correct all identified deficiencies, including non-affiliated IRB members participating in IRB activities in advance of WOC appointment; required GCP/CITI training not completed by all HRPP participants; the IRB approving waivers of informed consent and HIPAA authorization that do not satisfy all required criteria; and some elements of the HRPP SOPs inconsistent with VHA policy and/or local practices. CASE CLOSED.
103	01	Bedford (Edith Rogers)	I	**05/13/2014**	Remedial Actions: Obtain approvals for VASI stored on non-VA information systems; encrypt removable media used to store VASI; encrypt VA laptops connected to research devices; obtain approval for use of non-VA wireless network used for research; inventory non-VA IT equipment used for research.
104	10	Chillicothe	I	**05/20/2014**	Remedial Actions: ISO and PO summary review; PO final reviews missing; SOPs. CASE CLOSED.
105	10	Chillicothe	R	**05/20/2014**	Remedial Actions: Document local procedures with the main facility Research Service; must have a signed waiver from ORD allowing for less than 2 IRB representatives; MOU with main Research Service and affiliate IRB needs to be updated; MCD does not receive the annual review of the main facility VA Research subcommittees, R&DC minutes or the IRB minutes. CASE CLOSED.
106	10	Columbus (Chalmers Wylie)	H	**05/21/2014**	Remedial Actions: Develop SOPs for reporting human research related unanticipated problems or research information protection incidents. CASE CLOSED.
107	10	Columbus (Chalmers Wylie)	I	**05/21/2014**	Remedial Actions: ISO and PO summary review; PO final reviews missing; SOPs. CASE CLOSED.
108	10	Columbus (Chalmers Wylie)	R	**05/21/2014**	Remedial Actions: MCD must sign appointment letters for main facility IRB and R&DC members; MOU with main facility Research Service and affiliate IRB needs to be updated; ensure MCD receives copies of main facility RDC and IRB minutes. CASE CLOSED.
109	10	Chillicothe	H	**05/21/2014**	Remedial Actions: Correct all identified deficiencies, including no signed waivers from ORD allowing for less than two IRB representatives (memo requesting waiver has been recently submitted to ORD); no SOPs for reporting human research related unanticipated problems or research information protection incidents. CASE CLOSED.
110	23	Sioux Falls VA HCS	R	**06/10/2014**	Remedial Actions: R&DC must conduct annual reviews of its subcommittees, review all final minutes; discontinue expedited review processes; improve project approval communications among subcommittees, R&DC, and ACOS. The ACOS must conduct annual quality assurance reviews. The program must notify ORO of change in IRB roster within 30 days. CASE CLOSED.
111	23	Sioux Falls VA HCS	H	**06/10/2014**	Remedial Actions: Correct all identified deficiencies, including IRB alternate members' professional specialty, qualifications, and experience not always comparable to those of the primary member for whom they could substitute; noncompliant practices for use of alternate IRB members; IRB minutes not documenting that members attending through teleconferencing had received relevant materials prior to the meeting; HIPAA authorizations not obtained from all subjects when required. CASE CLOSED
112	07	Tuscaloosa	H	**06/10/2014**	Remedial Actions: SOP; Chair served indefinitely; documenting review in minutes; using PHI for recruitment without waiver; and pharmacy procedures. CASE CLOSED.
113	07	Tuscaloosa	R	**06/10/2014**	Remedial Actions: Review publications; documenting members and vote in minutes; and annual program reviews. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
114	10	Cleveland (Louis Stokes)	R	**06/17/2014**	Remedial Actions: Pharmacy must document receipt, storage, security, labeling, dispensing, and disposition of all investigational drugs and supplies used in clinical investigations. CASE CLOSED.
115	10	Cleveland (Louis Stokes)	H	**06/17/2014**	Remedial Actions: Pharmacy must document receipt, storage, security, labeling, dispensing, and disposition of all investigational drugs and supplies used in clinical investigations. IRB must document recusals in meeting minutes. CASE CLOSED.
116	04	VA Pittsburgh Healthcare System	R	**06/23/2014**	Remedial Actions: ACOS must not send CR approval notifications to investigators before completion of all R&DC and subcommittee approvals; R&DC must ensure that the R&DC is properly constituted; local SOPs and organizational chart(s) must accurately reflect local practice and comply with VA policy; R&DC must perform annual review of VHA CIRB; facility must ensure that terms of members are compliant with local and VHA policies. CASE CLOSED.
117	04	VA Pittsburgh Healthcare System	H	**06/23/2014**	Remedial Actions: IRB must ensure that the protocols and ICDs are consistent with the HIPAA Authorizations; MCD must direct HRPP; registry protocols must comply with the requirements in VHA Handbook 1200.12.
118	04	VA Pittsburgh Healthcare System	I	**06/23/2014**	Remedial Actions: Obtain approvals for VA information and VASI stored on non-VA information systems; update the system security plan with accurate description of non-VA information systems; encrypt mobile devices and removable media used to store VASI; encrypt VA laptop connected to research devices; inventory non-VA IT equipment used for research.
119	06	Richmond (McGuire)	S	**06/24/2014**	Remedial Actions: ORO did not identify any programmatic regulatory concerns associated with the RSSP.
120	08	Tampa (James Haley)	R	**07/15/2014**	Remedial Actions: Correct deficiencies in HRPP organizational chart, R&DC SOP, and minutes documentation; missing ACOS/R&D notification; and approving non-VA research. CASE CLOSED.
121	08	Tampa (James Haley)	H	**07/15/2014**	Remedial Action: Correct deficiencies in HRPP SOP; protocol approval period; meeting minutes documentation; informed consent form and templates; and investigational drug labeling. CASE CLOSED.
122	11	Ann Arbor	R	**07/22/2014**	Remedial Actions: R&DC to separate VA vs affiliate research in their approvals; MCD to sign-off on cost-share agreements; R&DC to ensure all subcommittees approve a project before they approve it; exempt projects to be reviewed by the R&DC on an annual basis; R&DC to complete annual review of all its subcommittees; ACOS/R to conduct annual review of all research agreements; research office to stop using ACOS/R stamp of retired ACOS/R; ACOS/R to document approval of scopes of practice;
123	11	Ann Arbor	H	**07/22/2014**	Remedial Actions: IRB to determine and document protocols requiring mandatory flagging; PO and ISO to provide summary report prior to IRB review and approval; ICD template must include all required elements; RCO to provide timely audit report results to the R&DC and other relevant committees; Investigators to ensure that the research pharmacy receives all required documents.
124	19	Eastern Colorado	A	**07/22/2014**	Remedial Actions: Establishment of reporting procedures; monthly check of animal facility emergency safety shower.
125	20	Portland	E	**08/5/2014**	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
126	23	Iowa City	H	**08/12/2014**	(1) The HRPP must develop and implement procedures to ensure that the minutes of IRB-03 meetings (including all required elements) are reviewed and approved by the convened IRB. (2) The HRPP must develop and implement procedures to ensure that the minutes of IRB meetings identify those members who are participating by audio/video conference. (3) The HRPP must develop and implement procedures to ensure that actions by the Chair (or designated reviewer) to approve the clearance of minor conditions for study approval are documented in the minutes of the next IRB meeting. (4) The HRPP must develop and implement procedures to ensure that complete minutes of IRB meetings (containing all required elements), reviewed and approved by the convened IRB, are submitted to the R&DC.
127	23	Iowa City	R	**08/12/2014**	Lack of required reviews and approvals; non-compliant R&DC operations; lack of R&DC SOPs
128	11	Battle Creek	R	**08/19/2014**	The MCD must receive the R&DC meeting minutes that contain actions related to the facility; either the Research Coordinator's research records must contain all documents required in the facility's SOPs or the SOPs must be revised; the MOU between this facility and the facility operating the R&DC and IRB must be updated. CASE CLOSED.
129	11	Battle Creek	H	**08/19/2014**	Investigator's research records must include all required documents; progress notes must be entered into CPRS for follow-up research visits, when appropriate; research subject's medical records in CPRS must be flagged when the IRB determines flagging is appropriate. CASE CLOSED.
130	11	Saginaw (Aleda E. Lutz)	R	**08/27/2014**	(1) The MCD must delegate an ACOS/R&D or C for R&D within the facility to manage the research program. (2) SOPs must be updated to distinguish the responsibilities of the facility ACOS/R&D (or C for R&D) from those of the affiliated VA facility's ACOS/R&D. (3) VISN Director must continue to serve as a signatory to the MOU, if the affiliated VA facility's R&D office will continue to assume administrative responsibilities for the facility research program. (4) Current MOU between the facility and the affiliated VA facility must be updated to reflect changes to the agreement. (5) A process to ensure that the facility ACOS/R&D (or C for R&D) approves scopes of practice for each member of the research team must be developed, documented in an SOP, and communicated to the research community.
131	11	Saginaw (Aleda E. Lutz)	H	**08/27/2014**	(1) The IRB must review all HIPAA waivers to ensure the IRB Chair or qualified voting member had signed and dated the HIPAA waiver form. The IRB must determine corrective actions for invalid HIPAA waivers. (2) The PO must review all protocols with valid HIPAA waivers to ensure all criteria is present and provide final documentation that the protocol meets all VA privacy requirements. (3) The RCO must provide a report of all audit results to the IRB in a timely manner. (4) Revise ICD template and review all active ICDs for appropriate inclusion of federal agency statement. (5) Review and revise all active ICDs to ensure the version date is listed in the header or footer or the ICD.
132	06	Salisbury (Hefner)	I	**09/22/2014**	(1) Obtain appropriate documentation for storage of PHI at affiliate. (2) Additional training to the research oversight committees and investigators with respect to de-identification of data, in particular, with respect to de-identification of dates directly related to an individual. (3) The Research Service must work with the ISO to ensure that all researchers who transport, transmit, download, and/or store VA sensitive information (all formats and media) outside of the VA obtain written approvals by their VA supervisor; otherwise the VASI must remain and/or be returned to the facility. (4) Facility must ensure that all CDs containing research-related VASI are protected with FIPS 140-2 certified encryption when possible, or else the required approvals must be obtained, and the noted instance of noncompliance must be remediated.
133	00	VA Central Office HRPP	H	**09/24/2014**	1) Establish all required protocol files, and verify that all required documentation is retained in established files. (2) Establish and implement procedures to ensure that expedited review decisions and eligibility categories are consistently included in the IRB minutes of the next convened meeting. (3) Establish and implement procedures to ensure that draft minutes are available for review within 3 weeks of the meeting.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
134	16	Central Arkansas (Little Rock)	H	**10/24/2014**	(1) Revise SOPs. (2) Revise ICD. (3) Revise authorization and template. CASE CLOSED.
135	16	Central Arkansas (Little Rock)	R	**10/24/2014**	Improve meeting minutes documentation. CASE CLOSED.
136	19	Eastern Colorado (Denver)	H	**10/30/2014**	(1) The HRPP SOP must be modified to clarify that substantive changes cannot be made to projects without IRB review and approval. (2) The HRPP must ensure that the R&DC SOP is modified to clarify that substantive changes cannot be made to human subject research protocols without IRB review and approval. (3) The HRPP must ensure that the ACOS/R&D approval letters do not imply (or indicate) that a human subject research protocol was modified by the R&DC without review and approval by the IRB.
137	19	Eastern Colorado (Denver)	R	**10/30/2014**	(1) The R&DC must develop and implement procedures to ensure that it serves as the committee of record for all required reviews (i.e., initial, continuing, and modification reviews) and approvals of protocols not assigned to a subcommittee. (2) The R&DC must review its research portfolio and ensure that all applicable protocols receive appropriate R&DC review. (3) The program must develop and implement a plan to ensure that all personnel-related requirements are consistent with (minimum) VHA requirements and applicable local SOPs. (4) The program must remediate specific personnel-related deficiencies identified in the report. (5) ACOS/R&D must conduct an annual quality assurance review to ensure all research employees involved in human subject research are working within their scopes of practice and privileges. (6) MCD must appoint alternate R&DC members in writing.
138	01	Central Western Massachusetts	R	**10/30/2014**	(1) R&DC must develop broad objectives for research program. (2) R&DC must perform subcommittee and program reviews. (3) R&DC must ensure that all committee and subcommittee members are properly appointed. (4) R&DC meeting minutes must capture the voting categories, document recusals and indicate quorum present for vote. (5) SRS must be properly constituted.
139	01	Central Western Massachusetts	H	**10/30/2014**	(1) Facility to revise local SOP 'Reporting Research Events and Problems'. (2) Privacy Officer reviews must be completed.
140	15	Kansas City	R	**11/07/2014**	(1) The R&DC must discontinue the use of expedited review and modify local SOPs to reflect this correction. (2) The R&DC must ensure that all substantive modifications to IRB approved protocols are re-reviewed by the IRB. Local SOPS should reflect this change in procedure. (3) A process should be put in place to ensure all staff and committee members have completed training requirements in a timely manner. Local SOPs should reflect a plan to discipline those not in compliance. (4) A plan must be implemented to collect financial conflict of interest forms at continuing review. Local SOPs should reflect this practice.
141	15	Kansas City	H	**11/07/2014**	(1) The IRB must re-review and approve all actions items approved at the improperly constituted convened meeting at a convened meeting with an appropriate quorum. (2) The IRB must ensure that changes in PI are submitted to the IRB for review and approval. (3) The IRB must ensure that PIs submit protocol modifications to the IRB for review and approval. (4) The IRB must ensure that changes in PI are submitted to the IRB for review and approval. (5) The PO must submit a final report to IRB staff after the IRB approves a waiver of HIPAA authorization.

Case	VISN	Facility	Focus	Date of Review	TABLE 1B. PROACTIVE ROUTINE ONSITE REVIEWS (FULL REPORT AVAILABLE UPON REQUEST)
142	18	Southern Arizona (Tucson)	I	**11/21/2014**	(1) The Research Service and OI&T must take immediate steps to ensure that when sensitive research information entrusted to the VA is transmitted using web-based application, the transmissions are encrypted using FIPS 140-2 validated encryption when transmitted. Otherwise, the Research Service and OI&T must apply for a Deputy Assistance Secretary for the Office of Information Security (DAS OIS) risk based decision (RBD) to allow for transmissions that are encrypted using modules that have not been FIPS 140-2 validated. (2) The facility must develop a plan to ensure that all uses of mobile devices for research have been first authorized by the facility CIO and that all request and registration requirements have been met. The instances of non-compliance identified in this Finding must be remediated. (3) The mobile devices identified in the Finding must be encrypted using FIPS 140-2 validated encryption. If encryption is not technically possible, the required documentation and approvals must be obtained. (4) The Research Service must work with OI&T staff to ensure that all research folders on the facility network, including the folders identified in this Finding, are properly configured to allow only authorized staff access to those folders.
143	03	Hudson Valley	H	**11/24/2014**	(1) R&DC must perform an annual review of the R&D program. (2) Facility must create a facility organization chart that displays relationships between the IO, COS, Research Service, R&DC Subcommittees, and affiliated VAMCs. (3) MOUs, FWAs, and SOPs must be developed according to procedures in inter-institutional MOU and in compliance with VA policies.
144	03	Hudson Valley	R	**11/24/2014**	(1) The R&DC must perform the required annual review of the facility R&D program. (2) Reporting lines and relationships must be clearly described. (3) Facility MCD and COS must be recognized as nonvoting members of the R&D Committee. (4) The MOU must be revised for consistency and to comply with VA requirements.
145	18	Phoenix	H	**12/11/2014**	The HRPP must ensure that its SOPs are consistent and compliant with current VHA requirements.
146	18	Phoenix	R	**12/11/2014**	(1) R&DC subcommittees must provide the R&DC with signed notifications of project approvals. (2) The ACOS/R&D must consistently communicate R&DC and subcommittee approvals to PIs. (3) The R&DC must conduct a thorough review of the ACUP, including the affiliate IACUC. (4) The R&DC must approve all subcommittee minutes.
147	16	Houston (DeBakey)	H	**12/12/2014**	(1) Revise SOP; (2) Revise ICD template and determine actions needed for noncompliant ICDs used; (3) Obtain completed record and audit all drug logs to ensure real-time records.
148	16	Houston (DeBakey)	R	**12/12/2014**	(1) Conduct substantive review of each exempt protocol. (2) Revise SOP and conduct business only at convened meetings. (3) Ensure quorum present when conducting business, determine actions needed for meetings conducted without quorum. (4) Ensure alternate member appointment meets VHA requirements.
149	15	Wichita (Dole)	R	**12/18/2014**	(1) ACOS must implement the process of notifying investigators of RDC and subcommittee approvals. This process must be added to the RDC SOP. (2) ACOS must implement a process whereas CRADAs, MOUs, and other agreements are reviewed by the ACOS. Results must be reported to the RDC on an annual basis. This process must be added to the RDC SOP. (3) The RDC roster must be revised to include all facility ex officio nonvoting members. The RDC meeting minutes must include all facility members in the attendance record of the meeting.
150	15	Wichita (Dole)	H	**12/18/2014**	(1) Training to make PIs who conduct investigational drug study aware of the required documentation in the subject's health record. Update Investigational Drug policy. (2) PO must provide a final review for all active protocols in which the IRB granted a waiver of HIPAA authorization. In the future, this final review must be provided for all protocols.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS

ORO onsite technical assistance reviews constitute an additional proactive approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Onsite technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Summary

- 8 = Case Continuing from Previous Calendar Year
- **11 = New Cases – January 1 through March 31**
- **21 = New Cases – April 1 through June 30 ***
- **14 = New Cases – July 1 through September 30**
- **18 = New Cases – October 1 through December 31**
- 64 = Total New Cases in Calendar Year
- 72 = Total Cases (Continuing Plus New) in Calendar Year

***** Case #27 was inadvertently omitted from the 2nd Quarter report.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	TECHNICAL ASSISTANCE PROVIDED
1	22	VA Greater Los Angeles HS	A	06/15/2011	Technical Assistance: Follow-up to review and provide guidance on remedial actions from previous on-site review. New compliant animal unit HVAC system per facility-wide upgrades. CASE CLOSED.
2	06	Asheville	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.
3	06	Durham	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.
4	06	Salem	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.
5	06	Salisbury (Bill Hefner)	S	02/18/2013	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	TECHNICAL ASSISTANCE PROVIDED
6	23	Fargo	E	12/11/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
7	22	VA Greater Los Angeles HS	A	12/16/2013	Technical Assistance: Confirm that all issues associated with the routine review of the ACUP performed June 2010, and the subsequent TAV conducted in June 2011 were resolved.
8	08	Orlando	I	12/17/2013	Technical Assistance: RISP review of information security and privacy policies and procedures for the research program. CASE CLOSED.
9	05	Washington DC	H	01/06/2014	Technical Assistance: Observed IRB meeting - IRB tabled 4 studies without summarizing contingencies or voting; deviation report contained 12 pp. of scanned CPRS notes & PHI, no comment on inappropriate disclosure. CASE CLOSED.
10	05	Washington DC	H	01/27/2014	Technical Assistance: Observations: ACOS/R as rights POC on ICDs; primary reviewer's expertise mismatched assigned study; ACOS/R assigns scientific reviewers for IRB and RDC; contingent approval for CR substantive changes; incomplete and late packets. CASE CLOSED.
11	21	San Francisco	A	02/23/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; visit to animal research facility. CASE CLOSED.
12	05	Washington DC	H	02/24/2014	Technical Assistance: Observations: IRB failed to determine whether fabricating an "IRB approved" ICD was serious; and PI's history of changes without IRB approval was continuing. IRB reviewed collaborating facility event when both collaborating facility reps were absent. Report to MCD. CASE CLOSED.
13	12	Hines IL (Edward Hines)	I	02/24/2014	Technical Assistance: Research data repositories; proposed Research Biomed IT model; System Security Plans; research data access, storage and backup; VASI on external system approval process; removable media encryption; changes in VA policy since last review; facility training system. CASE CLOSED.
14	08	Bay Pines	A	02/25/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; VA /affiliate institutional relationships and use of MOUs. CASE CLOSED.
15	08	Tampa (James Haley)	A	02/26/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.
16	08	Tampa (James Haley)	S	02/26/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.
17	16	Central Arkansas (Little Rock)	E	02/27/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
18	16	Oklahoma City	E	03/11/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
19	06	Salem	E	03/26/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
20	05	Washington DC	H	04/7/2014	Technical Assistance: Recommend establishing educational forum for IRB members; increased IRB knowledge of expedited review criteria; full board review of tabled study; potential COI issues for IRB staff; improved SAE reviews by IRB. CASE CLOSED.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	TECHNICAL ASSISTANCE PROVIDED
21	21	VA Central California HCS	E	04/15/2014	Technical Assistance: Reviewed audit plan; interpersonal communication and dynamics with research program; decision support systems in research program office and RCO office; and progress towards audit goals. CASE CLOSED.
22	05	Washington DC	E	04/21/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
23	05	Washington DC	H	04/27/2014	Technical Assistance: Minutes from the two telephonically convened IRB meetings must be provided for review and approval by the IRB; recommend that the IRB Agenda format currently used should be modified to integrate study submissions with reported SAEs, unanticipated problems, protocol deviations and audit reports in order to provide a more comprehensive, integrated approach to IRB study reviews; PO/ISO checklists completed and timely summary report to IRB; expedited study rescheduled for full board. CASE CLOSED.
24	21	VA Northern California HCS	A	05/6/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA/affiliate institutional relationships and use of MOUs; protocol and research record file management.
25	21	VA Northern California HCS	S	05/6/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA/affiliate institutional relationships and use of MOUs; protocol and research record file management.
26	21	VA Central California HCS	S	05/9/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA/affiliate institutional relationships and use of MOUs; Common RSSP Routine Review findings. CASE CLOSED.
27	15	Wichita	E	05/13/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
28	17	VA North Texas HCS	A	05/13/2014	Technical Assistance: Discuss ACUP updates, local compliance program management, and post-approval monitoring. CASE CLOSED.
29	17	VA North Texas HCS	S	05/13/2014	Technical Assistance: Present overview of common ORO Routine Review Findings and discuss SRS and/or IBC logistics and impact of safety program on other research areas. CASE CLOSED.
30	17	Central Texas Veterans HCS	A	05/14/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA/affiliate institutional relationships and use of MOUs. CASE CLOSED.
31	17	Central Texas Veterans HCS	S	05/14/2014	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA/affiliate institutional relationships and use of MOUs. CASE CLOSED.
32	05	Washington DC	H	05/19/2014	Technical Assistance: ACOS/R must avoid active engagement in IRB deliberations; IRB needs to familiarize itself with relevant sections of VHA Handbook 1058.01 (e.g. Chapter 7); IRB should waive documentation of informed consent when appropriate (VHA Handbook 1200.05, Chapters 30-36). CASE CLOSED.
33	05	Washington DC	H	06/9/2014	Technical Assistance: It was noted that the IRB reviewed and tabled a study on patients with acute decompensated heart failure, recruited through the emergency room without discussing VA policy on planned emergency research; IRB members received an outdated ICD but approved a revised version including substantive changes based on an oral description from the primary reviewer. ORO suggested that IRB members review VHA Handbook 1200.05 and FDA regulations on planned emergency research and that all IRB members received complete submissions, including ICDs, before the meeting. CASE CLOSED.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	TECHNICAL ASSISTANCE PROVIDED
34	15	Columbia MO (Harry Truman)	A	**06/10/2014**	Technical Assistance: Discuss ACUP updates, local compliance program management, protocol and records management, training requirements, and oversight of off-site research.
35	15	Columbia MO (Harry Truman)	S	**06/10/2014**	Technical Assistance: Present overview of common ORO Routine Review Findings; discuss SRS logistics and impact of safety program on other research areas.
36	15	Kansas City	A	**06/10/2014**	Technical Assistance: Animal facility and laboratory inspections; review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
37	15	Kansas City	S	**06/10/2014**	Technical Assistance: Animal facility and laboratory inspections; review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
38	23	VA Nebraska-Western Iowa HCS	E	**06/17/2014**	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals.
39	06	Richmond (HH McGuire)	A	**06/24/2014**	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs. CASE CLOSED.
40	05	Washington DC	H	**06/30/2014**	Technical Assistance: Observe IRB meeting to address quorum questions raised in previous meeting. CASE CLOSED.
41	10	Cleveland (Louis Stokes)	H	**07/09/2014**	Technical Assistance: ORO assisted assist facility to develop compliant research pharmacy oversight of all investigational drugs and supplies. CASE CLOSED.
42	05	Washington DC	H	**07/15/2014**	Noted that IRB gave contingent protocol approval based on unspecified changes (rewrite) to ICD recommended stating specific changes as part of the motion. Quorum issues continued. IRB was unable to review study with affiliated facility component because representative members were unable to connect via video or conference call. Recommended seeking IRM support and using relatively low-tech back-up methods (cell phone on speaker) to ensure remote reps' participation. CASE CLOSED.
43	22	Southern Nevada	H	**7/17/2014**	Technical Assistance: ORO recommendations: Research Advisory Committee should be the first reviewer of human subjects research protocols; Research Pharmacist position work load should be scalable; the pharmacy residency coordinator should submit a request to the IRB to lift the suspension to permit new retrospective chart review studies; Facility should continue to explore alternatives to the main facility IRB and R&DC. CASE CLOSED
44	12	Hines IL (Edward Hines)	H	**07/21/2014**	Attended IRB meeting with open dialog after the meeting concerning definition of serious or continuing noncompliance and apparent systemic problem related to HIPAA issues. Observed lack of engagement by Research Service management. Discussed with research management IRB staffing and operational issues and interviewed new AO and had open dialog on her indoctrination. Discussed with facility and research management unfilled IRB Coordinator positions and discussed stand-up of the new R&DC. CASE CLOSED.
45	16	Southeast Louisiana Veterans	E	**07/22/2014**	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
46	19	Eastern Colorado	S	**7/22/2014**	Technical Assistance: Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	TECHNICAL ASSISTANCE PROVIDED
47	05	Washington DC	H	**8/11/2014**	Provided assessment that IRB review process was not organized resulting in difficulty for video or teleconference participants to follow the discussions and engage in the reviews; provided guidance that review discussions should reference VA and other regulations as appropriate. CASE CLOSED.
48	05	Washington DC	H	**9/8/2014**	IRB gave contingent protocol approval based on unspecified changes (rewrite) to ICD recommended stating specific changes as part of the motion. Quorum issues continued IRB was unable to review study with affiliated facility component because representative members were unable to connect via video or conference call. Recommended seeking IRM support and using relatively low-tech back-up methods (cell phone on speaker) to ensure remote participation. CASE CLOSED.
49	16	Gulf Coast (Biloxi)	E	**09/09/2014**	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
50	16	Muskogee (Jack Montgomery)	H	**9/16/2014**	Onsite TA was conducted as scheduled including an interview with facility Director and Chief of Staff, and an education session for research management team and review committees. CASE CLOSED.
51	16	Muskogee (Jack Montgomery)	R	**9/16/2014**	Onsite TA was conducted as scheduled including an interview with facility Director and Chief of Staff, and an education session for research management and review committees. CASE CLOSED.
52	07	Atlanta	E	**09/22/2014**	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
53	12	Captain James A. Lovell FHCC	R	**09/22/2014**	Discussed with current Acting MCD the VA/DoD collaboration and effects on research program. Discussed with research administration challenges facing research program, activation of the R&DC, staffing; and SOPs and organizational chart and process flow charts. Interviewed RCO and he defined his involvement in extra facility committees. Attended mock R&DC meeting and had an open dialog with the R&DC Chair and members. Stressed their role and responsibilities of oversight of the research program. CASE CLOSED.
54	05	Washington DC	H	**09/30/2014**	(1) The IRB considered a waiver of documentation of consent involving use of a patient information sheet. Discussion did not clarify whether the IRB intended to require a full consent process including the elements in 38 CFR 16.116(a). The patient information sheet omitted several required elements. (2) The ACOS/R announced that he is revising the scopes of practice policy, but the IRB failed to complete their deliberations on whether residents engaged in research required a scope or functional statement.
55	06	Hampton	E	**10/3/2014**	Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
56	07	Charleston (R Johnson)	A	**10/7/2014**	Review of applicable VHA handbooks, policies and directives; Federal regulations; VA/affiliate institutional relationships; Protocol and research record file management.
57	07	Charleston (R Johnson)	S	**10/7/2014**	Review of applicable VHA handbooks, policies and directives; Federal regulations; VA/affiliate institutional relationships; Protocol and research record file management.
58	05	Washington DC	H	**10/16/2014**	(1) Consulted with IRB chair immediately after IRB meeting and 10 days later, via phone discussed IRB's obligation to address scientific design regarding IRB approval criteria (specifically, that risks must be minimized through sound research design, and risks must be reasonable in relation to anticipated benefits). Chair agreed to discuss with mentor and explore ways to improve board's capacity for evaluating these issues.

TABLE 1C. PROACTIVE TECHNICAL ASSISTANCE ONSITE REVIEWS
(FULL REPORT AVAILABLE UPON REQUEST)

Case	VISN	Facility	Focus	Date of Review	TECHNICAL ASSISTANCE PROVIDED
59	22	Long Beach	S	**10/29/2014**	Review of applicable VHA handbooks, policies and directives and Federal regulations; Laboratory safety basics; Chemical Hygiene Plan; Hazardous waste; Fire protection; Biosafety cabinets and laboratory fume hoods.
60	22	Long Beach	A	**10/29/2014**	Review of applicable VHA handbooks, policies and directives; Federal regulations; Collaborations with other institutions.
61	22	San Diego	A	**10/29/2014**	Review of applicable VHA handbooks, policies and directives; Federal regulations; RCO audit requirements; VA / affiliate institutional relationships and use of MOUs.
62	22	San Diego	S	**10/29/2014**	Review of applicable VHA handbooks, policies and directives and Federal regulations; Laboratory safety basics; Chemical Hygiene Plan; Hazardous waste; Fire protection; Biosafety cabinets and laboratory fume hoods.
63	04	Clarksburg (L Johnson)	E	**11/13/2014**	Technical Assistance for new RCO. No regulatory concerns and no action required. CASE CLOSED.
64	05	Washington DC	H	**11/17/2014**	Technical Assistance to new IRB Chair and members regarding requirements of VA Handbooks, the Common Rule, and the Belmont Report principles, including standards for determinations of serious or continuing noncompliance with consideration of systemic protections.
65	01	Providence	R	**11/24/2014**	Consultation on R&DC operations and SOPs. No regulatory concerns noted.
66	10	Cleveland (Stokes)	A	**12/10/2014**	(1) Review of applicable VHA handbooks, policies and directives; Federal regulations; VA/affiliate institutional relationships; Protocol and research record file management.
67	10	Cleveland (Stokes)	S	**12/10/2014**	(1) Review of applicable VHA handbooks, policies and directives; Federal regulations; VA/affiliate institutional relationships; Protocol and research record file management.
68	21	Palo Alto	E	**12/10/2014**	Evaluation of RCO program. No regulatory concerns. No action required. CASE CLOSED.
69	21	San Francisco	E	**12/11/2014**	Evaluation of RCO program. No regulatory concerns. No action required. CASE CLOSED.
70	18	New Mexico (Albuquerque)	H	**12/17/2014**	(1) Implementation of Internal IRB. (2) Implementation of policies and procedures relating to the HRPP and the constitution of an internal VA IRB. (3) Updating SOPs to reflect new VHA Handbook 1200.05. CASE CLOSED.
71	20	Boise	A	**12/18/2014**	(1) Review of applicable VHA handbooks, policies and directives; Federal regulations; VA/affiliate institutional relationships; Protocol and research record file management.
72	20	Boise	S	**12/18/2014**	(1) Review of applicable VHA handbooks, policies and directives; Federal regulations; VA/affiliate institutional relationships; Protocol and research record file management.

TABLE 2. REMOTE RESEARCH COMPLIANCE REVIEWS

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Certain compliance cases can be evaluated and managed remotely through written communications with facility leadership and facility compliance personnel. Among these reviews are remote reviews of apparent noncompliance that have been identified by sources external to the facility's HRPP. Such sources include, but are not limited to, apparent noncompliance identified by ORO, by other VA offices, by government regulatory agencies, and by industry sponsors. Table 5 summarizes ORO's remote reviews of apparent noncompliance identified by such external sources. NOTE: Cases under the jurisdiction of additional offices (for example, OIG or FDA) or involving physical infrastructure improvements may remain open for extended periods.

Summary

- 42 = Cases Continuing from Previous Calendar Year
- **47 = New Cases – January 1 through March 31**
- **37 = New Cases – April 1 through June 30**
- **157 = New Cases – July 1 through September 30**
- **40 = New Cases – October 1 through December 31**
- 281 = Total New Cases in Calendar Year
- 323 = Total Cases (Continuing Plus New) in Calendar Year

***** Case #15 and Case #19 were inadvertently omitted from the 1st Quarter report.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	07 MA	Atlanta	I	06/16/2010	A physician's assistant recorded patient data on a personal laptop for unknown purposes; then left the VA. Data return was requested. Destruction of the information could not be confirmed.	Remedial Actions: OIG criminal investigation; results pending.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
2	00	VA Central Office	R	04/03/2013	The FDA reported to ORO that one VA facility conducting a VA Cooperative Study clinical trial of treatment of schizophrenia appeared to be overdue to submit study results to the *ClinicalTrials.gov* database.	Remedial Actions: CSP is determining software modifications to access and post all required data points, this will require major programming; as interim measure, CSP posted 5 study publications in the website's study results section and responded to comments from *ClinicalTrials.gov* quality assurance personnel. CASE CLOSED.
3	09	Memphis	I	04/19/2013	NSOC reported that Ex-employee A found some old disks, flash drives and folders on her personal computer containing research files with VA patient first initial of last name plus the last 4 of the SSN, admission dates, discharge dates and some dates of death for approximately 172 Veterans.	Remedial Actions: Ex-employee returned storage devices to the VA; OIT scrubbed devices except zip drives that contain original data; facility unable thus far to locate software to transfer data to secure network storage; zip drive locked securely in research office. CASE CLOSED.
4	00	VA Central Office	H	08/05/2013	A participating site in the Million Veterans Program may have collected blood specimens prior to obtaining written informed consent to participate in the study in as many as 1,000 Veterans.	Remedial Actions: Enrollment suspended at the site, site personnel deactivated in the recruitment/enrollment application, site visit being scheduled, training provided to local study team, and notification letter sent to potentially affected participants. CASE CLOSED.
5	05	VA Maryland HCS	P	08/20/2013	OIG hotline referral with several allegations related to HRPP, Info Security, and misconduct in the facility's GRECC - facility response is due to OIG 10.08.13.	Remedial Actions: IRB suspended 7 studies due to safety concerns; most suspensions lifted with no further biopsies; PIs to increase oversight of protocol & coordinator, revise SOPs re PI oversight; PIs to certify coordinator's competence to perform assigned tasks; CRs reduced to 6 months. CASE CLOSED.
6	00	VA Central Office	I	09/09/2013	NSOC reported that the informed consent document and HIPAA authorization of one participant at a local study site of a VA multicenter study were lost.	Remedial Actions: Re-consent obtained, subject to receive a HIPAA letter of notification, and refresher training provided to study staff. CASE CLOSED.
7	16	Central Arkansas (Little Rock)	H	10/03/2013	Sponsor notified the facility that treatment Arm A in this high-risk melanoma study is suspended due to a greater number of grade 5 serious adverse events than expected. The local facility does not have any subjects enrolled in Arm A.	Remedial Actions: PI to close Arm A; provide IRB with revised protocol, ICD and other related documents concerning the closure of Study Arm A. PI to obtain justification from Sponsor and/or DMSB to reopen Study Arm A. CASE CLOSED.
8	15	St Louis	I	10/09/2013	NSOC reported research protocols and other information were stored on a server without the proper permissions. PHI included one file with names and last four of 100 patients.	Remedial Actions: OIT staff has correctly permissioned the folders; going forward, access will be granted only upon email request from ACOS and/or AO. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
9	20	Portland	I	11/05/2013	NSOC reported ICDs containing first, last name and last 4 SSN for two participants in a VA tinnitus research study were inadvertently placed in the incorrect mailers. Veteran A notified the team of the occurrence & will mail back the form. Veteran B will return the envelope unopened upon receipt.	Remedial Actions: Veteran A returned Veteran B's ICF; the envelope containing Veteran A's ICF was returned to the VA unopened; HIPAA notification letter being prepared for Veteran B; checklist for ICF mailings deemed adequate by the IRB and will be initiated. CASE CLOSED.
10	19	VA Salt Lake City HCS	I	11/07/2013	NSOC reported transmission of an unencrypted email from an affiliate to a VA research coordinator requesting that a previous VA research participant be contacted for another affiliate study. PHI included name, affiliate medical record number and imaging date.	Remedial Actions: Email recipients instructed to permanently delete the message; reminder sent to properly encrypt sensitive messages; PO determined the particular data was not VA data. CASE CLOSED.
11	08	VA North Florida/South Georgia HCS	H	11/13/2013	NSOC reported a research study coordinator obtained informed consent but overlooked the HIPAA authorization required with the study protocol.	Remedial Actions: PI and study coordinator education on consenting procedures including HIPAA authorizations; PI to educate study staff; data collection or disclosures on hold until authorizations signed; authorization obtained from one subject; PI to conduct weekly enrollment audits. CASE CLOSED.
12	18	New Mexico VA HCS	I	11/20/2013	NSOC reported several missing laptops and computers belonging to the research service. Records indicate the laptops were most likely turned in; however the turn-in process was not completed as required. Documentation provided attested the laptops were either encrypted or did not contain PHI.	Remedial Actions: Research Service will conduct a manual inventory and track equipment that may contain PHI; CIO implemented an improved accountability process for all IT equipment. CASE CLOSED.
13	23	Iowa City	H	11/21/2013	DSMB identified safety concerns in an advanced liver cancer study (potential imbalance in treatment-related deaths between the two study arms) and suspended enrollment. Facility had enrolled two subjects into this trial.	Remedial Actions: Temporary suspension of new enrollment; further resolution pending DSMB review. CASE CLOSED.
14	11	Indianapolis (Roudebush)	H	11/22/2013	Facility reported the affiliate IRB suspended this multiple myeloma treatment study due to increase in the frequency of myelosuppressive adverse events.	Remedial Actions: Sponsor amending the protocol to a lesser drug dose, IRB suspended study until amendment presented to Committee. CASE CLOSED.
15	16	*Central Arkansas (Little Rock)	I	11/25/2013	Facility reported Veteran research PHI for 610 participants in three protocols and from 2,349 participants in one protocol was found during EOC rounds in an unlocked cabinet in an unlocked room. Upon discovery, records were immediately secured by the Research Administration	Remedial Actions: RCO conducted for-cause audit; Facility Service Leader wide record inventory and security attestation; research records have been secured or submitted to Research for storage; R&D to develop action plan to ensure all research records have been secured. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
16	16	Central Arkansas (Little Rock)	I	11/26/2013	NSOC reported that research data on 65 subjects in spreadsheet format had not been moved from an email mailbox to a network drive and was inadvertently deleted when a Research Co-Investigator left the VA. The report stated no privacy violation occurred. The study is being administratively closed.	Remedial Actions: Must ensure process of requesting network folder to store data and subsequent storage of data. CASE CLOSED.
17	23	Minneapolis	H	11/26/2013	DSMB notified facility to suspend enrollment in this advanced liver cancer study due to safety concerns (potential imbalance in treatment-related deaths between the two study arms). Two subjects had been enrolled at facility but previously withdrawn due to disease progression.	Remedial Actions: Approved a protocol amendment to change the enrollment criteria. CASE CLOSED.
18	08	VA Caribbean HCS (San Juan)	H	11/26/2013	Facility reported that 27 ICDs for a study of blood glucose after facet joint, epidural and trigger point injections were not scanned into CPRS within 2 business days as required by site SOP.	Remedial Actions: The PI submitted all twenty-seven ICDs and HIPAAs for scanning; in addition, re-training of the research team was completed. CASE CLOSED.
19	18	*Phoenix VA HCS	I	11/26/2013	NSOC reported inadvertent transmission of an internal unencrypted email to an incorrect recipient with a payment voucher attachment containing name and last four SSN of up to 38 research participants.	Remedial Actions: PO received confirmation all copies of the email were deleted from Outlook; research staff trained to encrypt emails with payment voucher attachments; Research Service wide dissemination of Federal Record and retention educational materials provided by Records Manager. CASE CLOSED.
20	03	VA New York Harbor HCS	I	12/04/2013	NSOC reported a folder containing 25 research consent forms went missing. The forms contained the subject's full name and full SSN. None of the forms had been scanned into the medical records.	Remedial Actions: Letters offering credit protection services were sent; IRB allowed use of data because a former ICD audit had found that the subjects had signed consent for this minimal risk study; RCO to audit all other PI's studies with informed consent. CASE CLOSED.
21	12	Milwaukee (Zablocki)	I	12/05/2013	NSOC reported a missing desktop computer used for research. The last known inventory date was Dec 2012. A second search was unsuccessful and research personnel had no information about its current location.	Remedial Actions: Immediate inventory of all research equipment, secure storage of computers with PII or PHI stored securely if not in use; tag VA equipment more clearly; subsequently determined PC did not store PII/PHI. CASE CLOSED.
22	02	VA Western New York HCS	I	12/06/2013	NSOC reported that facility research department cannot find two desktop computers assigned to their inventory list. Investigation underway to determine if PHI was involved.	Remedial Actions: Inventory completed in research building; frequency of inventories will be increased; Research Department Staff reeducated on importance of safeguarding equipment and reporting lost IT equipment in a timely manner; no PHI based upon facility investigation. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
23	08	VA North Florida/South Georgia HCS	I	12/10/2013	NSOC reported an unencrypted research VA laptop used for three pulmonary studies was missing from a locked room that was only accessible by electronic key. Subject initials and DOB were entered; then pulmonary fitness test data were collected.	Remedial Actions: Key-card audit entry locking system is now connected and working properly; backup copies of data available from server; laptop replaced, encrypted and secured via cable; laptops will be tracked on the proper IT inventory; report of survey. CASE CLOSED.
24	00	VA Central Office	I	12/11/2013	NSOC reported ICDs and HIPAA authorizations were missing for two participants at one site of the Million Veteran Program study. A search for the documents is ongoing.	Remedial Actions: Facility contacted the two participants, who both declined to re-sign ICD and HIPPA authorization documents and were withdrawn from the study. CASE CLOSED.
25	09	VA Tennessee Valley HCS	I	12/11/2013	NSOC reported ICDs and HIPAA authorizations are missing for two MVP participants. A search for the documents was unsuccessful.	Remedial Actions: The two participants declined to re-sign an ICD and HIPAA authorization; no data or specimens collected for the participants can be used; both participants were withdrawn from the study. CASE CLOSED.
26	05	Washington DC	H	12/13/2013	NSOC reported that research PHI (participants' initials) was shared with a non-VA facility (affiliate) on a study on palliative care in people living with AIDS.	Remedial Actions: PI and study team retrained on handling and safeguarding PHI during research, and attend upcoming research compliance education seminar. CASE CLOSED.
27	00	VA Central Office	H	12/13/2013	CIRB reported that an expired coronary stent was implanted in a study participant at one study site. The patient does not appear to have been harmed.	Remedial Actions: Patient advised of the event and is stable in clinical follow-up 18 months after the event. CASE CLOSED.
28	00	VA Central Office	H	12/13/2013	CIRB reported that the study coordinator at one site of a multicenter study of tests for detection of colon cancer consented a participant 30 minutes after the participant had received medications that could impair decision making.	Remedial Actions: Consent invalidated, study coordinator received additional training; CSP Coordinating Center verified no other participating site was using this type of invalid consent process. Subject notified he is not enrolled in the study. CASE CLOSED.
29	00	VA Central Office	H	12/13/2013	CIRB reported that the overall PI for a multicenter study of tests for detection of colon cancer found there was no protocol procedure for follow-up to ensure subjects received and returned test kits, resulting in delay in the diagnosis of cancer in one patient and the risk of delay for others	Remedial Actions: Participating sites notified of issue; study team implemented a reporting/monitoring system to identify pending test kits requiring follow-up; test kits were mailed to study participants. CASE CLOSED.
30	00	VA Central Office	H	12/13/2013	The VA Central IRB determined that an SAE occurring in a multi-center study of treatment for depression was possibly related to the research. A participant experienced weakness, lightheadedness, fainting, heaviness in the chest and tingling/numbness in the extremities due to hyperventilation.	Remedial Actions: The participant recovered uneventfully and the IRB did not require any further action. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
31	00	VA Central Office	H	12/13/2013	The VA CIRB found numerous instances of insufficient and inadequate study documentation in the conduct of a multicenter study of treatment for high blood pressure at one study site.	Remedial Actions: Local study coordinator relieved of her position; Regulatory Audit by local RCO and site visit by National Study Team. CASE CLOSED.
32	06	Durham	I	12/17/2013	NSOC reported a research participant failed to return two devices used for smoking cessation, despite promises to return the devices. No identifiers are contained on either device; PHI on the encrypted android phone consists of facial image (subjects are instructed to record only profile images).	Remedial Actions: Postage-paid mailer sent to participant without a response; Research participant returned devices after phone calls; no loss of PHI; facility revised NSOC ticket. CASE CLOSED.
33	08	Miami	H	12/17/2013	NSOC reported that a patient was consented to perform exams to determine eligibility criteria to participate in the research study; however, HIPAA authorization was not obtained.	Remedial Actions: Modification to the RCO's initial reporting, to include the PO. Education to the PI to disseminate understanding that a HIPAA waiver for initial screening does not apply when actively conducting research thru interventions. CASE CLOSED.
34	16	Houston (Michael DeBakey)	H	12/18/2013	Facility provided study information to an individual who no longer held a VA appointment.	Remedial Actions: IRB determined that the noncompliance was not serious or continuing. CASE CLOSED.
35	08	VA Caribbean HCS (San Juan)	I	12/18/2013	NSOC reported a document containing PHI (full name and full SSN) was found unattended on a research service copier machine located in a secure room.	Remedial Actions: Facility clarified this document was not related to a research participant. Reporting to ORO therefore not required. CASE CLOSED.
36	01	VA Boston Healthcare System	I	12/19/2013	NSOC reported an accidental erasure of research data. A database server that maintains survey responses was erroneously decommissioned and the server backup could not be restored. In addition, facility did not report to ORO according to required timelines.	Remedial Actions: Study team has begun weekly back-ups of data on a local VA server. CASE CLOSED.
37	12	Hines IL (Edward Hines)	H	12/20/2013	The DSMB suspended enrollment of a melanoma study arm due to an unusually high number of Grade 5 toxicities. No enrollment had yet occurred at the facility.	Remedial Actions: Facility to provide DSMB summary and reported timeframes of the event; study team submitted amendment; IRB approved amendment. CASE CLOSED.
38	08	VA North Florida/South Georgia HCS	I	12/20/2013	NSOC reported that two unencrypted laptops used for VA research were not accounted for during an inventory assessment.	Remedial Actions: Both laptops were located upon search; no further actions required. CASE CLOSED.
39	20	VA Puget Sound HCS	H	12/23/2013	CIRB-managed unanticipated problem consisting of some participants in a colorectal screening study not receiving or not returning test kits.	Remedial Actions: Review of processes that will identify pending kit orders in real-time allowing lab personnel to address issues preventing kits from being mailed. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
40	20	Portland	I	12/24/2013	NSOC reported an unsealed envelope with ICD, HIPAA authorization, and picture/voice consent for one Veteran was left over the weekend in a hallway box in a non-public non-access controlled area. Documents contained full name, last 4 SSN. Risk of exposure low.	Remedial Actions: Reminder to study team on appropriate methods for VASI delivery to Research office; subject notification not required by NSOC. CASE CLOSED.
41	08	VA North Florida/South Georgia HCS	I	12/26/2013	NSOC reported that Veteran A received Veteran B's research study related information thus disclosing Veteran B's PHI.	Remedial Actions: HIPAA notification letter was mailed to Veteran B; study medication was promptly returned with confirmation that neither the prescription bottle or medication bag was opened; staff re-education; subjects to verify receipt of correct medication and sign form. CASE CLOSED.
42	22	VA Loma Linda HS	I	12/31/2013	NSOC reported one un-redacted page of data was inadvertently sent to a research sponsor. Investigation underway to determine the data that may have been compromised.	Remedial Actions: Information shredded by sponsor; study staff will provide blinded documents to the regulatory specialist prior to sending offsite. CASE CLOSED.
43	16	Houston (Michael DeBakey)	H	**01/06/2014**	RCO ICD audit of a TBI and PTSD neuroimaging study revealed that 10 subjects signed ICDs with the wrong version date, although it was not expired.	Remedial Actions: IRB required the PI to place a note-to-file in all subjects' records to document the irregularity; IRB required the RCO to audit the study; Research Office re-educated PI. CASE CLOSED.
44	06	Durham	I	**01/10/2014**	VHA program office identified failure of a VA contractor involved in VA research to take required VA training and requested that ORO investigate and provide guidance.	Remedial Actions: Based on the facility report ORO determined that the contractor is not required to take information security and privacy awareness training under current OIT policies because the contractor does not have access to VASI or to VA information systems. CASE CLOSED.
45	00	VA Central Office	H	**01/10/2014**	VA CIRB reported multiple informed consent deficiencies identified by RCO audit at one site participating in a study of cross-cultural competence of VA primary care. Deficiencies include missing ICDs, use of an ICD not approved by the IRB, missing signatures, and undated or misdated ICDs and HIPAA authorizations.	Remedial Actions: Study placed on administrative hold while documentation was corrected, study coordinator's appointment expired and was not renewed due to the scope and severity of noncompliance, training provided for study team, quality assurance plan implemented. CASE CLOSED.
46	02	VA Western New York HCS	I	**01/14/2014**	NSOC reported an IT equipment inventory identified that a palm pilot assigned to a VA researcher is missing.	Remedial Actions: Outside ORO jurisdiction as no PHI was involved. CASE CLOSED.
47	16	Houston (Michael DeBakey)	H	**01/16/2014**	A CSP monitor discovered during a routine review of a vein graft stent study that an unanticipated and serious event was not reported to the CIRB within 5 business days of becoming aware of the event.	Remedial Actions: PI to be more diligent on asking if participant is in another trial; and report noncompliance within 5 days. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
48	21	San Francisco	I	**01/17/2014**	NSOC reported a potential data breach involving several hundred individuals who received multiple emails pertaining to research that contained full names, SSN#, and gross pay of employees.	Remedial Actions: Outside ORO jurisdiction as incident was determined to be unrelated to research. CASE CLOSED.
49	17	VA North Texas HCS	H	**01/17/2014**	Study sponsor terminated an investigational drug study of cardiovascular event outcomes due to safety concerns. No local SAEs were reported.	Remedial Actions: Study closure (in response to sponsor directive) approved by the IRB. Local participants (2) had not reported symptoms related to safety concerns. CASE CLOSED.
50	06	Durham	I	**01/22/2014**	NSOC reported transmission of an internal unencrypted email containing PHI (full name and phone number) for one Veteran. Both the sender and recipient were research employees.	Remedial Actions: Sender immediately realized error, attempted an email recall, and deleted all instances of email in respective folders; recipient also removed all instances of emails. CASE CLOSED.
51	12	Hines IL (Edward Hines)	I	**01/22/2014**	NSOC reported researchers misplaced paperwork consisting of dispensing log files from two studies that are closed to accrual. PHI included initials, study ID numbers, and drug dispensing dates for 33 subjects. The Pharmacy office believes the files are misplaced within the Pharmacy service.	Remedial Actions: Pharmacy will store logs according to SOPs; segregate studies actively dispensing from those no longer dispensing; if required by sponsor, drug dispensing history can be recreated from the pharmacy database. CASE CLOSED.
52	05	VA Maryland HCS	I	**01/27/2014**	NSOC reported a vital sign sheet containing PHI was missing from a research project.	Remedial Actions: HIPAA notification letter was sent to one Veteran. CASE CLOSED.
53	01	VA Boston Healthcare System	I	**01/29/2014**	NSOC reported research data related to nine protocols was inadvertently deleted from a server. It was subsequently determined the data was not contained on back-up tapes.	Remedial Actions: Data irretrievably lost; change system level passwords to ensure only facility OIT staff has access to alter system level functions; install recently purchased data storage equipment; store each research project in separate locations; ensure backups of all critical data; separate production systems from development/training systems. CASE CLOSED.
54	18	New Mexico VA HCS	I	**01/30/2014**	NSOC reported unencrypted email containing PHI of three Veterans (name, full SSN) was sent from an external non-VA email account.	Remedial Actions: Verification received that the unencrypted emails were deleted by sender and recipient; sender reminded to use encryption when sending III/PHI; sender is current on HIPAA training. CASE CLOSED.
55	00	VA Central Office	I	**02/03/2014**	NSOC reported that an unencrypted email containing a subject's PHI was sent from a contract laboratory to the study coordinator at one site of a multicenter study on prevention of serious adverse events following angiography.	Remedial Actions: All unencrypted emails were deleted from both VA and contractor IT equipment. CASE CLOSED.
56	01	VA Boston Healthcare System	H	**02/04/2014**	NSOC reported an estimated 200 HIPAA authorizations were not obtained for a colonoscopy study.	Remedial Actions: RCO provided PI and staff education; study closed to enrollment; PI to obtain HIPAA Authorization from research participants.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
57	00	VA Central Office	H	**02/04/2014**	Veteran A study participant was mailed Veteran B study participant's research consent document and Veteran B was mailed A's document at one study site of a multicenter study of colon cancer prevention. The Veterans names, date of birth, and partial social security numbers were disclosed.	Remedial Actions: Retraining of study staff, institution of double check procedure by second study staff member to review documents before mailing, both participants offered credit protection services. CASE CLOSED.
58	01	VA Connecticut HCS	H	**02/04/2014**	ORO on-site review identified that the IRB approved a DoD/VA study of descriptive eyewitness statements without all the necessary information to do a thorough review of the study. In addition, no documentation that the entity was covered under any assurance.	Remedial Actions: Confirm if entity covered by FWA or DoD assurance; interview PI to obtain more information on budget and study process. CASE CLOSED.
59	07	Atlanta	E	**02/05/2014**	ORO Remote Technical assistance for RCEP on 2-5-2014.	Technical Assistance: Reviewed corrective actions submitted regarding the delinquent audits. CASE CLOSED.
60	00	VA Central Office	I	**02/06/2014**	NSOC reported that at one CSP study site of neuropsychological outcomes in OIF veterans two participants each received an envelope with their correct address but containing a letter intended for the other. One opened the letter and saw the name and address of the other veteran.	Remedial Actions: The supervisor reviewed correct mailing procedures with the responsible employees; the facility Privacy Officer sent a notification letter to the veteran whose personal information was disclosed. The protocol deviation was reported to the VA Central IRB. CASE CLOSED.
61	23	Minneapolis	H	**02/10/2014**	DSMB notified facility that high doses of a study drug for a chronic bronchitis and obstructive pulmonary disease study accelerated the growth of experimental lung cancers in mice and human lung cancer cells (in vitro). DSMB stated risk was insufficient to stop trial for safety reasons.	Remedial Actions: DSMB recommended a change in the ICD and in protocol to include additional monitoring; PI elected to close study and submit modification to IRB for approval. CASE CLOSED.
62	21	San Francisco	I	**02/10/2014**	NSOC reported boxes and bags of files left outside of an office in an unsecured, highly trafficked area of the hospital. Preliminary review has determined that they contain animal research information.	Remedial Actions: Facility clarified that the unsecured boxes and bags did not contain data on patients or research subjects; VA PHI was not involved. CASE CLOSED.
63	01	VA Boston Healthcare System	I	**02/11/2014**	NSOC reported the inadvertent destruction of signed research informed consents for a moral injury study. It was later reported that a waiver of HIPAA authorization had been obtained for this study despite collecting PHI on the consent form.	Remedial Actions: IRB has suspended the research study; study data may not be used unless the participants are re-consented; PI submitted amendment to change PI and re-open the study to re-consent applicable subjects; ORO provided guidance that the IRB, in consultation with the Privacy Officer, required HIPAA provisions have been addressed if the study involves the collection and use of PHI. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
64	01	VA Boston Healthcare System	I	**02/14/2014**	Unencrypted emails containing PHI sent from contracted laboratory to multiple local VA sites participating in a CSP angiography study.	Remedial Actions: Confirmation that the emails were deleted from all applicable mailboxes; contracted laboratory services company investigated and determined the cause of the unencrypted email transmissions; IRB requested study SOPs describing in detail how the researchers respond to data and/or privacy breeches; ISO, PO, and IRB reviewed the research services contract. CASE CLOSED.
65	05	VA Maryland HCS	H	**02/14/2014**	NERO reviewed ORO's analysis of 2013 FDC (Tables 8&9), recent cases, and OIG hotline referral re GRECC staff performing procedures outside their scopes. Concluded that facility has apparent programmatic noncompliance re scopes & required training.	Remedial Actions: Synthesizing 3 forms into one; writing procedures for and pilot testing new form; consulting others to learn how they track Scopes & Training; hired 2 new staff 1 to track scopes, 1 for training; Institutional education program on Scopes implementation procedures. CASE CLOSED.
66	00	VA Central Office	H	**02/21/2014**	Informed consent was not properly obtained from a participant at one study site in a multicenter study of colorectal cancer screening methods, and a participant was enrolled in the study arm he chose rather than the arm randomly assigned.	Remedial Actions: Patient desiring screening test other than randomization assignment to remain in study; patient who received informed consent from untrained study team member to be re-consented by a trained and authorized team member. CASE CLOSED.
67	00	VA Central Office	I	**02/21/2014**	NSOC reported discovery of missing laptops and printers while conducting inventory.	Remedial Actions: ORD management investigated and tracked down where the laptops were assigned before they went missing. Laptops were taken out of service and put in OIT inventory under OIT control. ORD management confirmed that no PHI was on the missing laptops. CASE CLOSED.
68	06	Durham	H	**02/26/2014**	NSOC reported transmission of an internal unencrypted email containing name, SSNs, subject IDs and date of study visits for 139 VA patients and two non-VA subjects.	Remedial Actions: Sender and recipient immediately deleted from all folders; sender taking remedial information security and privacy training; supervisor provided verbal counseling. CASE CLOSED.
69	23	Minneapolis	H	**02/26/2014**	Action in response to PBM Bulletin.	Required Actions: IRB determined PBM alert constituted an unanticipated problem that was serious and study-related, but determined that modification of informed consent was not warranted. CASE CLOSED.
70	06	Durham	I	**02/27/2014**	NSOC reported transmission of an internal unencrypted email containing last name of one research participant in the subject line.	Remedial Actions: Recall successful for 3 of the 4 recipients, the 4th recipient was contacted to delete message from all folders. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
71	04	VA Pittsburgh HCS	I	**02/27/2014**	NSOC reported informed consent documents with fax coversheets containing name, partial SSN, and diagnoses of 7 Veterans were found in a lobby/information area.	Remedial Actions: HIPAA notification letters were mailed to affected Veterans; fax machine placed in RCO's locked office in a secure area card that requires card access. CASE CLOSED.
72	00	VA Central Office	H	**02/28/2014**	CIRB reported that RCO audit at one study site of a CSP multicenter study of the genetics of serious mental illness found that two participants were consented using an older version of the ICD rather than the current version.	Remedial Actions: All pre-printed copies of the ICD were removed from study files; the importance of verifying that only the current version of the ICD is always used was reviewed with the study team by the LSI. CASE CLOSED.
73	00	VA Central Office	H	**03/03/2014**	It was found during continuing review that an investigator at one study site of a CSP multicenter study of screening methods for colon cancer had not been approved by the VA Central IRB through an oversight.	Remedial Actions: A protocol deviation report and an amendment to add the investigator to the study were submitted to the VA Central IRB. The IRB approved addition of the investigator to the study. CASE CLOSED.
74	20	Portland	I	**03/06/2014**	NSOC reported a non-study team member was given a signed ICF and HIPAA authorization to deliver to the Research Administration office. PHI on the forms: name, DOB, full SSN and study (psychogenic non-epileptic seizures). The employee worked on a different study and had completed research training.	Remedial Actions: Approved research team members on specific protocol will personally carry documents with research PHI or send through facility internal methods within sealed envelopes. CASE CLOSED.
75	00	VA Central Office	H	**03/06/2014**	Inquiry as to status of VA research at the MITRE Corporation.	Status: Clarified that MITRE Corporation is conducting no VA-funded research and that its FWA status is being resolved. CASE CLOSED.
76	00	VA Central Office	H	**03/07/2014**	CIRB notified ORO that study supplies were given to two patients who were not study participants at one site of a multicenter study of colon cancer prevention.	Remedial Actions: Patients who received study supplies identified and their Primary Care Providers notified of incident; supplies moved & more secure controls established over their distribution; procedures changed to directly notify LSI of discrepancies in distribution of supplies. CASE CLOSED.
77	00	VA Central Office	H	**03/12/2014**	One study site in a multicenter study of saphenous vein graft stenting failed to report a SAE to the VA Central IRB within 5 days as required by policy.	Remedial Actions: The VA Central IRB determined that the site did not have a pattern of late reporting of incidents and that this did not constitute serious or continuing noncompliance. The IRB did not require corrective actions. CASE CLOSED.
78	00	VA Central Office	H	**03/12/2014**	RCO audit found that participants at one site of a multicenter study of treatment for severe, resistant heartburn signed an incorrect version of the HIPAA authorization form.	Remedial Actions: Study team contacted all participants to obtain their signature on the correct VA form. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
79	00	VA Central Office	I	**03/12/2014**	NSOC reported that at one site of a multicenter study of non-epileptic seizures in Veterans, an individual who was not a member of the study team or otherwise authorized to access PHI for this study hand-carried a signed ICD and HIPAA authorization to the Research Administration Office	Remedial Actions: the noncompliance was determined not to be serious and it did not compromise the facility's information security program. In future, all documents will be delivered by study team members or in a sealed envelope. CASE CLOSED.
80	23	Iowa City	H	**03/17/2014**	NSOC reported storage of VASI on an affiliate server without HIPAA authorization (29 subjects).	Remedial Actions: PI must obtain valid HIPAA authorization from affected subjects or may not use data concerning these subjects; study staff to complete Privacy and HIPAA related training; data relocated to VA. CASE CLOSED.
81	08	VA North Florida/South Georgia HCS	I	**03/17/2014**	NSOC reported Veteran A was mailed Veteran B's research ICD and Veteran B was mailed Veteran A's ICD. PHI disclosed was names and DOBs.	Remedial Actions: Both Veterans received letters offering credit protection services; errant research ICDs were received back from each of the Veterans. Each Veteran was provided with the correct ICD copy; employee involved in this incident retook VA Privacy and Information Security and Rules of Behavior training. CASE CLOSED.
82	01	White River Junction	H	**03/17/2014**	For cause remote review of systemic non-compliance by university IRB (IRB of record for facility) involving expedited approval to be granted by IRB analysts.	Remedial Actions: Identify studies that received improper expedited approval; IRB re-review and re-approval of these studies; SOP revised to ensure specific VA requirements are clearly described.
83	21	San Francisco	I	**03/19/2014**	NSOC reported that an affiliate PI's personal laptop was stolen. The laptop contained information on several research participants, including a Veteran and the Veteran's family members. Facility subsequently clarified that no VA research information or VA PHI was involved in this incident.	Remedial Actions: VA Incident Resolution Team determined no fault of the VA and not a VA data breach. VA Privacy has agreed to assist facility in protecting Veteran and family's privacy. CASE CLOSED.
84	12	Madison (William Middleton)	I	**03/20/2014**	NSOC reported a GFE laptop purchased for a research project is missing from its expected location. PI states it was left at the VA when he terminated employment. NSOC update stated the laptop was not encrypted and did not contain PHI/III.	Remedial Actions: None required due to determination that the laptop did not contain PHI or III. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
85	01	Bedford (Edith Rogers)	I	**03/24/2014**	NSOC reported a VA employee allowed a family member to enter VA dental research survey data into her computer. The surveys contained study ID number and PHI consisting of demographic information (address, phone #s, birth year, gender) but did not include name or SSN.	Remedial Actions: The non-VA employee's data entry was checked and verified for accuracy; the non-VA employee will no longer be allowed in the work area; PO retrained employee; VA NSOC Incident Resolution Team determined the incident had a low probability of a risk of compromise and notified the PO that there was no privacy breach, however, there were policy violations including unauthorized access and disclosure of data. CASE CLOSED.
86	06	Durham	I	**03/24/2014**	NSOC reported transmission of an internal unencrypted email containing PHI/III from one VA employee to another VA employee.	Remedial Actions: Both employees immediately deleted email; training provided to both employees as well as training during team meetings. CASE CLOSED.
87	16	Jackson (Sonny Montgomery)	I	**03/24/2014**	NSOC reported facility failed to complete annual review on an affiliate DTA and it expired April 2013. Subsequently, research information on 21 patients was provided to the research POC.	Remedial Actions: Computer access removed for the WOCs appointed to the study; ISO and Research AO are working with affiliate to complete a new DTA; R&DC must approve DTA before further data is provided; WOC appointment renewal; R&DC ensure all written agreements are reviewed annually. CASE CLOSED.
88	00	VA Central Office	H	**03/25/2014**	An RCO audit at one site of a multicenter study on detection of colon cancer found that only 112 of 115 study participants had completed Informed Consent/HIPAA documents.	Remedial Actions: The study team located missing documents and pages of documents or obtained newly signed documents from participants and scanned them into the study file. CASE CLOSED.
89	23	Iowa City	H	**03/26/2014**	NSOC reported an RCO audit found that 10 subjects were enrolled without signing a HIPAA authorization.	Remedial Actions: HIPAA authorization from the 10 affected subjects; additional training to PI's regarding privacy, HIPAA, and the location of HIPAA authorization documents in the electronic IRB system privacy and HIPAA training. CASE CLOSED.
90	00	VA Central Office	H	**04/02/2014**	Laboratory specimens from one site of a multicenter study of screening methods for colon cancer were mislabeled due to transcription errors, resulting in duplicate laboratory reports for 4 participants in the study.	Remedial Actions: Laboratory records were reviewed. One participant who received two reports with discordant results was advised of the correct results. The other three participants had concordant results and did not receive duplicate notices. The VA Central IRB determined that no further action was necessary. CASE CLOSED.
91	22	VA Long Beach Healthcare System	I	**04/02/2014**	NSOC reported missing equipment that may have been misplaced. It was stated that research data was stored on the computer; however, unknown at case initiation whether or not PHI/III was included.	Remedial Actions: Facility management determined this incident did not involve any VASI on the missing computer based upon facility ISO investigation and staff interviews; ISO subsequently requested closure of the NSOC ticket. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
92	00	VA Central Office	H	**04/03/2014**	RCO audit found at one site of a multicenter study of evidence-based medicine that all 12 subjects enrolled in the study had been consented with an ICD that did not include a required statement about treatment for research-related injury.	Remedial Actions: The VA Central IRB determined that this incident did not constitute serious or continuing noncompliance because this was a minimal risk study with little or risk of injury to participants. The IRB did not require re-consenting of subjects or other remedial actions. CASE CLOSED.
93	00	VA Central Office	H	**04/04/2014**	An incorrect box of medication was dispensed to a participant at one site of a multi-center study of treatment for traumatic brain injury. The participant took 5 doses of the incorrect medication before the error was discovered, but did not appear to be harmed.	Remedial Actions: A complete inventory of study medication boxes was completed. Procedures for double checking the accuracy of medication dispensing were reinforced and adopted nationally for all study sites. CASE CLOSED.
94	00	VA Central Office	H	**04/04/2014**	The study team at one site of a multi-site study of dental root canal therapy gave patient data to a non-study team member; the non-study team member gave the data to a family member for data entry on the employee's computer.	Remedial Actions: Facility PO provided guidance to employee regarding VA privacy policy, data rechecked to assure accuracy, family member is no longer allowed in the workspace. CASE CLOSED.
95	23	Minneapolis VA HCS	I	**04/07/2014**	NSOC reported a Researcher sent an unencrypted email to a patient/subject regarding weight loss and completing a survey. Email did go to the correct recipient.	Remedial Actions: Email deleted from sender's inbox and deleted items folder; study team was reminded not to email research participants and that emailing research participants is not approved by the IRB for this protocol. CASE CLOSED.
96	18	Phoenix VA HCS	I	**04/09/2014**	NSOC reported a Clinical Research Coordinator sent a copy of one subject's signed ICF to the RCO in an unencrypted internal VA email. Information at risk is subject's full name, full SSN.	Remedial Actions: RCO removed email from mailbox; PO addressing incident with Research Coordinator for message recall and to remove email from mailbox. CASE CLOSED.
97	08	Miami VA Healthcare System	H	**04/11/2014**	Facility reported a determination from the CIRB of an UPR, pertaining to a study participant being dispensed the wrong study drug box on the study titled: Rivastigmine Patch in Veterans with Cognitive Impairment Following TBI.	Remedial Actions: A complete inventory of drug boxes was completed. Procedures for double checks were reinforced and adopted nationally. CASE CLOSED.
98	23	Minneapolis VA HCS	R	**04/11/2014**	Unapproved (IRB-exempt) research.	IRB-exempt research initiated in advance of R&DC approval. Remedial Actions: R&DC review and approval; remedial education for PI and staff; revised processes for communication regarding IRB exemptions (to include the R&DC coordinator) and ensure ISO and PO reviews. All identified concerns addressed and resolved. CASE CLOSED.
99	20	VA Puget Sound HCS	H	**04/14/2014**	Unanticipated, serious, study-related incident in a CSP study.	Remedial Actions: Resolution by the VA CIRB and the CSP laboratory center documented in the context of ORO Case 0079-101-H. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
100	00	VA Central Office	I	**04/16/2014**	NSOC reported that ORD folder permissions were misconfigured, allowed access to Letters of Agreement containing SSNs.	Remedial Actions: No PHI involved. Folders containing reviewers' names and SSNs were reconfigured for limited access within one business day of discovery. CASE CLOSED.
101	01	VA Boston Healthcare System	I	**04/21/2014**	NSOC reported transmission of an internal unencrypted email containing the names and VA locations of 10 Veterans.	Remedial Actions: Employee deleted all copies of the email; recipient to do same; Veterans' names are to be removed from all billing materials; PI to create SOPs describing in detail how the CSP Coordinating Center will respond to reported data and/or privacy breaches, adverse events and other study events, IRB to review SOPs; IRB concluded contract was approved by the appropriate parties (ISO, PO and VABHS contracting); employees were counseled on rules of behavior. CASE CLOSED.
102	00	VA Central Office	H	**04/21/2014**	A routine RCO audit found that signatures of some participants and of the person obtaining informed consent were missing from Informed Consent Documents at one study site in a multicenter study of mental health recovery.	(1) Signatures were obtained on the ten ICDs lacking the signature of the person obtaining consent and one of the two lacking the participant's signature (the other participant had retired and could not be contacted). CASE CLOSED.
103	23	Minneapolis VA HCS	I	**04/23/2014**	NSOC reported transmission of an internal unencrypted email containing two lists of research subjects.	Remedial Actions: Emails deleted from sender and recipient's Outlook folders; the Incident Resolution Team has determined that an unencrypted e-mail was sent to an intended recipient internal to the VA network. No data breach has occurred. CASE CLOSED.
104	05	Washington DC	I	**04/23/2014**	NSOC reported OI&T transmitted an external unencrypted email with an attachment containing a limited data set that included HIPAA identifiers (subject visit dates). The study-defined method was to upload to secure FTP (file transfer protocol).	Remedial Actions: Study team colleagues outside VA (affiliate and private healthcare IT company) deleted the email within 24 hours of the event; PI reinforced to the OI&T staff that the limited datasets must be transmitted in a secure manner. CASE CLOSED.
105	04	VA Pittsburgh Healthcare System	I	**04/28/2014**	NSOC reported HIPAA authorization forms for two research participants could not be located and are misplaced. The study coordinator believes it was possible that these two forms may have been accidentally placed in a confidential shred bin for disposal during a recent move between campuses.	Remedial Actions: The PI provided written confirmation that the affected subjects have signed a second HIPAA authorization. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
106	04	VA Pittsburgh Healthcare System	I	**04/30/2014**	NSOC reported a research staff member identified that a subject contact form containing PHI (full SSN, name, address, phone number and other contact information) was missing. It is unknown if the form was inadvertently shredded or whether or not it had ever been collected; study team provided written assurances that all study files are maintained in the coordinator's locked cabinet in a locked office (no one else has a key to the office and cabinet).	Remedial Actions: The participant was offered credit protection services. CASE CLOSED.
107	04	VA Pittsburgh Healthcare System	I	**04/30/2014**	NSOC reported a missing HIPAA Authorization form for one study subject containing the subject's name, SSN and signature. It is unknown if the form was lost or was never obtained. The participant is no longer active, is not undergoing any research related activities, lives out-of-state, and does not have any plans to return to this facility.	Remedial Actions: PI provided written assurance that the participant had signed another HIPAA authorization; use of subject's data was permitted due to new HIPAA authorization. CASE CLOSED.
108	04	VA Pittsburgh Healthcare System	H	**05/08/2014**	ORO received a report that a research participant's contact form was found to be missing at one study site. The contact form includes the full SSN, name, address, and other information about the participant.	Remedial Action: The Incident Resolution Team determined that the Veteran will receive a letter offering credit protection services since the missing form contained the full SSN. CASE CLOSED.
109	03	VA NY Harbor Healthcare System	I	**05/14/2014**	NSOC reported that while conducting an assessment on the Research study process, it was realized that two patient's digital images containing patient information such as first and last name and full SS# were being stored on an unencrypted affiliate computer.	Remedial Actions: Study team removed the images from the affiliate computer; PI is currently working with the facility ISO to determine whether the image analysis software can be loaded onto a VA computer. The discussions are on-going and no image transfers will occur until that issue is resolved. PI will submit SOP outlining transfer of data from VA to non-VA systems, including data de-identification and steps to prevent future occurrences. CASE CLOSED.
110	04	Philadelphia	I	**05/16/2014**	NSOC reported a VA employee stored research data on a CD and did not have IRB approval prior to storing this information on CD. Employee has since retired from the VA and this was discovered when he submitted the request to the IRB to close his study.	Remedial Actions: Upon review of the CDs, it was determined no PHI was stored on the media; it was confirmed that the data stored on the affiliate computer was deleted and a copy of the VA research data remains on the facility secure server. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
111	20	Portland	I	**05/20/2014**	NSOC reported found the full names and last four SSNs of six Veterans were left on a white board in a Research conference room after research staff had analyzed information from a tumor analysis. The conference room is not located in a secure space.	Remedial Actions: Clarified as a cancer committee that reviews patient cases and develops care plans and is not a research committee. ISO added an activity note to the NSOC ticket stating this was not a research incident but was an incident that involved the Medical Center Lung Cancer Tumor Board. CASE CLOSED.
112	18	New Mexico VA HCS	H	**05/22/2014**	ORO received a report of two participants in a multicenter study of tests to reduce mortality from colorectal cancer receiving two discordant test results from the same study specimen due to a computer software error.	Remedial Actions: The participants were notified of the error. Programming changes already in development to prevent provisional and/or conflicting results from being recorded into the database were implemented and are functioning as intended. CASE CLOSED.
113	21	San Francisco	H	**05/22/2014**	The affiliate IRB employed practices that are prohibited by VHA policy (remote meetings via electronic mail) for the review of VA research. Assessment and remediation are Pending.	Remedial Actions: Facility contends the prohibited practice used was not VA subjects and therefore not subject to VHA policy. ORO reminds the IRB to not use electronic voting practices, when taking action on VA research matters. CASE CLOSED.
114	08	Miami VA Healthcare System	I	**05/29/2014**	ORO Southern Regional Office referred via an HRPP and R&DC report Observation IV.3 that regulatory binders containing sensitive information were stored on an open shelf in the presence of non-study personnel. Facility was instructed to remediate with ORO RISP through this case.	Remedial Actions: Applicable regulatory binders were secured; all PHI files will be maintained in a locked file cabinet; ongoing monitoring, education, and consistent HIPAA practices to prevent future occurrences. CASE CLOSED.
115	00	VA Central Office	H	**06/05/2014**	ORO received a report that local study staff at one site of a multicenter study was storing study data including Veterans' protected health information on an affiliated university computer without appropriate approvals and security safeguards in place.	Remedial Actions: The VA data was deleted from the affiliate's database and returned to the VA. The NSOC Incident Response Team determined that no breach had occurred. The VA Central IRB determined that the event did not constitute serious or continuing noncompliance and that the corrective action was appropriate. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
116	19	VA Eastern Colorado HCS	I	**06/05/2014**	NSOC and the facility ISO reported that 721 patients PHI including full name, full SS#, and date of birth were being stored on an unapproved affiliate computer.	Remedial Actions: Facility ISOs investigated storage and security of system and requested data removal with a signed Certificate of Data Removal attestation; affiliate removed data and sent back the signed Certificate of Data Removal attestation; VA Office of General Counsel reviewed the signed Certificate of Data Removal attestation; ISO verification of data removal and file Certificate of Data Removal attestations; VA NSOC Incident Resolution Team determined this incident was not a security breach. CASE CLOSED.
117	06	Durham	I	**06/09/2014**	NSOC reported that a research participant's PHI including full name, full SS#, and date of participation was inadvertently sent to the affiliate printer located in a copy room on a card only access floor.	Remedial Actions: Affiliate employee was instructed to immediately shred the payment form, VA received confirmation of payment form destruction; printer settings will be verified on computers post updates and on all new installations; Project Coordinator will only print payment forms on a VA owned computer. CASE CLOSED
118	01	Bedford (Edith Rogers)	I	**06/10/2014**	NSOC reported a shipping service lost a package that contained informed consent, HIPAA Authorization, audio/picture consent, and self-reported survey forms for five study subjects.	Remedial Actions: The incident was the result of an error made by United Parcel Service and not the VA; both NSOC and CIRB found that notification letters or credit protection services were not required because the lost documents did not contain subjects' dates of birth or SSNs. CASE CLOSED
119	00	VA Central Office	H	**06/10/2014**	ORO received a report that UPS lost a package containing personal health information of 5 Veterans participating at one site of a multicenter study of Veterans preferences for exchanging information.	Remedial Actions: The VA Central IRB reviewed the incident and determined that it was unanticipated, related to the research, but not serious because the potential for harm was not substantive. There was no noncompliance on the part of the study team. The IRB did not require any further action. CASE CLOSED.
120	15	Kansas City	H	**06/12/2014**	ORO received a report of apparent continuing noncompliance based on an RCO ICD audit findings for a non-medical intervention study comparing two standards of care for diagnosis of colorectal cancer. Multiple ICD and HIPAA subject signature pages included corrections made by the subject without adhering to GCP guidelines.	Remedial Actions: CIRB approved the mailing of ICD/HIPAAs to prospective subjects to complete at home without research staff oversight; a determination was made that the events reported do not constitute continuing non-compliance; additional education for the study team was recommended, and per the study coordinator the CSP monitor has initiated this education. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
121	00	VA Central Office	H	**06/12/2014**	ORO received a report of the suspension of human subject research at one site of a multicenter study on improving the quality of care in Parkinson's disease due to a shortage of research personnel to carry out and oversee the research.	Remedial Actions: The VA Central IRB reviewed the incident and determined that it was unanticipated, related to the research, but not serious because the potential for harm was not substantive. There was no noncompliance on the part of the study team. The IRB did not require any further action. CASE CLOSED.
122	05	Washington DC	I	**06/12/2014**	NSOC reported that an unauthorized research equipment PC connected to the VA LAN.	Remedial Actions: The LAN port was disabled at the switch and the cable was removed from the PC; local research personnel reminded that systems cannot be connected to the LAN without approval; ISO recommendation is to scan the system offline. Facility affirmed that the computer involved did not contain PHI. CASE CLOSED.
123	04	VA Pittsburgh Healthcare System	I	**06/18/2014**	NSOC reported one original signed ICD in a study of atrial fibrillation was missing. A signed copy of the subject's ICD is present in the electronic medical record.	Remedial Actions: Credit protection service was offered to the subject. CASE CLOSED.
124	11	VA Ann Arbor Healthcare System	I	**06/20/2014**	NSOC reported that a researcher mailed 5 separate agreements to participate in a research study that contained the subjects' last name to the wrong individuals.	Remedial Actions: HIPAA letters of notification were mailed to the 5 affected individuals; process of printing survey cover letters was automated within the study database as a mail merge option; last name only will be included on the survey cover letters; second staff will double check the packet for correctness prior to mailing. CASE CLOSED.
125	01	VA Boston Healthcare System	I	**06/23/2014**	NSOC reported a blood sample containing a label with participant name, date of birth and four-digit number was mailed to the incorrect VA lab. The sample was never out of VA control and the label was only seen by VA trusted agents.	NSOC reported a blood sample containing a label with participant name, date of birth and four-digit number was mailed to the incorrect VA lab. The sample was never out of VA control and the label was only seen by VA trusted agents. CASE CLOSED.
126	00	VA Central Office	H	**06/30/2014**	ORO received a report of serious noncompliance due to a protocol deviation at one study site of a multicenter study of methods for the early detection of colon cancer. The site enrolled 12 participants who were not eligible for the study due to age exclusion. There were no patient safety issues.	Remedial Actions: The VA Central IRB determined that serious noncompliance had occurred and that the improperly enrolled subjects must be withdrawn from the study. No data from the improperly enrolled participants may be used in the study. The participants may be re-enrolled in the study if they become age-eligible. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
127	08	North Florida/ South Georgia	I	**7/1/2014**	NSOC reported that a mail-out merge to pre-screened participants failed, disclosing approximately 23 Veteran names when the letters were sent to another Veteran's address. Veteran's name was the sole data element of disclosed PHI.	Remedial actions: PI remediation plan included using smaller batches of letters per merge which will lead to less room for error; a second person will review and ensure name and address match before the mailings are sent; IRB approved remediation plan; VA-NSOC required no credit protection or notification letters. CASE CLOSED
128	06	Salem	I	**7/2/2014**	NSOC reported the NPC Research Institute is unable to locate devices during inventory; two desktops and seven laptops reported missing. NPC policy is to encrypt devices.	One desktop computer and five laptop computers were located; a Report of Survey initiated for the missing computers; located devices were confirmed as encrypted per policy; PIs signed attestation letters stating PHI is not on the missing devices; NPC equipment inventory policy changes with implementation in appropriate departments. Report of Survey Board determined poor record keeping and recommended items be removed from inventory. CASE CLOSED.
129	23	Minneapolis	I	**7/2/2014**	NSOC reported that a researcher emailed a spreadsheet with data containing date of birth, procedure date, and date of diagnosis to fellow researchers at the affiliate. This was not approved by the IRB nor was a HIPAA Authorization in place. Additionally, the spreadsheet was transmitted without encryption.	Remedial Actions: The PO verified that the email was deleted from all folders; PI was provided educational material on ethics and minimizing risks; PI will retake VA HIPAA and privacy training. CASE CLOSED.
130	04	VA Pittsburgh	I	**7/3/2014**	NSOC reported a missing HIPAA authorization containing first & last name, plus date signed for one participant. It was determined that the incident has a low probability of a risk of compromise.	Remedial Actions: Staff re-education; the participant signed a new HIPAA authorization. CASE CLOSED.
131	23	VA Nebraska-Western Iowa	I	**7/3/2014**	NSOC reported informed consents for research were being done in VA leased space at an affiliate hospital and sent interoffice mail from there to the VA, but they never made it to their destination in the VA.	Remedial Actions: The interoffice mailing process will be reviewed for improvements and education on the process will be provided; two Veterans will be sent HIPAA notification letters. CASE CLOSED.
132	17	VA North Texas	H	**7/9/2014**	ORO received a report of a VA CIRB finding of serious noncompliance with instructions to report the incident to WRO and OHRP.	Data use limited to subjects who have provided HIPAA authorization. No further action required. ORO concludes oversight of the reported noncompliance and closes the case. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
133	00	VA Central Office	H	**7/11/2014**	ORO received a report of an unanticipated serious adverse event at one study site of a multicenter study comparing two methods to detect colon cancer. A study participant developed shakiness and palpitations over two days following a colonoscopy procedure, requiring hospitalization and treatment for hypertension, low magnesium and atrial fibrillation.	It was found that the patient had discontinued his regular medications prior to the study procedure despite having been instructed not to do so. The patient recovered and was discharged from the hospital. No further patient safety issues were identified and there was no recommendation for further action. CASE CLOSED.
134	00	VA Central Office	H	**7/11/2014**	ORO received a report of a missing HIPAA authorization form for one participant in a study of treatment for low back pain in older Veterans.	Remedial Actions: The study team contacted the affected individual, who signed a new HIPAA authorization form; staff will double check forms to prevent future occurrences. CASE CLOSED.
135	00	VA Central Office	H	**7/11/2014**	ORO received a report of 8 missing subject binders at one site of a multicenter study of Veterans' health outcomes. The binders contain the subjects' signed informed consent document and HIPAA authorization form, which include the subjects' full name, date of informed consent, and study ID Number.	Remedial Actions: The study site initiated an investigation, including a 100% audit of all files for this study. Five of the missing binders were located and it was determined that a sixth did not exist because the Veteran did not enroll in the study. A study staff member was terminated and the study coordinator resigned. Staffing was restructured to limit recruitment and phlebotomy responsibilities to VA nurses. CASE CLOSED.
136	07	Birmingham	I	**7/11/2014**	NSOC reported that 8 subject binders containing subject informed consent documents and HIPAA authorization forms were missing. PHI included full name, dates, and subject identification numbers.	Remedial Actions: MVP and CSP audits completed; 6 of the 8 missing binders located; NSOC closed the ticket and did not require any additional actions; other actions pending.
137	16	Houston (Michael DeBakey)	I	**7/11/2014**	NSOC reported that 2 missing HIPAA authorizations may have been shredded.	Remedial Actions: NSOC determined that there was no data breach and subject notification was not required. The data and specimens related to the two research subjects will not be utilized.
138	20	Portland	I	**7/14/2014**	NSOC reported a study team inadvertently accessed an incorrect Veteran's health record (Veteran A) when attempting to send a recruitment letter to a Veteran (B) in a group covered by an approved waiver of informed consent for recruitment (Veteran B). The letter was addressed in the name of Veteran B; however contained the address of Veteran A. Veteran B contacted the study team and indicated he did not open the envelope.	Remedial Actions: Study staff requested Veteran B return the envelope which he will do if retrievable from the trash; PO re-educated the study team to confirm the names match their list of potential eligible Veterans with the CPRS entry; the Incident Resolution Team determined that the Veteran will receive a notification letter. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
139	10	Cleveland (Louis Stokes)	H	**7/15/2014**	Facility reported IRB actions to administratively close a PI's unfunded diabetic drug protocol due to multiple lapses in approvals, late/deficient submissions, uncertain and discrepant enrollment numbers, and failure to meet IRB required corrective actions timeline.	Remedial Actions: IRB requires an accounting of the data source used in publications; PI may no longer access or use any study data collected; IRB administratively closed the study. RDC Chair will contact PI regarding accounting of the source of data used in publications. CASE CLOSED.
140	19	VA Eastern Colorado	I	**7/16/2014**	NSOC reported transmission of an unencrypted external email with an attached spreadsheet containing 472 Veterans' PHI (full name, full SSN, provider name and firm, consult request date, ICD-9 code, and diagnosis date). The list derived from 2011 echocardiograms associated with a current VA research protocol and was sent by a pharmacy resident from her VA computer through her gmail account and sent to her personal email account.	Resident deleted all copies of the email; Resident confirmed the file was not saved to another computer system or sent anywhere else. ISO recommended education for Pharmacy Residents that data containing PHI cannot be emailed outside the VA-protected environment; facility ISO confirmed the events and remedial actions taken by the Resident. CASE CLOSED.
141	04	VA Pittsburgh	I	**7/28/2014**	NSOC reported a missing initial screening form containing name and race/ethnicity for one participant. The staff is uncertain whether the document is missing or if it was ever created.	Remedial Actions: VA-NSOC determined incident does not require notification to the subject. The IRB and R&DC determined there was no evidence of apparent serious or apparent continuing non-compliance or requirements for additional action. CASE CLOSED.
142	08	North Florida/South Georgia	I	**7/30/2014**	NSOC reported a research employee inadvertently mailed two payment vouchers to a grants specialist at the affiliate.	Remedial Actions: The affiliate employee contacted the VA employee who promptly retrieved the vouchers; a checklist was created to track and verify reimbursement procedures for each subject; VA-NSOC determined that subject notification was not required; CASE CLOSED.
143	20	VA Puget Sound	I	**7/30/2014**	NSOC reported a research coordinator inadvertently disclosed a research participant's name and type of study during a call to the number provided by the Veteran. The person answering the phone initially responded that he was the correct person, but after hearing the name of the study, stated he was the Veteran's supervisor. The reason for the untrue statement is not known.	The coordinator immediately terminated the call upon learning that the person speaking was not the correct research participant; VA NSOC stated no breach and no notifications required; PI instituted process changes including that local study staff will now confirm the Veterans' identify by asking their first name, last name and last four of their social security number. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
144	20	VA Puget Sound	I	**7/30/2014**	NSOC reported a research blood sample labeled with a Veteran's name, SSN, and DOB was lost in transit from a Community Based Outpatient Clinic to the main facility.	Chain of custody evaluation by PO was inconclusive; main VA facility division laboratory marked receipt of only one of two tubes on the shipping manifest; due to a Community Based Outpatient Clinic blood draw staff departure, no facility confirmation the missing blood tube ever left Community Based Outpatient Clinic; transport company queried by VA PO and stated no access to the container and no unusual activity reported by their staff; VA NSOC required a credit protection letter. CASE CLOSED.
145	17	Central Texas	H	**7/31/2014**	NSOC reported that 12 participants' dates of birth were collected without a signed HIPAA authorization.	The twelve Veterans will be sent a notification letter; retraining of all the study staff regarding the consenting of subjects; a reminder to the PI that no actions, including corrective actions should be taken outside of the protocol without the approval of the IRB and; per the PO, a face to face meeting with each of the 14 subjects to re-sign the HIPAA form, explain the issues. CASE CLOSED.
146	18	Phoenix	I	**8/1/2014**	NSOC reported that while conducting EOC rounds the Research PO found two pages in an unapproved recycle bin that contained 57 Veterans' full names and full SSNs. A search of the area was conducted and another unapproved recycle bin was found.	Research PO investigation clarified this was not research related information; Research PO was performing EOC rounds for facility PO and discovered the materials in a non-research area; papers secured and bin relocated away from the high traffic area. CASE CLOSED.
147	22	VA Greater Los Angeles	I	**8/6/2014**	NSOC reported the PO discovered a clinic appointment list was attached to a protocol submission during a review process. The clinic appointment list was inadvertently integrated into a bundled print job on a shared printer and then scanned and uploaded into a SharePoint site for new protocol submissions.	Clarified by ACOS/R investigation as not a research related clinic appointment list with no research participants; the clinic appointment list was removed from the SharePoint site and protocol submission; research staff reminded to verify documents prior to uploading to the Research SharePoint site. CASE CLOSED.
148	16	Central Arkansas (Little Rock)	I	**8/7/2014**	NSOC reported transmission of external unencrypted email containing PHI (100 scrambled SSNs and subject identifications). Email was sent to the intended recipient.	Recipient deleted email; The VA-NSOC determined that a data breach did not occur; staff retraining. CASE CLOSED.
149	18	New Mexico	I	**8/7/2014**	A WOC research assistant emailed a single file that included a patient identifier to an external affiliate address.	Verified that both the sender and receiver deleted the message from their email accounts. The sender was provided reminders not to transmit sensitive information without PKI encryption. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
150	04	VA Pittsburgh	I	**8/11/2014**	NSOC reported that two research coordinators were inadvertently exposed to the individually identifiable information (name, date of birth and study identification) of research subjects enrolled at other sites.	Facility clarified that this facility is not engaged in this research sub-study (no facility patients, data or staff involvement). The 5 VA sites participating in this sub-study were advised to report the issue to their local IRBs. No further action required. CASE CLOSED.
151	22	VA San Diego	I	**8/11/2014**	NSOC reported several boxes of research documents including checkbook registers were left unsecured after a PI vacated her office. The documents contained PHI (names and partial SSN).	PO investigated and collected documents; all documents were in a secured room accessible only to select research staff; PO discussed the problem with the PI and plans to inspect the location where these documents will be stored; PO determined there was no incident upon investigation. CASE CLOSED.
152	06	Durham	I	**8/12/2014**	NSOC and facility reported to ORO that a HIPAA authorization form including a Veteran's name and full SSN had been inadvertently left on a copier located in a medical administrative staff area with very little, if any, patient/visitor traffic. The volume of medical staff would be in the medium range. Unknown how long the form was on the copier but probably less than 1 day. There is no indication that the information was inappropriately disclosed.	The form was secured and given to the ISO; facility submitted VA NSOC ticket; VA NSOC determined that the incident was a low probability of a risk of compromise and required no notifications. CASE CLOSED.
153	01	VA Boston	I	**8/13/2014**	NSOC reported missing research information that may be in the shred bin or removed from the protected environment by an employee without authorization. The Privacy Officer is investigating and awaiting more information.	Remedial Actions: Removal of the information from the shred bin was witnessed by the PO; it is believed all of the documentation is accounted for, but the PO is awaiting final report from the RCO's investigation. Based on numerous concerns, the IRB requested an audit of the study.
154	20	Portland	I	**8/13/2014**	NSOC reported that a VA research study's data for 52 enrolled subjects had been stored in an online cloud location. Staff mistakenly believed the data were de-identified and therefore it was permissible to use the storage location; however, the location is not identified in the study documentation. The data included a description of the subject's drug use with PHI consisting of study visit dates and potentially ages (if > 89 years). There has been no reported misuse of the information.	The data was removed from the online cloud location and relocated to the secure local VA network. CASE CLOSED.
155	04	VA Pittsburgh	I	**8/18/2014**	NSOC reported ten original signed informed consents in a current study are missing. PHI included the name only and the date the form was signed.	Remedial actions: The facility contacted ORO to report that the consent forms were not missing; rather a local study site had not yet sent them to the facility. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
156	05	VA Maryland	H	**8/21/2014**	ORO received a report of failure to follow protocol procedures found on an audit by academic affiliate's HRPP of a balance improvement/falls prevention study. Protocol deviations included incomplete cognitive status exams (51/104 participants) and rest period was not offered as required to one participant after first 15 trials in lab balance/step recovery testing.	Re-education of study staff on protocol procedures; revision of lab balance/step recovery data form to include check box documenting offer of rest period; training on cognitive status exam documentation with PI requirement to submit timely evidence to the IRB of the proposed training. Revised consent form to more accurately describe risks and procedures. CASE CLOSED.
157	04	Coatesville	H	**8/22/2014**	Facility reported that DSMB reports pertaining to a study of a Clostridium Difficile Toxoid Vaccine were not submitted to the IRB in accordance with local procedures and were not reviewed by the IRB Chair to determine whether or not the reported event was serious and unanticipated and related to the research.	(1) The IRB Chair will review the submission and determine whether or not the event was serious and unanticipated and related to the research. The procedure for submitting and reviewing Safety Reports was clarified for both the PI and the newly appointed IRB Coordinator. CASE CLOSED.
158	17	Central Texas	H	**8/25/2014**	Study suspension by IRB Chair in response to protocol deviations.	Program reviewed for other cases of similar noncompliance (3 others identified); all cases addressed and resolved by counseling and staff re-training. CASE CLOSED.
159	02	Syracuse	I	**8/27/2014**	NSOC reported VA research data was stolen from an employee's vehicle. Items consisted of a non-VA (NPC-owned) encrypted password-protected laptop containing coded participant interview data; paper research forms identified by code only (no III); and a HIPAA envelope with copies of pages from 3 participant consent forms. These contained the Veteran participants' names, SSNs, and home addresses. The employee did have the proper authorization on file to transport VASI outside of the VA.	The three Veterans whose PHI was stolen were offered credit monitoring. The study staff received education on the proper securing of PHI. The IRB reviewed the incident as an unanticipated problem and accepted the investigator's remediation plan for proper transport and storage of sensitive materials. CASE CLOSED.
160	15	VA Eastern Kansas	S	**8/27/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
161	15	Wichita (Robert Dole)	S	**8/27/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
162	21	VA Sierra Nevada	S	**8/28/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
163	07	Charleston (Ralph H. Johnson)	S	**9/2/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
164	21	VA Central California	S	**9/2/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
165	23	Fargo	S	**9/3/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
166	17	South Texas (San Antonio)	I	**9/4/2014**	NSOC reported a research consent form containing full name and full SSN was sent to the incorrect subject (patient). Upon investigation, the PO determined that the other subject did not receive an incorrect form.	One research participant sent an offer letter for credit protection services; SOP developed to have a second person verify name and address on ICDs before mailing; research staff involved with incident were counseled; copy of incorrect ICD returned by research participant to facility PO for disposition. CASE CLOSED.
167	08	Orlando	S	**9/5/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
168	11	Indianapolis (Richard Roudebush)	I	**9/5/2014**	Two affiliate University workstations being turned in by the Research Service to the IT staff did not have hard drives. The hard drives had been removed by non-IT staff. Subsequent information obtained by RCO from the ISO and ACOS that the incident did not involve research-related VA PHI or III.	The incident did not involve the unauthorized transmission, removal, theft, loss, or destruction of VA PHI related to research. CASE CLOSED.
169	06	Asheville	S	**9/10/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
170	08	Miami VA	S	**9/10/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
171	01	Bedford (Edith Nourse Rogers)	I	**9/11/2014**	NSOC reported a VA researcher lost his VA Blackberry containing PHI (names and phone numbers) of 10-11 research participants. The device was encrypted and disabled once the loss was recognized; therefore NSOC Incident Response Team determined there was no actual breach.	BlackBerry confirmed as encrypted and was disabled; PI had permission to store research-related PHI from ACOS/R on device to facilitate community visits with Veterans; ISO and CIO reviewed and approved issuance of mobile media that meet VA security requirements; copy of data from lost BlackBerry maintained in VA project specific network folder. CASE CLOSED.
172	00	VA Central Office	H	**9/12/2014**	ORO received a report that a study team member performed two psychological screening exams that were research procedures before obtaining informed consent from prospective participants in a multicenter trial of treatments for improving outcomes of depression.	(1) The responsible team member received informed consent training. An RCO audit did not identify any further serious or continuing noncompliance and no further remedial actions were required by the IRB. CASE CLOSED.
173	16	Houston (Michael DeBakey)	I	**9/12/2014**	NSOC reported a research subject received the payment voucher for another research subject and returned the voucher to the issuing department.	(1) Research subject will be sent a letter offering credit protection services. Refresher training completed. Voucher disbursement forms will be maintained in individual folders. Subjects will be asked to verbally state their names which will be cross checked with the information on the vouchers.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
174	21	VA Palo Alto	H	9/12/2014	A member of the research community informed the RCO that research had been initiated in advance of R&DC approval (and ACOS/R authorization.)	PI trained by research mentor and service chief on the research approval process; and research suspended until all required approvals are secured. CASE CLOSED.
175	01	Providence	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
176	06	Richmond (Hunter Holmes McGuire)	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
177	08	Bay Pines	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
178	08	West Palm Beach	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
179	09	Louisville (Robley Rex)	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
180	15	Kansas City	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
181	21	VA Pacific Islands	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
182	22	Loma Linda	S	9/15/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents (and Toxins BSATs) identified. CASE CLOSED.
183	00	VA Central Office	S	9/16/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
184	08	VA Caribbean	S	9/16/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
185	04	Philadelphia	S	9/17/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
186	18	Phoenix	I	9/17/2014	A Senior Clinical Research Coordinator reported to the Privacy Officer that during a routine audit noncompliance was identified a protocol deviation--screening research participants prior to consent and disposal of research records including possibly a VA flash drive.	The facility is to provide a plan to ensure all new study members who will be obtaining informed consent are appropriately trained; and a Research Compliance Officer audit to be completed if there had not been an audit in the past month by another oversight authority.
187	23	Sioux Falls	S	9/17/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
188	02	VA Western New York	S	9/18/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
189	04	Coatesville	S	9/18/2014	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
190	06	Salisbury (Hefner)	S	**9/18/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
191	15	Kansas City	I	**9/18/2014**	NSOC reported an employee lost a thumb drive containing research protocols' grants and 'important files'. Unknown at present if research PHI was contained on the thumb drive. Facility ACOS clarified that no PHI or III data were stored on the thumb drive; rather the synthetic chemist used it to design chemical structures of compounds and to store grants.	Because no Veteran's PHI or III was contained on the drive, ORO closed the case; however the researcher was reminded to keep secure all devices containing VA sensitive information even though identifiable information was not involved. CASE CLOSED.
192	21	San Francisco	S	**9/18/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
193	23	St. Cloud	S	**9/18/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
194	03	VA New Jersey	S	**9/19/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
195	05	Washington DC	S	**9/19/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
196	07	Birmingham	S	**9/19/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
197	10	Cleveland (Louis Stokes)	S	**9/19/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
198	23	Iowa City	S	**9/19/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
199	01	VA Connecticut	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
200	02	Canandaigua	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
201	03	VA NY Harbor	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
202	04	Clarksburg (Louis A. Johnson)	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
203	04	VA Pittsburgh	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
204	04	Wilkes-Barre	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
205	06	Durham	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
206	07	Columbia SC (Wm. Jennings Bryan Dorn)	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
207	18	Phoenix	H	**9/22/2014**	An internal QA review identified that 4 subjects had provided documentation of informed consent on a noncompliant form (i.e., not the most current version).	Re-consenting completed. IRB determination of serious noncompliance with re-education required (completed). CASE CLOSED.
208	21	VA Palo Alto	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents (BSATs) identified. CASE CLOSED.
209	23	Minneapolis	S	**9/22/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents (BSATs) identified. CASE CLOSED.
210	00	VA Central Office	H	**9/23/2014**	ORO received a report of an event that was unanticipated, serious, and probably related to the research at one site of a multicenter study of screening tests for colorectal cancer. A participant randomized to undergo colonoscopy had his anticoagulant medication stopped prior to the procedure, and the day after the procedure developed slurred speech and was found to have had a cerebrovascular accident. Stopping anticoagulants is usual medical care to prevent bleeding from the colonoscopy.	Remedial Actions: The participant was hospitalized for stabilization and the anticoagulant medication was restarted. CASE CLOSED.
211	01	Bedford (Edith Nourse Rogers)	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
212	01	VA Central Western Massachusetts	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
213	01	White River Junction	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
214	05	VA Maryland	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
215	06	Salem	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
216	07	Atlanta	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
217	07	Augusta (Charlie Norwood)	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
218	08	Tampa (James Haley)	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
219	09	Memphis	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
220	11	Detroit (John D. Dingell)	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
221	15	St. Louis	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
222	17	VA North Texas	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
223	18	New Mexico	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
224	18	Southern Arizona	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
225	20	VA Puget Sound	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
226	22	VA Greater Los Angeles	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
227	22	VA Greater Los Angeles	H	**9/23/2014**	PI's COI statement was forwarded by the facility's Research Compliance Analyst to the Office of General Counsel (OGC) Ethics Specialty Team, West, with the following concerns: (a) The PI had received common stock shares as compensation for serving as a Director for a non-publicly traded company associated with the research. (b) The PI was a co-inventor of patents and patent applications which had been assigned to the company. (c) The study's principal hypothesis could result in an increase in the value of the PI's stock shares. The OGC advised GLA of the appearance of a causal link between the PI's research and the PI's financial interests.	(1) The PI was (a) permitted to remain at VA but completely divest from the company, with no future dealings; or (b) required either to have no further participation in the study and arrange for another PI to complete the project or to leave the VA. CASE CLOSED.
228	22	VA Long Beach	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
229	22	VA San Diego	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
230	23	VA Nebraska-Western Iowa	S	**9/23/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
231	02	Syracuse	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
232	03	Bronx (James J. Peters)	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
233	03	Northport	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
234	07	Tuscaloosa	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
235	09	Huntington	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
236	09	Lexington	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
237	09	Mountain Home (James H. Quillen)	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
238	09	Tennessee Valley	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
239	11	Indianapolis (Richard Roudebush)	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
240	12	Captain James A. Lovell FHCC	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
241	12	Hines IL (Edward Hines)	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
242	15	Columbia MO (Harry Truman)	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
243	16	Jackson MS (Sonny Montgomery)	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
244	16	Oklahoma City	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
245	17	Central Texas	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
246	17	South Texas	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
247	19	VA Eastern Colorado	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
248	20	Boise	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
249	20	Portland	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
250	21	VA Northern California	S	**9/24/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
251	01	VA Boston	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
252	02	Albany (Samuel S. Stratton)	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
253	03	VA Hudson Valley	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
254	10	Cincinnati	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
255	11	VA Ann Arbor	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
256	12	Jesse Brown	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
257	12	Madison (William Middleton)	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
258	16	Central Arkansas (Little Rock)	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
259	16	Southeast Louisiana	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
260	16	VA Gulf Coast	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
261	18	Phoenix	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
262	19	VA Salt Lake City	S	**9/25/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
263	01	Togus	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
264	02	Bath	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
265	04	VA Pittsburgh	H	**9/26/2014**	A potential research subject's III was submitted to affiliate institution for payment purposes without obtaining HIPAA authorization on a study evaluating prompting methods for cognitive assistive devices.	The IRB determined that no remedial actions were required based on information presented and the fact that no PHI had been disclosed. CASE CLOSED.
266	05	Martinsburg	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
267	06	Hampton	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
268	08	North Florida/South Georgia	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
269	10	Chillicothe	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
270	10	Columbus (Chalmers P. Wylie)	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
271	16	Shreveport (Overton Brooks)	S	**9/26/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
272	20	VA Puget Sound	I	**9/26/2014**	(1) PHI from a VA research subject was sent via VA email and affiliate email. (2) One missing original HIPAA authorization form with protected health information sent from VA to research participant through US postal mail was missing.	(1) Email messages with form attachment were removed from the applicable mailboxes, no credit monitoring or HIPAA notification letters were required, no forms will be typed so as to further minimize the possibility that PHI will be inappropriately sent through email. (2) Study staff were reminded to review the documents for corrections while the participant is still at the VA, research participant checked with neighbors for erroneous mail delivery, no credit monitoring or HIPAA notification letters were required, study personnel involved in this incident have retaken their VA privacy trainings, research participant re-consented to the study.
273	01	Manchester	S	**9/29/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
274	10	Dayton	S	**9/29/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
275	11	Battle Creek	S	**9/29/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
276	15	Columbia MO (Harry Truman)	I	**9/29/2014**	1) Two Veterans complained that patients' medical diagnosis was openly printed on post cards sent to 304 Veterans.	(1) PI submitted an amendment and discontinued usage of the postcard containing the diagnosis. (2) MCD ordered review of the 304 veterans who received incorrect postcards; found no adverse events r/t patients not showing for appointments or inability to contact patients regarding access to care. CASE CLOSED.
277	16	Muskogee (Jack C. Montgomery)	S	**9/29/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
278	16	Veterans of the Ozarks	S	**9/29/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
279	21	San Francisco	I	**9/29/2014**	A Research Study Coordinator inadvertently included a subjects full name, full SSN, and DOB in a research Adverse Event Report. The report was uploaded into an affiliate maintained data web-base.	(1) The Research Office communicated with IRB regarding this issue and both parties are in agreement that subject identifiers should not be included in IRB documents. A reminder to remove all subject identifiers is already included on the adverse event reporting form. The R&DC determined that the Research Office should again remind all clinical research investigators and their staff that subjects' identifiable private information should be removed or redacted from IRB documents that are submitted the online submission system. VA-NSOC Incident Resolution Service Team determined that no data breach had occurred. The adverse event report with PHI was removed from online submission system and the unencrypted email mailboxes. CASE CLOSED.
280	22	VA Southern Nevada	S	**9/29/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
281	00	VA Central Office	H	**9/30/2014**	ORO received a report of a serious adverse event occurring at one site of a multicenter study of screening methods to detect and prevent colon cancer that was probably related to the research. A study participant was randomized to the colonoscopy arm of the study and had a cardiac event during the colonoscopy procedure.	Remedial Action: The study subject was hospitalized for a cardiac evaluation, which proved to be negative. The subject was cleared to undergo another colonoscopy procedure. CASE CLOSED.
282	11	Saginaw (Aleda E. Lutz)	S	**9/30/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents and Toxins (BSATs) identified. CASE CLOSED.
283	20	Portland	I	**9/30/2014**	NSOC reported a PI unintentionally uploaded motion sensor data to the vendor who built the sensors. Disclosure to the vendor was not included in the study ICD or HIPAA authorization. PHI consisted of data collection dates but did not include direct identifiers.	Vendor indicates the data saved to their system was completely deleted; study coordinator and research team were re-educated on incident reporting requirements. CASE CLOSED.
284	23	Minneapolis	I	**10/1/2014**	NSOC reported an Apple laptop (believed to not contain encryption software) used by a researcher was identified during the inventory process as missing. The researcher had not reported a loss of equipment. Further information pending to determine whether PHI/III was stored on the laptop.	The laptop did not contain PHI or III and was destroyed. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
285	00	VA Central Office	H	**10/3/2014**	(1) Protected health information (PHI) of one participant in a multicenter study was inadvertently disclosed. (2) ORO received notice that the protected health information of a participant at one site of a multicenter study of saphenous vein graft stents had been text-messaged to a non-VA employee and to the personally-owned devices of two local study site personnel.	(1) The Interim Facility Director sent an email to all facility personnel explicitly stating that the use of personal cell phones to transmit Veterans' personally identifiable information or health information is prohibited. (2) All texting activities related to the study were immediately stopped. (3) Cardiac Catheterization Laboratory personnel received refresher Privacy Training. The Veteran was sent a notification letter and offered credit monitoring. (4) In addition to actions already taken under RC-1 E, the Veteran was sent a HIPAA notification letter. CASE CLOSED.
286	12	Milwaukee (Zablocki)	S	**10/3/2014**	Governmentwide Research Safety Stand-Down.	No Biological Select Agents (BSATs) identified. CASE CLOSED.
287	06	Salisbury	H	**10/8/2014**	Facility self-report found during RISP routine onsite review of a PTSD cognitive function study that Waiver of HIPAA Authorization was never obtained from the IRB, and an unapproved clinical staff member was screening for potential study participants.	Remedial Actions: PI retraining; enrollment closed; data may be used. CASE CLOSED.
288	11	Ann Arbor	H	**10/8/2014**	(1) 2 of 55 HIPAA authorizations were missing the subject signature.	(1) Pending. (2) Study team received training on proper ICD procedures; it was found that no PHI was collected by the study team, IRB allowed PI to retain data collected on the two subjects. (3) IRB determined that findings did not constitute serious or continuing noncompliance. CASE CLOSED.
289	18	New Mexico (Albuquerque)	I	**10/10/2014**	NSOC reported discovery of missing desktops and laptops while conducting inventory.	Pending.
290	21	Northern California (Sacramento Martinez)	H	**10/10/2014**	(1) Apparent Conduct of Unapproved Human Subject Research.	(1) R&DC to ensure appropriate review and approval of the research protocol. CASE CLOSED.
291	04	Philadelphia	I	**10/15/2014**	(1) Backpack with a 262 name research participant recruitment list containing PHI in the form of first and last names was stolen from a research employee's car.	(1) Research team will not print participant name lists and all recruitment calls will occur from VA facility. VA NSOC determined no notifications required. Offsite VASI procedures reviewed. CASE CLOSED.
292	20	Portland	I	**10/17/2014**	NSOC reported that 25 subjects' specimens were transferred without proper authorization to the affiliate University with labels that included the date they were taken and study number.	Revise combined ICF and HIPAA authorization to allow for disclosure of study visit dates; pending

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
293	16	Central Arkansas (Little Rock)	I	**10/24/2014**	(1) SRO on-site review found that facility had granted a local waiver of FIPS 140-2 encryption requirement for transmitting VA sensitive information over websites.	(1) Facility plans to submit a Deputy Assistant Secretary for Information Security (DAS OIS) Risk Based Decision (RBD) request to allow the use of websites without FIPS 140-2 compliant encryption for the transmission of VA research data in the clinical trials studies.
294	00	VA Central Office	H	**10/27/2014**	(1) Study team members at one site of a multicenter study comparing two methods for detecting colorectal cancer initiated study procedures without obtaining required local approvals. The team members lacked scopes of practice and documentation of training.	(1) The study team was required to verify that all current study personnel have met all local VA facility requirements for participation in a VA research study team and that all team members have been trained in all local VA facility policies governing human subjects research that are applicable to this study. The study team's response was reviewed and approved by the VA Central IRB; no further remedial action was required. CASE CLOSED.
295	00	VA Central Office	H	**10/28/2014**	(1) A participant who met exclusion criteria for a study was enrolled in the study despite there being documentation in CPRS that the participant had had a colonoscopy within a disqualifying interval.	(1) The participant was hospitalized and treated for the adverse event. The study team reviewed the medical records and interviewed the patient and family, determining that the participant was in fact eligible for the study, but that screening procedures needed improvement. The study team submitted a corrective action plan to improve screening procedures which was reviewed and approved by the VA Central IRB; no further remedial action was required. CASE CLOSED.
296	00	VA Central Office	H	**10/30/2014**	(1) A sub-investigator added to the study in April 2014 did not have an approved Research Scope of Practice. This apparent noncompliance was identified by the local RCO during a triennial regulatory audit of the study.	(1) The apparent noncompliance was reported to the CIRB and the sub-investigator developed a Research Scope of Practice. The CIRB determined that this event did not constitute serious or continuing noncompliance and did not require any further corrective action. CASE CLOSED.
297	00	VA Central Office	H	**10/30/2014**	(1) ORO received a report of a request for urgent amendment of a protocol for the sake of patient safety in a multicenter study on adverse events related to angiography. The amount of fluid infused before and after the procedure is calculated based on the patient's weight, which can result in fluid overload in obese patients and worsening heart failure.	(1) A revised procedure capping the weight used in calculating the amount of fluid was adopted immediately and the protocol amendment was reviewed and approved by the VA Central IRB. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
298	20	Portland	I	**10/30/2014**	(1) Research ICF was delivered to the facility Research office by a Research Assistant who is not on the list of approved study staff. PHI viewed was name, last 4 SSN, the study title and date of consent.	(1) PI required by IRB to ensure only study team members address activities approved by IRB on their specific assigned protocol. NSOC determined there was a policy violation, an unauthorized access/disclosure of data and that the incident has a low probability of a risk of compromise. CASE CLOSED.
299	12	Jesse Brown	H	**11/2/2014**	(1) Lapse in IRB approval.	(1) The IRB is requiring that the PI and his research study staff complete two on-line training courses: #112 Lapses in IRB Approval and #113 Lapsed Protocols Part II . The PI must provide documentation that the training courses have been completed. CASE CLOSED.
300	06	Durham	I	**11/3/2014**	(1) VASI stored on the affiliate University's server per subjects HIPAA authorizations. Data ownership remains unclear.	(1) Data released per executed HIPAA authorizations. Project is not considered collaborative or multi-site. Copy of data retained at VA.
301	08	North Florida South Georgia (Gainesville)	I	**11/4/2014**	(1) An investigator's emails to Veterans participating in a study were unencrypted and contained study type, patient appointments, email address and telephone numbers. No misuse of the information has been discovered.	(1) Investigator has stopped using email to communicate with Veterans participating in the research study. The unencrypted emails were deleted from the sender's Outlook folders. Training provided. CASE CLOSED.
302	22	Long Beach	H	**11/7/2014**	(1) IRB-directed suspension of study enrollment because of failure to submit AE information and DSMB reports with applications for Continuing Approval; also, delayed reporting to ORO (i.e., of the suspensions of enrollment).	(1) PI must provide information regarding study risk, DSMB reports, and submit revised continuing review applications. (2) PI must provide information regarding study risk, DSMB reports, and submit revised continuing review applications. CASE CLOSED.
303	23	Minneapolis	H	**11/7/2014**	(1) A subject inadvertently signed the HIPAA Revocation form instead of the HIPAA Authorization form, and a disclosure was made to the sponsor before the subject signed the HIPAA Authorization form.	(1) Document management practices have been improved. No further remedial action required. CASE CLOSED.
304	16	Central Arkansas (Little Rock)	I	**11/12/2014**	(1) Transmission of an external unencrypted email from facility staff to the affiliate IRB Administrator who is not listed as a participant on this protocol. PHI included subject number (protocol ID) with month/year of birth, gender, race, ethnicity, disease, and dates associated with this individual.	(1) Deletion of email from all email folders.
305	18	New Mexico (Albuquerque)	I	**11/12/2014**	(1) Correspondence containing PHI and PII for a Cooperative Studies Program protocol was being investigated for possible mail forwarding to an apartment of a former VA employee.	(1) Investigation and inventory determined no mail or specimens forwarded by US Postal Service. Interview with former employee who filed change of address from research site and US Postal staff confirmed. CASE CLOSED.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
306	04	Pittsburgh	I	**11/14/2014**	(1) Research Clinical Coordinator sent an unencrypted email containing subject's last name and last 4 of SSN to the study sponsor. (2) The HIPAA authorization did not authorize the study sponsor to receive the PHI.	(1) Emails containing PHI were deleted; staff was reminded not to transmit unencrypted PHI; The IRB determined no additional remediation was required. (2) The IRB determined that non-compliance had occurred but it was not serious or continuing. The remediation described in RC-1 was accepted and the data could be used in the study. CASE CLOSED.
307	20	Portland	I	**11/21/2014**	(1) 46 research subjects PHI was disclosed to a non-VA coordinating site. The ICF and HIPAA authorization documents for the study did not indicate that identifiable information would be disclosed. (2) PHI transmitted via unencrypted email, online web-based system and secured courier for paper media.	Disclosure of information and specimens will not be permitted until the incident has been resolved. The study has been placed on hold until the PI has updated the protocol, informed consent, HIPAA authorization and re-consented all 46 past participants. The VA NSOC has determined all participants will be sent a letter offering credit protection services.
308	15	Columbia MO (Truman)	H	**11/24/2014**	(1) A provider accessed 62 Veteran's medical records without IRB or R&DC approval, and without a waiver of HIPAA authorization.	(1) All unauthorized data was deleted by the provider on 11/13/2014. IRB and R&DC will further review the case.
309	11	Battle Creek	H	**12/5/2014**	(1) The current MOU assigns required responsibilities to a collaborating VA ACOS/R and not the local Coordinator for Research. (2) SOPs and Medical Center Memoranda describe that a collaborating VA ACOS/R and not the local Coordinator for Research must fulfill required oversight/support of the research program.	(1) The MOU with the collaborating VA must be revised to require the Coordinator for Research to fulfill the required responsibilities as the ACOS/R. (2) SOPs and MCMs must be revised to document the responsibilities of the Coordinator for Research and the processes to fulfill those responsibilities.
310	18	Phoenix	I	**12/10/2014**	(1) Unencrypted emails were sent to the study sponsor containing participants' date of study visit and the first case report also included DOB.	Pending.
311	20	Portland	I	**12/10/2014**	(1) Research subject was mailed a questionnaire that included another research subject's questionnaire with full name and study health inclusion criteria information. Questionnaire returned to VA.	Pending.
312	22	San Diego	I	**12/10/2014**	(1) A study registration form that included PHI (full name and SSN) for one research participant was inadvertently included in postal mail with a questionnaire to a different research participant.	(1) Network printer in metabolic unit locked to password protected job printing for VASI to prevent inadvertent paper mixing. New printer installed in coordinator office. Credit protection letter mailed. CASE CLOSED.
313	00	VA Central Office	H	**12/15/2014**	(1) ORO received notice that blood was drawn from a Veteran prior to the Veteran giving written consent to the study at one study site of a multicenter longitudinal study of Veterans' health.	(1) The local study site personnel were temporarily removed from the study to undergoing retraining in human subject protection procedures. The local site investigator apologized to the affected participant, who withdrew from the study.

TABLE 2A. REMOTE REVIEWS OF EXTERNALLY IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
314	00	VA Central Office	H	12/15/2014	(1) A study site for a multicenter study of quality of life in spinal cord injury patients did not obtain IRB approval prior to implementing a change in the consenting procedure.	(1) Remedial action pending.
315	16	Central Arkansas (Little Rock)	H	12/15/2014	(1) Subject enrolled against inclusion/exclusion criteria.	(1) Inform subject he was enrolled in study in error. (2) Data may not be included in data analysis. (3) Subject may continue in study if s/he wishes. If continues, protocol must be followed, including any reimbursements for time and effort.
316	23	Minneapolis	H	12/15/2014	(1) Lack of HIPAA authorization prior to use, and disclosure to the affiliate nonprofit and an outside laboratory.	(1) Veteran will be sent a notification letter concerning the unauthorized disclosure, and will be asked to sign the HIPAA authorization.
317	22	Greater Los Angeles	H	12/16/2014	(1) Audio tapes containing health information from a survey were sent to a transcription service without a HIPAA waiver, HIPAA authorization, or contract/Memorandum of Understanding (MOU).	Pending.
318	00	VA Central Office	H	12/17/2014	(1) ORO received notice that an RCO audit at one study site of a multicenter trial of treatment in depressed patients identified an enrolled subject who should have been excluded from the study.	Pending.
319	04	Pittsburgh	I	12/23/2014	(1) One lost completed HIPAA authorization with research-related PHI.	(1) VA-NSOC required notification letter to one participant. Participant re-signing HIPAA authorization. Pending.
320	05	Maryland	I	12/23/2014	(1) Missing partial HIPAA authorizations with research-related PHI.	Pending.
321	17	North Texas (Dallas)	I	12/24/2014	(1) Sixty original informed consent documents are missing.	Pending.
322	11	Ann Arbor	I	12/30/2014	(1) An unlocked shred bin possibly involves research PHI.	Pending.
323	07	Atlanta	I	12/31/2014	(1) VA sensitive information stored off-site on a non-VA laptop.	Pending.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

The Director of each VA research facility is required to report promptly to ORO any serious or continuing noncompliance in the facility's research program. ORO requires that the facility develop an acceptable remediation plan and monitors implementation of the plan until remediation is complete.

Summary

- 23 = Cases Continuing from Previous Calendar Year
- **48 = New Cases – January 1 through March 31**
- **57 = New Cases – April 1 through June 30**
- **61 = New Cases – July 1 through September 30**
- **38 = New Cases – October 1 through December 31**
- 204 = Total New Cases in Calendar Year
- 227 = Total Cases (Continuing Plus New) in Calendar Year

***** Case #4 and Case #9 were inadvertently omitted from the 1st Quarter report.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	01	White River Junction	H	03/13/2013	Facility reported programmatic non-compliance in a prostate cancer study. The R&DC approved an amendment involving collection of data from pregnant partners and child of participant.	Remedial Actions: R&DC Approval letter was not sent; PI and study staff informed to not enroll any pregnant women or children into the study, Education regarding the requirement for CRADO waiver provided to PI and study staff. CASE CLOSED.
2	01	White River Junction	H	03/29/2013	Facility reported prostate cancer study suspension due to R&DC approval prior to IBC review and approval. One subject had been consented; no study evaluations had yet occurred and will not occur until IBC approval obtained.	Remedial Actions: Staff education; R&D Committee education; quality improvement team chartered; IBC review and approval of protocol, update MOU with affiliate IBC. CASE CLOSED.
3	20	Boise	H	06/20/2013	Facility reported unapproved research, involving two studies (cardiopulmonary resuscitation and distance learning DOD funded) conducted by the same PI, that could be potentially exempt from IRB.	Remedial Actions: Noncompliance acknowledged by IRB; closure of prior study; new study exempted from IRB review, to be managed by R&DC. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
4	01	*White River Junction	H	09/12/2013	Facility reported affiliate IRB committee membership issues including misidentification of scientist vs non-scientist. In addition, four studies had issues during the approval process and need to be re-reviewed.	Remedial Actions: Research halted at the facility, active protocols undergoing detailed review to ensure appropriate approval. Five protocols re-reviewed by full committee and 15 re-reviewed by expedited process. CASE CLOSED.
5	07	Atlanta	H	09/17/2013	Facility reported unauthorized study staff member access to database with PHI in cardiology genetic risk assessment study (data analysis).	Remedial Actions: PO/ISO review; PI retakes Human Subjects Protections training; study closure; RCO audits of current studies; PI mentoring. CASE CLOSED.
6	16	Shreveport (Overton Brooks)	H	09/18/2013	Facility reported that a subject in the MVP study had blood drawn prior to signing an ICD and HIPAA authorization.	Remedial Actions: Clinical phlebotomists will be educated not to draw research blood samples until signed informed consent and HIPAA documents have been verified; consent subject or destroy blood sample. CASE CLOSED.
7	05	VA Maryland HCS	H	09/19/2013	Facility reported the IRB suspended a venous thromboembolism prophylaxis study due to concerns about inconsistencies between protocol and ICD arising from numerous recent modifications to both documents.	Remedial Actions: PI must rewrite protocol and ICD to incorporate required descriptions of procedures, eligibility criteria, usual care, sponsorship, in consultation with the Clinical Research Training Mentoring Program. CASE CLOSED.
8	06	Durham	H	09/20/2013	Facility reported that a nutritional study failed to obtain HIPAA authorizations for subjects.	Remedial Actions: Subjects contacted and will be given option to sign HIPAA at next scheduled visit; staff education related to need to obtain both ICD and HIPAA Authorizations at enrollment; IRB approved HIPAA Waiver for future use of data. CASE CLOSED.
9	16	*Central Arkansas (Little Rock)	H	10/03/2013	Facility reported notification from the sponsor that treatment Arm A in this high-risk melanoma study is suspended due to a greater number of grade 5 serious adverse events than expected. The local facility does not have any subjects enrolled in Arm A.	Remedial Actions: PI to close Arm A; provide IRB with revised protocol, ICD and other related documents concerning the closure of Study Arm A. PI to obtain justification from Sponsor and/or DMSB to reopen Study Arm A. CASE CLOSED.
10	17	VA North Texas HCS	A	10/21/2013	Facility reported a protocol deviation in which a mouse was allowed to exceed the protocol approved weight loss of 20%.	Remedial Actions: Report to ORD, OLAW and AAALAC; the IACUC will investigate if post-operative procedures were properly followed; The PI will receive a letter requesting adherence to all IACUC policies regarding postsurgical monitoring and submitting amendments. CASE CLOSED.
11	01	White River Junction	R	10/24/2013	Facility reported one subject in a CIRB approved depression study did not meet inclusionary criteria. The subject was taking an exclusionary drug at the time of enrollment.	Remedial Actions: Staff education, review of inclusion/exclusion criteria and event reporting procedures; remediation plan developed and accepted by CIRB, training provided on PI responsibilities and event reporting. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
12	16	Central Arkansas (Little Rock)	H	11/01/2013	Facility reported a subject was enrolled into a prevention of postoperative nausea and vomiting study against exclusion criteria.	Remedial Actions: Education; complete deviation/violation form; and provide justification for the IRB to consider the continued use of the subject's data. CASE CLOSED.
13	08	Orlando	H	11/08/2013	Facility reported the approved IRB consent lacked the required VA injury statement. Two subjects signed the consent prior to identification of the issue. Additionally, VA Form 10-9012 Investigational Drug Information Record) was found to lack required signatures.	Remedial Actions: The PI re-consented the subject with the correct ICD. Changes were made to the IRB reviewers checklist so that injury language will be carefully reviewed in the future. Training for IRB, R&DC members and research personnel was initiated. CASE CLOSED.
14	01	Providence	H	12/06/2013	Facility reported IRB's failure to report to ORO suspension of a study evaluating use of topical investigational agent in Diabetic patients for treatment of diabetic foot ulcers due to protocol deviation	Remedial Actions: Study suspension; refresher training for IRB members by RCO. CASE CLOSED.
15	05	VA Maryland HCS	H	12/08/2013	Facility reported that research blood was drawn from a Cardiac Intensive Care Unit patient who was not enrolled in this pharmacogenetics study.	Remedial Actions: Study staff retraining, coordinator will verify participant ID before order is placed. CASE CLOSED.
16	18	New Mexico VA HCS	H	12/10/2013	Facility reported a research assistant performed venipuncture within three protocols (MVP and two mental health studies) despite the scope of practice not including venipuncture. The assistant is trained and certified in venipuncture.	Remedial Actions: Research Scope of Practice and VetPro updated to reflect training and certification in venipuncture procedures. CASE CLOSED.
17	01	VA Connecticut HCS	H	12/12/2013	Facility reported nine subjects were entered into a study on Veterans at risk for hospital readmission without signed consent forms, HIPAA authorizations, or picture/voice consents. No PHI data left the facility.	Remedial Actions: PI and research team education; PI continue to closely monitor the study; participants to be re-contacted to obtain consents and authorizations; data will not be used for those who do not provide consents and authorizations. CASE CLOSED.
18	18	Phoenix VA HCS	I	12/18/2013	Facility reported a CRC inadvertently gave a research subject her husband's cell phone number instead of her own number. The subject called the husband's cell phone; therefore the subject's name and phone number were accidentally disclosed to the husband who is not involved in the research study.	Remedial Actions: Facility PO ensured that all research participant data removed from cell phone; Research Coordinator reminded to verify phone numbers given to participants; NSOC determined no notifications required; IRB accepted remedial actions with no further requirements. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
19	21	San Francisco	H	12/19/2013	Facility reported a PI of a chronic obstructive pulmonary disease observational study arranged for 4 subjects to undergo an additional blood draw prior to IRB approval of an amendment despite the research nurse manager informing the PI this draw was not yet authorized.	Remedial Actions: IRB warned PI that such future offense could result in suspension; PI counseled. CASE CLOSED.
20	21	San Francisco	H	12/19/2013	Facility reported the conduct of a retrospective chart review of patients treated for glaucoma without R&DC approval.	Remedial Actions: Cessation of unapproved research pending. VA approval and established a plan to ensure prompt reporting to ORO. CASE CLOSED.
21	11	Indianapolis (Roudebush)	H	12/20/2013	Facility reported staff member on lung cancer study removed VA data outside VA protected environment. Data was returned to PI without incident.	Remedial Actions: No further actions required. CASE CLOSED.
22	22	VA Loma Linda HS	I	12/23/2013	Facility reported the inadvertent disclosure of a deceased subject's address to the study sponsor. This was a study of type 2 diabetic and acute coronary syndrome patients.	Remedial Actions: Information shredded by sponsor; study staff will provide blinded documents to the regulatory specialist prior to sending offsite. CASE CLOSED.
23	09	Memphis	H	12/26/2013	Facility reported a CIRB determination of serious noncompliance for a CSP colorectal cancer study consisting of invalid consent of one subject. The subject was consented 30 minutes after receiving sedation for another procedure.	Remedial Actions: Subject's consent not valid, re-consent if subject is to be enrolled; additional training regarding proper consenting procedures. CASE CLOSED.
24	21	San Francisco	A	**01/08/2014**	Facility reported the suspension of a PI's animal use privileges due to serious welfare concerns (unapproved burn procedure performed on some anesthetized mice).	Remedial Actions: Indefinite suspension of all animal use privileges for the PI; performance of an Administrative Review regarding the conduct of the PI.
25	06	Salem	H	**01/13/2014**	Facility reported that a PI of an observational health assessment study self-identified that 6 HIPAA Authorizations were not signed.	Remedial Actions: All missing HIPAA's were obtained; Corrective & Preventative action plan put in place. CASE CLOSED.
26	23	Iowa City	I	**01/14/2014**	Facility reported that consent documents for an Internet health information study were mailed via USPS to two subjects for signatures; however, the forms were lost in the mail and not received. PHI consisted of name, full SSN and home address. Both subjects have since reported locating their research documents.	Remedial Actions: PO reeducated study team on proper mailing procedures; staff will not pre-fill forms for mailing; modify protocol to specify forms will not be pre-filled; credit protection services were offered to two Veterans. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
27	16	Houston (Michael DeBakey)	H	01/16/2014	Facility reported that research was initiated without R&DC review and approval for a retrospective chart review study of diabetic Veterans who remain ambulatory after amputations. The study enrolled 35 participants and data collection has already been completed.	Remedial Actions: PI must submit the protocol for review and approval to the R&DC; R&DC must decide on use of the research data obtained from this IRB-approved study. CASE CLOSED.
28	06	Durham	I	01/21/2014	Facility reported transmission of an internal unencrypted email containing PHI (name, address, last 4, phone numbers) of 13,197 VA-registered patients. Information was collected under a waiver HIPAA authorization. Occurrence reported as required with NSOC closure same day.	Remedial Actions: The email was promptly deleted by the sender and recipient; both employees have received training on protecting PII. CASE CLOSED.
29	08	Orlando	H	01/28/2014	Facility reported that 2 subjects on a Hepatitis C drug study were improperly dose reduced per the direction of the sponsor for grade 4 labs. There was a delay in reporting the deviations.	Remedial Actions: The initial corrective action plan submitted was for the IRB chair to meet with the PI to review the protocol deviations and to discuss the importance of timely reporting. Improved protocol deviation form 023. CASE CLOSED.
30	09	Louisville (Robley Rex)	P	01/31/2014	Facility reported that the PI of a tumor growth study sponsored by ORD did not submit 2 publications, resulting from the study, to the ACOS/R prior to publication. However, the articles did appropriately acknowledge the VA.	Remedial Actions: Investigator was provided a copy of the publication handbook and local publication flow-chart; remedial actions complete, CASE CLOSED.
31	21	San Francisco	H	01/31/2014	Facility reported that an ineligible Veteran, who was at risk for excessive post-operative bleeding, was enrolled in a pilot safety and efficacy investigational drug study for patients with peripheral artery disease who undergo angioplasty.	Remedial Actions: Sponsor and FDA notified; PI to review lab results and eligibility criteria one week prior to surgery; PI must have IRB approval to enroll any subjects who do not meet eligibility criteria. CASE CLOSED.
32	01	VA Connecticut HCS	S	01/31/2014	Facility reported lapse in SRS approval of nine safety protocols.	Remedial Actions: Investigators will be queried to determine if research continued during lapses in approval. CASE CLOSED.
33	06	Hampton	H	02/03/2014	Facility reported that a university employee without VA affiliation used VA information in publishing (with permission) a student's doctoral dissertation. CASE CLOSED.	Remedial Actions: Re-education and re-training the PI regarding the use of VA data. CASE CLOSED.
34	16	Central Arkansas (Little Rock)	I	02/03/2014	NSOC reported unencrypted email transmission by contractor containing PHI.	Remedial Actions: Rectified at CSP Coordinating Center. CASE CLOSED.
35	16	Central Arkansas (Little Rock)	H	02/05/2014	Facility reported that a monitor report for a vascular stent graft system study noted 3 SAEs, which were reported to the Sponsor, but not the IRB.	Remedial Actions: The investigator was reminded of reporting time frames. No additional corrective actions were required. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
36	18	Southern Arizona VA HCS	H	02/06/2014	Facility reported multiple protocol deviations in a CSP Diabetes Trial Follow-up Study consisting of omitted evaluations, failure to compensate subjects per protocol, failure to flag as research in CPRS, and absence of a timely report.	Remedial Actions: Previous study team removed from study; PI has confirmed that all deviations have been disclosed and data may be included for analysis despite missing elements; all evaluations will be completed; subject payments with IRB-approved letter of apology; CPRS research flags. CASE CLOSED.
37	01	VA Boston Healthcare System	I	02/06/2014	Facility reported to ORO and NSOC that letters to two research participants in a CSP OIF mental health outcomes study were inadvertently reversed. PHI exposed was name and address. One participant opened the envelope and returned it to the VA; the other participant returned the envelope unopened.	Remedial Actions: Notification letter to participant whose PHI was exposed; education provided to staff on correct mailing procedures. CASE CLOSED.
38	05	VA Maryland HCS	H	02/06/2014	Facility reported a study coordinator left research participant charts (after hours, admitted by a housekeeper) in a locked GCRC but failed to place the charts in a secondary locked unit per protocol (study of staph cultures).	Remedial Actions: Update study chart procedures; retrain coordinator on study chart procedures and document security. CASE CLOSED.
39	22	VA Southern Nevada HS (Las Vegas)	H	02/10/2014	Facility reported the IRB of record suspended new enrollment in human subject studies and suspension of initiation of new studies at this facility. Concern was raised regarding lack of research support and resources provided by facility administration.	Remedial Actions: Facility is developing a strategic plan that will identify how it can effectively conduct research; suspension reissued for all studies; multiple research staff positions posted and potential candidates sent to managers for review; research advisory committee developed to provide local guidance for research program.
40	06	Salem	H	02/11/2014	Facility reported use of an ICD without the signature line for the person obtaining consent (10 subjects).	Remedial Actions: IRB corrective & preventative actions; PI corrective actions; SRO suggestion for staff retraining. CASE CLOSED.
41	05	VA Maryland HCS	A	02/12/2014	Facility reported protocol deviations in a study involving rodents consisting of a change in the euthanasia agent used; behavioral tests not described in the protocol; and unauthorized personnel.	Remedial Actions: Submission of amendments; additional of personnel; staff training on regulatory compliance. CASE CLOSED.
42	05	VA Maryland HCS	H	02/12/2014	Facility reported IRB-determined continuing noncompliance based on RCO reg. audit, findings: 4/22 participants started study prior to informed consent; PI signed 10/10 eligibility checklists 1 - 21 days after consent; 4/10 participants; research assistant signature missing on item 7 (documents payment voucher completion).	Remedial Actions: No data will be used from ineligible participants per PI; IRB accepted PI's remedial actions. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
43	07	Atlanta	R	02/13/2014	Facility reported noncompliance related to R&DC oversight of collaborative research activity (VA and affiliate IACUC) and continuation of research beyond approval period.	Remedial Actions: Amend affiliate/VA IACUC MOU to include approval by VA IACUC of any collaborative work performed at either affiliate or VA; memo to all VA PIs re: approval by VA IACUC of any research activity at VA even though previously approved by Affiliate IACUC; amend VA PI study. CASE CLOSED.
44	05	VA Maryland HCS	I	02/18/2014	Facility reported that a vital signs sheet containing PHI (name, date of study visit and participant vital signs) was missing from one participant's research chart. Team assumes the document was misfiled and not lost. This is an exercise trial in chronic kidney disease.	Remedial Actions: Form revised to contain only the study ID number and date; HIPAA notification letter sent to the participant. CASE CLOSED.
45	08	Bay Pines	H	02/20/2014	Facility reported an inadequate medical record (lack of CPRS documentation) based on an administrative review of a PTSD treatment study.	Remedial Actions: The IRB suspended recruitment of new participants into the study and currently enrolled participants should continue with study interventions without interruption according to the approved protocol. The study monitor conducted 100% chart review of all subjects. PI changed, Protocol revised and approved, staff trained, suspension lifted. CASE CLOSED.
46	01	VA Boston Healthcare System	H	02/20/2014	Facility reported inadvertent shredding of original ICDs in a study of "measuring moral injury".	Remedial Actions: Case misdirected to NERO - transferred to RISP for follow up in case #0131-523-I. CASE CLOSED.
47	01	VA Boston Healthcare System	H	02/20/2014	Facility reported 112 subjects were enrolled who fell outside of the age range specified in the eligibility criteria in a study of "attention and distraction in the brain".	Remedial Actions: Study suspended to new enrollment; eligibility checklist developed; PI must provide scientific justification for change in age range CASE CLOSED.
48	01	VA Boston Healthcare System	H	02/20/2014	Facility reported 182 missing HIPAA Authorizations in a colonoscopy study.	Remedial Actions: For Cause ICD audit conducted, HIPAA Authorizations must be obtained or data cannot be used, PI must correct some irregularities detected during ICD audit. CASE CLOSED.
49	15	Wichita (Dole)	H	02/20/2014	Facility reported multiple protocol deviations (pulmonary disease study) including investigational product errors, out of window visits, failure to re-consent as required, failure to timely report SAEs. Errors did not reflect risks to subjects; rather persistent failure to adhere to requirements.	Remedial Actions: PI education on reporting timeframes; RCO to audit study, provide further education; PI and study staff to initiate regular research education. CASE CLOSED.
50	16	Central Arkansas (Little Rock)	H	02/25/2014	Facility reported protocol violation of enrolling a subject into a cardiovascular study who met the exclusion criteria (taking a medication that increased risk of bleeding).	Remedial Actions: Remove involved subject's data; provide IRB enrollment risk assessment; and revise ICD that certain medications may increase risk of bleeding when taking with the study medication. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
51	04	VA Pittsburgh HCS	R	02/25/2014	Facility reported continuation beyond expiration date determined by the IBC for a study of metabolomics in psychosis and therapeutic monitoring.	Remedial Actions: Updated protocol reviewed by IBC; review for additional studies continuing beyond expiration dates; biosafety officer assessments of studies. CASE CLOSED.
52	17	VA Central Texas HCS	H	02/26/2014	Facility reported failure of the IRB to review an SAE report in a study to prevent herpes zoster in two types of cancer patients within the required timeframe. Noncompliance was apparently due to an administrative error (turnover in the SAE reviewer staff); no other SAE reports have been missed.	Remedial Actions: Additional email will be sent acknowledging receipt of SAE reports. PIs will be reminded quarterly to immediately report SAEs. Email group will be created for reporting SAEs. CASE CLOSED.
53	04	VA Pittsburgh HCS	S	02/26/2014	Facility reported lapse in IBC approval with continuation of research.	Remedial Action: PI required to submit a new biosafety protocol, which was approved with minor contingencies. Additional investigation into six other studies from the same PI is required to determine if they also lapsed with continuation of research. CASE CLOSED.
54	09	VA Tennessee Valley HCS	I	03/03/2014	Facility reported destruction of ICDs and HIPAA authorizations for two subjects consented and determined ineligible for this stem cell collection study. The two subjects were re-consented at a later time and enrolled in the study.	Remedial Actions: Education related to ICDs and records management was provided to study coordinator; occurrence documented per local policy. CASE CLOSED
55	07	Atlanta	A	03/04/2014	Facility reported unapproved research involving the use of mice.	Remedial Actions: Training; review of IACUC procedures. CASE CLOSED.
56	02	Syracuse	H	03/05/2014	Facility reported numerous events of apparent non-compliance and/or research improprieties (not substantiated as research misconduct per USH decision) on two NIH funded human behavioral health studies involving non-Veterans at an off-site private chemical dependency clinic. PI made modifications to a protocol and implemented without prior IRB approval; PI conducted follow-up visits on another protocol outside of approved time frame.	Remedial Actions: Independent Committee has been established to review the numerous apparent research improprieties; independent RCO audits for two protocols involved have been completed. IRB made the determination that PI cannot use the data collected on the two protocols to contribute to generalizable knowledge; IRB has recommended the R&DC consider additional restrictions on PI.
57	22	VA Greater Los Angeles HS	H	03/05/2014	Facility reported expiration of study approval with continuation of protocol activities during the period of lapsed approval. This is a study of CT scanning in chronic kidney disease.	Remedial Actions: Monthly report listing project expirations will be provided to the IRB; IRB staff will receive refresher education regarding continuing review and approval expiration. CASE CLOSED.
58	06	Durham	A	03/07/2014	Facility reported unapproved procedures in mice for study on melanoma therapy.	Remedial Actions: IACUC investigation; submission of ACORP amendment. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
59	06	Durham	A	03/07/2014	Facility reported unapproved procedures in mice for study on immunologic therapies.	Remedial Actions: IACUC investigation; submission of ACORP amendment. CASE CLOSED.
60	23	Minneapolis	R	03/07/2014	Facility reported administrative noncompliance consisting of initiation of three protocols (one evidence-based practice study and two renal studies) in absence of the required R&DC approval.	Remedial Actions: Process for determination of human vs nonhuman research; determination of status information collected prior to R&DC approval; and PI education. CASE CLOSED.
61	17	VA North Texas HCS	H	03/07/2014	Facility reported that a subject randomized to one arm of a colorectal cancer screening study was scheduled for the other study arm at subject's insistence instead of being withdrawn; one subject was consented by an unauthorized and untrained research assistant.	Remedial Actions: Withdraw subject who insisted on opposite arm; re-consent subject enrolled by unauthorized untrained research assistant. The CIRB determined that the noncompliance had been serious noncompliance, accepted the LSI's clarifications regarding retention of the study subject and the delay in reporting. CASE CLOSED.
62	06	Durham	A	03/10/2014	Facility reported the deaths of two mice due to lack of water bottle on cage being cared for by PI staff.	Remedial Actions: VMU staff will check all cages and research staff instructed to verify that all cages have sufficient food and water. CASE CLOSED.
63	22	VA Greater Los Angeles HS	H	03/13/2014	Facility reported a lapse in IRB approval for a randomized clinical trial on prevention of recurrent cardiovascular events. The PI recognized failure to apply for continuing review and took action; IRB approval was then obtained 14 days after the lapse.	Remedial Actions: Three subjects were permitted by the IRB to continue on protocol during the lapse; continuing approval granted; IRB instituting procedural and educational reforms to prevent a recurrence. CASE CLOSED.
64	16	Central Arkansas (Little Rock)	R	03/18/2014	Facility reported a lapse in approval of a protocol on religion and mental health care and suspension by the R&DC. The PI left VA employment without requesting closure or transfer of the study to another investigator.	Remedial Actions: Develop a process to verify that protocols under R&DC, IACUC or SRS are notified of continuing review lapses; consider ways that Research can be alerted to departure of PIs from VA employment; close this protocol or request a PI change. CASE CLOSED.
65	23	Iowa City	I	03/19/2014	Facility reported inadvertent transmission of an email containing Veteran PHI (name and SSN) outside of the VA to two affiliate addresses. This is a study of Internet use for health information.	Remedial Actions: Research assistant verification of information prior to emailing; encrypt when needed; will utilize network drive whenever possible to avoid emailing VASI; retraining on Privacy and HIPAA; email removed from all systems. CASE CLOSED.
66	09	Louisville (R Rex)	H	03/21/2014	Facility reported a PI of a diabetes and anemia retrospective chart review study self-identified that records were reviewed in excess of the IRB-approved number; the dataset included unapproved coded data; and 19,000 research records were destroyed (including IIHI).	Remedial Actions: Provide education to PI and staff for retrospective chart review guidelines and record retention; possible retrieval of data; implement a communication standard for retrospective data collections; report to OHRP pending. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
67	04	VA Pittsburgh HCS	H	03/21/2014	Facility reported that one subject, on a prevention of migraine study, did not have follow-up safety labs drawn as prescribed in the approved protocol. Labs were subsequently done and results were within normal limits.	Remedial Actions: PI to develop corrective action plan to prevent future occurrence of the problem; written confirmation from PI that laboratory test results were within normal limits. CASE CLOSED.
68	11	Ann Arbor HCS	I	03/24/2014	Facility reported transmission of an internal unencrypted email containing PHI of 23 enrolled subjects. This is a computer-assisted Cognitive Behavioral Therapy study.	Remedial Actions: Both parties immediately deleted the email; Public Key Infrastructure training completed; future transfers of identifiable information related to subject lists will occur via hard copy or fax; RCO will develop investigator specific instructions regarding the maintenance of PII in regulatory binders; note added in ORO closure communication informing facility that internal unencrypted emails containing VASI are to be reported to the VA-NSOC. CASE CLOSED.
69	15	St Louis	H	03/24/2014	Facility reported that study devices (screening kits) were provided to two patients who were not enrolled in this CSP colorectal screening study.	Remedial Actions: A thorough investigation was conducted by the local and national study teams; the teams developed a process to ensure more secure controls of the devices; the two patients could not be identified; local R&DC SOPs were updated to include CIRB SAE reporting to additional research office personnel. CASE CLOSED.
70	04	VA Pittsburgh HCS	S	03/28/2014	Facility reported overexposures to waste anesthetic gases and staff that had not completed required training.	Remedial Actions: Additional training; PI submitted corrective action plan to minimize future exposures. CASE CLOSED.
71	17	VA Central Texas HCS	A	03/31/2014	Facility reported two incidents involving injuries to rats.	Remedial Actions: Review of procedures; training; development of a tracking log to monitor animals. CASE CLOSED.
72	08	Bay Pines VA Healthcare System	I	04/01/2014	Facility reported a research coordinator sent four internal unencrypted emails to the pharmacy despite reminders to encrypt the messages. PHI included names and last four SSN. Facility did NOT report to the VA-NSOC as required by regulations.	Remedial Actions: PO verified that the unencrypted email messages were removed from the sender and recipient email accounts; ORO provided guidance and regulatory clarification regarding need to report to VA-NSOC. CASE CLOSED.
73	07	Charlie Norwood	A	04/01/2014	Facility reported a noncompliance involving post-operative care in mice.	Remedial Actions: IACUC investigation; increased post-operative monitoring; remedial training. CASE CLOSED.
74	08	North Florida/South Georgia Veterans Health System	H	04/08/2014	Facility reported that a stroke recovery training study consented four subjects on a consent form for testing and training when this specific control group completed the testing only.	Remedial Actions: Revision adding consent for healthy controls completing 1-day training activities only; all consent templates labeled in the footer as to the kind of activities to be performed; re-consent four subjects; letter sent to subjects. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
75	10	Dayton	H	04/09/2014	Facility reported that an unfunded, retrospective chart review study, on a matrix used to treat foot ulcers was conducted without IRB and R&DC review. Consequently no waivers of ICD or HIPAA were obtained for the 66 records reviewed.	Remedial Actions: PI was educated on the requirements of conducting human research, including chart reviews; PSETS ticket created. CASE CLOSED.
76	21	VA Palo Alto HCS	A	04/09/2014	Facility reported the unanticipated loss of life (8 mice).	Remedial Actions: Retraining VMU staff; engage levers for all cages in the horizontal position regardless of the presence of animals; update SOPs. CASE CLOSED.
77	23	Minneapolis VA HCS	H	04/11/2014	Facility reported that study staff continued to use CPRS to collect PHI from 16 Veterans' charts for 3 knee replacement surgery protocols after the IRB had implemented (ORO directed) study suspensions for serious and continuing noncompliance.	Remedial Actions: Study staff retrained; subject data obtained during protocol suspensions was sequestered; study coordinator's access to patient medical records was revoked. CASE CLOSED.
78	03	VA New Jersey HCS	H	04/11/2014	Facility reported PI contacting subjects after they declined to participate; sending questionnaires without IRB approval; and conducted research with a DoD facility without a proper MOU in a joint VA and DoD study of Veterans at risk for unexplained illness.	Remedial Actions: Education; submit amendment to change PI; cease contact with subjects; de-identify data; and submit list of subjects to IRB. CASE CLOSED.
79	17	VA North Texas HCS	A	04/11/2014	Facility reported use of expired anesthetic in research rats.	Remedial Actions: Retraining personnel; VMU Supervisor will conduct and document monthly controlled substance inspections and sign Controlled Substance Inspector's monthly audit; a letter detailing the event and actions was sent to the Principal Investigator. CASE CLOSED.
80	01	Bedford (Edith Rogers)	H	04/14/2014	Facility reported that the HIPAA authorization used with 15 subjects in a pilot study using fMRI to understand drug craving and control was missing a disclosure statement.	Remedial Actions: The study team will inform the 15 subjects of the omission and request new HIPAA authorizations. CASE CLOSED.
81	06	Durham	A	04/15/2014	Facility reported than an Investigator exceeded the approved number of mice on Protocol Number ACUC 0929-027; Prostaglandin E2 and Regulation of Kidney Function.	Remedial Actions: IACUC determined this deviation should be reported to ORO, ORD, OLAW, and AAALAC; the IACUC recommended that the PI assign a staff member to track animal use and submit monthly usage reports to the IACUC. CASE CLOSED.
82	18	Phoenix VA HCS	H	04/16/2014	Facility reported that 2 subjects in a drug study on the anti-inflammatory effects of an antibiotic on lung cells were enrolled without HIPAA authorization.	Remedial Actions: Data from the 2 study subjects segregated, new PI approved, attempting to obtain HIPAA authorization from the two subjects. If unable, their data will not be used. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
83	22	VA San Diego Healthcare System	H	04/21/2014	Facility reported that an unauthorized disclosure of drug use occurred during recruitment of a non-veteran into a study to investigate the safety and efficacy of Nepicastat to treat cocaine dependence.	Remedial Actions: The PI provided the study coordinator additional training and apologized to the prospective subject. CASE CLOSED.
84	16	Central Arkansas (Little Rock)	H	04/22/2014	Facility reported a deviation/ violation report submitted by the PI reported that the pharmacist incorrectly dispensed study medication.	Remedial Actions: Pharmacy will require monitoring visits for all studies including PI initiated studies; site initiation visit in which the sponsor/PI will meet with the pharmacy and review their drug handling procedures; pre-study dispense, which will allow the PI to see if the protocol is being adhered to properly prior to the first subject dispense. Additional monitoring will be scheduled as required. CASE CLOSED.
85	05	Washington DC	H	04/22/2014	Four subjects did not sign HIPAA Authorizations.	Remedial Actions: PI and staff plan to obtain signatures before using data collected so far. IRB requested an explanation and a CAP. CASE CLOSED.
86	06	Durham	I	04/29/2014	Facility reported that a research employee kept a protected health information (PHI) receptacle in his/her office. It was inadvertently emptied by Environmental Management Service (EMS) into the regular trash. The employee is uncertain whether or not PHI was in the emptied receptacle.	Remedial Actions: Training on the supervision of research privacy incidents completed by study staff. CASE CLOSED.
87	04	VA Pittsburgh Healthcare System	S	04/29/2014	Facility reported the suspension of research activities in a laboratory.	Remedial Actions: Suspension of research activities; periodic unannounced laboratory inspections to unsure research activities were discontinued. CASE CLOSED.
88	08	Tampa (James Haley)	H	04/30/2014	Facility reported that there was a programmatic deficiency obtaining waivers of informed consent and HIPAA authorization for screening purposes when the potential subjects are the Principal Investigator's or other study staff's own clinical patients.	Remedial Actions: The facility IRB determined this practice to be serious noncompliance; Service corrective plan included educating the principal investigators, study staff, research compliance, research administration, IRB personnel, and Privacy Officers with information via email. Investigators affected by this deficiency were instructed to submit amendments to the IRB requesting the appropriate waivers. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
89	03	VA New Jersey HCS	R	05/02/2014	Facility reported a study was active without SRS annual approval and continued beyond expiration date established by the SRS from October 28, 2003 to 2009 on a prospective study of functional status of Veterans at risk from unexplained illness. Report also indicated the saliva samples are still to be kept even though the DoD's IRB consent form stated they would be discarded after 3 years.	Remedial Actions: Education PIs and their staff of protocol submission procedures and R&RC staff of requirements for continuing review and approvals, verification if samples were de-identified, and whether the DoD IRB facility and the other VA facility and affiliate were notified of the DoD consent violation. CASE CLOSED.
90	10	Cincinnati	H	05/05/2014	Facility reported that in a diabetes mellitus study a WOC employee who had not been added to the study staff consented nine subjects.	Remedial Actions: Data can only be used for subjects who are re-consented; research team to receive training on study management software, WOC was approved as study personnel. CASE CLOSED.
91	10	Cincinnati	H	05/05/2014	Facility reported that 61 participants in a pre-op ear nose throat (ENT) education study had not signed a HIPAA Authorization.	Remedial Actions: PO reviewed the study and determined that a HIPAA authorization was not needed for those subjects; IRB determined the case was not serious or continuing noncompliance. CASE CLOSED.
92	16	Oklahoma City	H	05/06/2014	Facility reported the loss of an ICD and HIPAA.	Remedial Actions: This case is being followed by ORO RISP team. CASE CLOSED.
93	01	VA Boston Healthcare System	A	05/06/2014	Facility reported a suspension of surgical activities.	Remedial Actions: Supervise procedures; PI to submit copies of analgesic logs to IACUC Coordinator; VMO to review analgesic regimen; reassess new procedures; and update existing policies for contacting ARF staff. CASE CLOSED.
94	05	VA Maryland HCS	I	05/06/2014	Facility reported a missing data collection form containing PHI (last four SSN and the assigned unique study identifier) for one participant in an exercise study. The incident was reported to the NSOC and a search for the form is ongoing.	Remedial Actions: Name and last four SSN removed from the form; subject ID is sole identifier; files linking participant and PHI contained only behind VA firewall; study ID number for affected participant was changed to break link on lost form; participant will be notified. CASE CLOSED.
95	03	VA New Jersey HCS	S	05/06/2014	Facility reported lapse in continuing approval by the SRS.	Remedial Actions: Discard study samples; document length of sample retention; and evaluate need for SRS continuing review of data analysis studies. CASE CLOSED.
96	01	Providence	H	05/08/2014	Facility reported that PI enrolled Veterans in 'Strength at Home: Men's Program' a study involving intervention sessions to stop intimate partner aggression during the period when the Certificate of Confidentiality had expired.	Remedial Actions: PI must submit a request to NIMH for renewal of the Certificate of Confidentiality; PI must immediately stop the use of invalid ICFs; PI must submit corrected ICFs for any further recruitment; oral script without Certificate of Confidentiality language was approved for use by IRB. The NIMH has extended the expiration date of the Certificate of Confidentiality until end of calendar year. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
97	16	Central Arkansas (Little Rock)	H	**05/12/2014**	Facility reported continuing non-compliance due to a PI's repeated lapse of protocol approval due to delinquent submission of continuing review material to the IRB.	Remedial Actions: IRB closed the protocol and informed the PI that future lapses in IRB approval in other studies could result in further compliance review and potential study termination and/or revocation of research privileges. CASE CLOSED.
98	08	Tampa (James Haley)	H	**05/12/2014**	Facility reported a failure to obtain HIPAA authorization for one subject while obtaining informed consent.	Remedial Actions: The remedial action plan submitted to the IRB was to re-educate the study staff who are conducting the consenting process. CASE CLOSED.
99	07	Ralph H. Johnson (Charleston)	H	**05/13/2014**	Facility reported that RCO inquiry discovered the PI had two studies which were IRB-approved but never submitted to the R&DC.	Remedial Actions: The IRB determined that initiating research without VA R&DC approval constitutes serious non-compliance, but understood that this was the Investigator's first studies using an affiliate VA IRB. The VA R&DC subsequently reviewed and approved both studies. CASE CLOSED.
100	08	VA Caribbean HCS (San Juan)	H	**05/13/2014**	Facility reported the IRB's determination of continuing noncompliance of research staff in completing the required training, scopes of practice, and failing to comply with IRB's requested actions.	Remedial Actions: Submit changes in study staff removing both co-investigators who are non-compliant; submit a detailed plan to avoid training lapses in the future; submit a notification certifying that the co-investigators did not perform any research activities while the training and regulatory documents were expired. CASE CLOSED.
101	03	VA NY Harbor Healthcare System	H	**05/13/2014**	Facility reported suspension of a study of patients with advanced hepatocellular carcinoma when the independent DSMB for the study temporarily suspended enrollment to investigate an imbalance in treatment related deaths.	Remedial Actions: The independent DSMB recommending re-opening the study the study to accrual. The required protocol amendment has been approved by the local IRB and the study has been re-opened to local accrual. CASE CLOSED.
102	05	VA Maryland HCS	S	**05/14/2014**	Facility reported performance issues with an aging HVAC.	Remedial Actions: New coils for the air handling unit were installed; facility plans to install a new unit in the Fall of 2014. CASE CLOSED.
103	15	Columbia MO (Harry Truman)	H	**05/15/2014**	Facility reported a protocol deviation in which a human subject was enrolled into a study without first obtaining the primary care physician's assent/approval. IRB determined the event to be serious, unanticipated, and related to the research.	Required Actions: Subject to be removed from study; data from subjects cannot be used; assent process e.g. physician approval to be revamped; second level of approval for eligibility to be implemented. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
104	21	San Francisco	H	**5/21/2014**	Facility reported that approximately 35 subject complaints of perceived unethical practices were received. The complaints were related to a prompt for subjects to pay for an online subscription to a contracted company's website that had been hired to administer online study related assessments. This study aimed to develop an online Registry to identify and assess adults who were interested in participating in brain research.	Temporary enrollment suspension; PI must ensure that the user interface, frequently asked questions (on the website), Data License Agreement, study related information sheet and privacy statement, and protocol are modified; and PI must notify study sponsors. Facility VA not engaged in human subject research VA collaboration limited to storage and analysis of de-identified data. IRB and R&DC approved a revised protocol outlining the VA aspects of the collaborative research which henceforth assumes review and approving responsibilities for the VA aspects of the study. CASE CLOSED.
105	22	VA Greater Los Angeles Healthcare System	A	**05/21/2014**	Facility reported that rats on an IACUC approved protocol were being housed in an unapproved laboratory.	Remedial Actions: PI was notified; rats relocated. CASE CLOSED.
106	08	Tampa (James Haley)	H	**05/23/2014**	Facility reported a Principal Investigator's ongoing over-enrollment and failure to submit an amendment to increase enrollment as was requested by the IRB during the last continuing review.	Remedial Actions: PI submitted an amendment to increase enrollment and the amendment was approved. CASE CLOSED.
107	20	Portland	A	**05/23/2014**	Facility reported 30 mice died or had to be euthanized because of high blood ethanol concentrations (BEC) following administration of ethanol loading doses, and subsequent exposure in ethanol inhalation vapor chambers.	Remedial Actions: Replace chamber pumps; equipment assessments; increased animal monitoring; pilot validation studies. CASE CLOSED.
108	07	Birmingham	H	**05/27/2014**	Facility reported an investigator was requesting study participant payment requests outside the facility's 30 day window.	Remedial Actions: Payments being undertaken; apology letter sent; payment tracking mechanisms instituted. CASE CLOSED.
109	23	Minneapolis VA HCS	H	**05/27/2014**	Facility reported that the IRB suspended a retrospective chart review study concerning liver cancer after the PI failed to respond to required protocol modifications at continuing review.	A report from the IRB Administrator indicates that all outstanding continuing review items had been submitted by the Principal Investigator (PI). The IRB voted unanimously to remove the study suspension and also recommended that the ACOS/R meet with the PI to reinforce the investigator's responsibilities as a PI. CASE CLOSED.
110	01	VA Boston Healthcare System	I	**05/29/2014**	NSOC and facility reported that an employee mistakenly faxed three informed consent documents. Recipient called to report the problem and stated the faxed documents were shredded.	Remedial Actions: The fax was reprogrammed with the correct fax number; NSOC did not require any remediation. CASE CLOSED.

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111	22	VA Greater Los Angeles Healthcare System	A	05/29/2014	Facility reported a power outage in a research building housing rodents.	Remedial Actions: Securing electrical panel for the research building; assessment of monitoring systems. CASED CLOSED.
112	05	VA Maryland HCS	I	05/29/2014	NSOC and facility reported that a research participant was inadvertently sent and received PHI belonging to three other veterans. PHI included names, SSNs, DOB, provider, and enrollment priority.	Remedial Actions: One Veteran was offered credit monitoring and the next of kin of the two deceased Veterans were notified of the incident. CASE CLOSED.
113	20	VA Puget Sound HCS	H	05/30/2014	Two participants were mailed Fecal Immunochemical Test (FIT) negative results in June 2013; followed by positive results a year later (due to a computer problem). Affected subjects were notified of the erroneous results; the study staff implemented program changes already in development to prevent provisional and/or conflicting results from being recorded into the database and preventing future occurrences.	Remedial Actions: Affected subjects were notified of the erroneous results; the study staff implemented program changes already in development to prevent provisional and/or conflicting results from being recorded into the database and preventing future occurrences. CASE CLOSED.
114	01	VA Boston Healthcare System	A	06/02/2014	Facility reported the suspension of a rat protocol.	Remedial Actions: Amendment of protocol and surgical records; veterinary review of surgical procedures; weekly discussion on post-operative care schedule. CASE CLOSED.
115	01	VA Connecticut Healthcare System	H	06/03/2014	Facility reported serious noncompliance re: Imaging study investigating effects of rizulole on subjects with PTSD. Three subjects who had not been consented and enrolled in study had lab and EKGs pre-ordered from bio-studies unit. Two of the subjects did not receive lab work and EKGs when discovered by bio-studies nurses and the one remaining non consented subject completed lab and EKGs.	Remedial Actions: No pre-orders allowed for bio study unit; all subjects consented and enrolled first before orders entered; all existing orders reviewed by study team coordinator and discussed with bio-study unit nurses; PI and study staff education by RCO completed; data obtained from labs and EKG completed for the one subject cannot be used. CASE CLOSED.
116	16	Central Arkansas (Little Rock)	H	06/04/2014	RCO audit found lack of informed consent documentation in CPRS for 10 subjects as required by the IRB; the lack of a master list; the lack of completed case report forms; the lack of the use of subject codes; and a non-approved staff member collecting data.	Remedial Actions: Clarify where research data is being stored; maintain the original signed informed ICDs and HIPAA authorizations of subjects; clarify when the Veterans complete the PTSD Symptoms Scale form before or after signing the ICD; clarify if a patient/subject identifier, patient/subject code or both will be used; and ensure that all the data collected from the Sleep Log is carried over to the Case Report form. CASE CLOSED.
117	11	John D. Dingell (Detroit)	A	06/05/2014	Facility reported failure to provide a mouse post-surgical analgesic.	Remedial Action: Halted surgeries until analgesic procured. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
118	17	Central Texas Veterans HCS	A	06/06/2014	Facility reported unapproved procedures and unauthorized housing of mice.	Remedial Actions: Animal transport privileges temporarily revoked; training; counseling. CASE CLOSED.
119	16	Central Arkansas (Little Rock)	H	06/09/2014	Facility reported that a PI submitted a deviation/violation report which indicated that all five subjects enrolled signed a HIPAA Authorization that had expired.	Remedial Actions: Correct the expiration date until the 'end of study;' call each effected subject and apprise them of the error and send the updated HIPAA authorization with the request to return it signed in a prepaid envelope; the study team will not include any data from any subject from whom valid HIPAA authorization is not obtained. CASE CLOSED.
120	18	New Mexico VA HCS	S	06/10/2014	Facility reported a 2 year lapse in SRS annual review of a safety protocol	Remedial Actions: SOPs updated; tracking software implemented. CASE CLOSED.
121	16	Houston (Michael DeBakey)	H	06/13/2014	Facility reported that an RCO audit discovered that when 13 subjects were re-consented using an ICD with an older amendment date study, the coordinator back dated the dates on the re-consented ICDs to reflect the same date as the original consent. 2 ICDs were completed (i.e., signed and dated) by the study coordinator in anticipation that two subjects would be re-consented. However, the two subjects were never re-consented.	Remedial Actions: IRB determined this to be serious noncompliance. Research Office met with the PI to review the procedures for obtaining and documenting subjects' agreement to participate in research in accordance with the VHA Handbook requirements.
122	15	Columbia MO (Harry Truman)	A	06/17/2014	Facility reported one day without animal observations in VMU.	Remedial Actions: Counseling of VMU weekend supervisor; review of VMU weekend supervisor SOP. CASE CLOSED.
123	08	VA Caribbean HCS (San Juan)	S	06/18/2014	Facility reported transport of human tissues by staff that had not completed International Air Transport Association or US Department of Transportation approved training.	Remedial Actions: Facility will ensure staff take required training. CASE CLOSED.
124	17	VA North Texas HCS	A	06/18/2014	Facility reported 22 lapses in protocol annual reviews.	Remedial Actions: Revision of local policy to incorporate annual review (365 day) requirements. CASE CLOSED.
125	07	Atlanta	A	06/25/2014	Facility reported utilizing a method of euthanasia in rodents not compliant with regulatory guidelines.	Remedial Actions: Modify procedures to comply with the regulatory guidelines. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
126	16	Central Arkansas (Little Rock)	R	**06/26/2014**	Facility reported study obtained IACUC and SRS approval, however, failed to obtain subsequent R&DC approval.	Remedial Actions: Memos with protocols approved from all relevant subcommittees will be provided to the R&DC after each convened meeting; the assistant coordinator of each subcommittee will track protocol status and meet with the R&D Coordinator twice a month; all administrative staff will receive further training on the desktop SOP for publishing approval letters in IRBNet; and PIs and staff will receive an email reminding them that R&D approval is necessary prior to initiating any project. CASE CLOSED.
127	01	VA Connecticut Healthcare System	A	**06/27/2014**	Facility reported the unanticipated death of a non-human primate.	Remedial Actions: None, death of non-human primate was determined not research related. CASE CLOSED.
128	05	VA Maryland HCS	H	**06/27/2014**	Facility reported a serious, unanticipated and related problem on study exercise program for veterans with strokes. The university affiliated IRB received a report that a participant was found to have a clot in his arm and was subsequently admitted to the hospital for increased Coumadin and monitoring. IRB Chair assessed the incident as serious, unanticipated and related to study.	Remedial Actions: Veteran hospitalized for monitoring; the convened IRB reviewed the event and found it to be serious, unanticipated, and unrelated to the research. CASE CLOSED.
129	17	VA North Texas (Dallas)	H	**7/2/2014**	Facility reported a suspension of enrollment in response to a directive from the sponsor, to permit DSMB assessment of potential allergic reactions. The study sponsor sent a letter to all participating sites communicating the decision to permanently stop the trial.	The study sponsor sent a letter to all participating sites communicating the decision to permanently stop the trial. CASE CLOSED.
130	04	VA Pittsburgh	H	**7/3/2014**	Facility reported that a Percutaneous Coronary Intervention clinical trial was put on hold by sponsor due to potential serious allergic reactions. Out of forty subjects enrolled at the facility, only ten subjects were randomized.	Remedial Actions: IRB Chair suspended enrollment of new patients in the study; PI has confirmed that all enrolled subjects have completed study treatment; the local study team has commenced study close out procedures as requested by the sponsor. CASE CLOSED.
131	16	Central Arkansas (Little Rock)	A	**7/7/2014**	Facility reported unapproved animal research in mice.	Remedial Actions: Training for subcommittee coordinators; administrative enhancements to ensure completion of all subcommittee approvals prior to animal ordering. CASE CLOSED.
132	06	Durham	H	**7/8/2014**	Facility reported that a hypertension study SAE was received by the IRB but not reviewed by the IRB until 10 days after receipt.	Internal report tracking system implemented to be monitored daily by IRB staff. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
133	22	VA San Diego	A	**7/9/2014**	Facility reported the accidental death of one mouse.	Remedial Actions: Retraining of husbandry and research staffs. CASE CLOSED.
134	16	Central Arkansas (Little Rock)	H	**7/10/2014**	Facility reported late continuing review submissions resulting in lapse of IRB approval.	Remedial Actions: PI must submit closure of project within 14 days. CASE CLOSED.
135	22	VA Long Beach	H	**7/11/2014**	Facility reported PI failed to obtain subject signatures on 2 ICDs.	Remedial Actions: Consent obtained from one subject. The other was lost to follow-up and was withdrawn from the study. The data from this subject has been removed from the study. The IRB designated members to be available to proctor the PI's consent processes in all her studies until the PI has convinced the IRB that it is being done correctly. CASE CLOSED.
136	15	Kansas City	A	**7/14/2014**	Facility reported unapproved research activities involving a mouse protocol.	Remedial Actions: Halt of unapproved procedures; submission of new protocol and/or amendment; transfer of mice to holding protocol. CASE CLOSED.
137	06	Durham	I	**7/15/2014**	Facility reported a research interview was conducted and height, weight and vital signs obtained on a Veteran who was not the correct study participant due to this incorrect Veteran responding when the first and last name of the correct participant was called in the clinic. The incorrect Veteran had the same last but not first name and the error was discovered because the phone numbers of the two were discrepant. The Veteran that was interviewed expressed no concern over the error.	Research assistant will ask the individual to state his/her first and last names and the last four SSN; research procedures will only commence after this verification process. CASE CLOSED.
138	03	VA NY Harbor	A	**7/16/2014**	Facility reported the unapproved housing of a guinea pig outside the animal facility.	Remedial Actions: Lab temporarily suspended; training; study reinstated contingent to use of animals in veterinary medical unit. CASE CLOSED.
139	03	Northport	H	**7/17/2014**	Facility reported a PI did not request a waiver of HIPAA or informed consent prior to his research coordinator obtaining addresses and phone numbers of subjects from CPRS for a retrospective analysis of ankle arthroscopy (8 subjects).	Remedial Actions: NSOC entered; PI submitted a HIPAA and consent waiver to the IRB to obtain contact information for research purposes; RCO provided training to the principal investigator, to the IRB and to all investigators/coordinators involved in human research on the regulatory requirements; Application for Initial Approval was amended to require a HIPAA and consent waiver in this circumstance. CASE CLOSED.
140	12	Clement J. Zablocki Veterans Affairs Medical Center	H	**7/17/2014**	Facility reported that a moratorium is being placed on new IRB submissions until appropriate IRB staff members are hired. Continuing reviews, amendments, and SAE/noncompliance reviews will continue.	Remedial Actions: An HRPP coordinator was hired; job posting for senior IRB administrator is in progress. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
141	12	Madison (William Middleton)	A	**7/17/2014**	Facility reported an unapproved procedure in rats.	Remedial Actions: IACUC investigation; training in alternative techniques for blood collection; submission of a protocol amendment. CASE CLOSED.
142	16	Central Arkansas (Little Rock)	S	**7/17/2014**	Facility reported unapproved research activities involving mice.	Remedial Actions: Refresher training on publishing approval letters through the electronic data management system; establishment of administrative controls to ensure review/approval by all relevant subcommittees. CASE CLOSED.
143	22	VA San Diego	S	**7/18/2014**	Facility reported conduct of research activities by unauthorized personnel.	Remedial Actions: Obtaining WOC appointments prior to training activities; increased supervision of students in training; use of alternative (flameless) heat sources. CASE CLOSED.
144	08	Miami VA	S	**7/21/2014**	Facility reported lapse in safety approval for two protocols.	Remedial Actions: Review all studies requiring continuing reviews during the past two months. CASE CLOSED.
145	17	VA North Texas	A	**7/22/2014**	Facility reported a protocol noncompliance involving extended feeding of a special diet to mice.	Remedial Actions: Removal of the post-doctoral student from all animal protocols; PI and staff retraining; notification of intent to start animal experiments; additional monitoring; reinforcement of appropriate research behavior; and VMU staff retraining. CASE CLOSED.
146	23	VA Nebraska-Western Iowa	A	**7/22/2014**	Facility reported initiation of animal research prior to RDC approval due to error by IACUC coordinator.	Reassignment of some IACUC coordinator duties; additional training; new policies on notifications and communication. CASE CLOSED.
147	06	Durham	S	**7/24/2014**	Facility reported a research related employee injury (dislocated right patella) due to a fall on some spilled ice that had melted.	Remedial Actions: Employee evaluated by urgent care and referred to the affiliate Occupational Health Unit; employee expected to require extended surveillance; employee was retrained on basic laboratory safety, including the need to clean up spills immediately. CASE CLOSED.
148	17	VA North Texas	S	**7/24/2014**	Facility reported lapse in annual SRS review for one protocol.	Remedial Action: Conduct IACUC and SRS annual reviews concurrently; send notifications to appropriate email addresses. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
149	22	VA San Diego	I	**7/24/2014**	Facility reported one re-use of a reimbursement form that was given to a research participant. The form contained a crossed-out but still visible name, address and phone number of another research participant.	PO investigation determined that nine study participant compensation forms were re-used and all re-used forms were completely redacted except for one form; The PI and research coordinators will now provide enough blank participant forms to treatment providers to ensure that re-use does not occur in the future; VA NSOC determined a notification letter was required and was sent to the research participant and included guidance on how to protect the credit rating; PO retraining of PI and staff. CASE CLOSED.
150	15	Kansas City	A	**7/29/2014**	Facility reported a protocol noncompliance involving injection of a nonpharmaceutical grade substance in a rat.	Remedial Actions: Rat euthanasia; halting use of drug; submission of a protocol addendum. CASE CLOSED.
151	08	VA Caribbean HCS (San Juan)	H	**7/31/2014**	Facility reported that the staff of a pilot study of trigger point injections for the treatment of blood glucose level changes consented 4 subjects into the study and filed the paperwork away without scanning into CPRS. The PI found the forms and reported this issue to the IRB.	Remedial Actions: The IRB requested an RCO ICD audit and a copy of the master list of subjects; copies of all ICDs and HIPAAs to be scanned into the medical record. The CR was approved for 6 months. The IRB requested that the RCO conduct an audit of the first five (5) Informed Consent Documents signed. The IRB lifted the study suspension. CASE CLOSED.
152	20	VA Puget Sound	H	**7/31/2014**	Facility reported serious noncompliance in the conduct of a longitudinal observation and follow-up study of patients undergoing ankle surgery; the lead PI in the multicenter study implemented a protocol change without IRB approval.	Study staff attend the HRPP Orientation conducted twice monthly by HRPP staff; all participating sites' study staff be advised to look into additional training opportunities regarding research compliance at their local institutions; investigator and study staff seek additional training on best practices for serving as the coordinating center of a multicenter study. CASE CLOSED
153	06	Durham	H	**8/1/2014**	RISP forwarded to SRO an NSOC report indicating that a study participant agreed by phone to allow name and address be given to the NPC without written authorization.	Remedial Actions: Notification letter to be sent to participant. CASE CLOSED.
154	04	VA Pittsburgh	H	**8/4/2014**	Local IRB suspended enrollment in a Phase II/III study of image-guided radio-surgery for localized spine metastasis due to the frequency of risks being much higher than previously determined.	Modify ICF to include language describing who will manage usual/standard of care procedures; re-consent currently enrolled subjects using the new version of ICF once it has been approved; provide IRB with written confirmation once participants have been re-consented. CASE CLOSED.
155	23	Iowa City	A	**8/4/2014**	Facility reported unapproved procedures in mice.	Remedial Actions: Mice transferred to affiliate institution. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
156	18	New Mexico VA	S	**8/6/2014**	Facility report incomplete initial safety review and lack of continuing reviews.	Temporary halt of research; submission of safety protocol, hazardous chemical list, and IBC application. CASE CLOSED.
157	22	VA San Diego	H	**8/7/2014**	Suspected human subject research activity by a study staff member during a period of lapse in research without compensation (WOC) appointment.	Remedial Actions: Staff member restricted from all research activity. PI asked to provide data on appointment, training, and credentialing status of all his personnel on all human subjects protocols. PI asked to develop contingency plan for dealing with transition of care should any staff member become unavailable. A standardized process is being developed for communication of WOC appointment lapses/terminations. A retrospective QA review of all WOC terminations on active protocols. CASE CLOSED.
158	18	Southern Arizona VA	H	**8/11/2014**	Report from facility describing a suspension of enrollment in response to a directive from the study sponsor, based on observation of potentially serious allergic reactions.	DSMB recommended (and sponsor directed) that all enrollment should cease. Because no local enrollment had occurred, the IRB and R&DC will direct study closure. CASE CLOSED.
159	09	Robley Rex	H	**8/12/2014**	Locally required abstract progress report noted enrollment of nine subjects with improperly executed informed consent documents, no documentation of study enrollment, and no HIPAA authorizations for this study providing education to subjects diagnosed with skin cancer to reduce risks of sun exposure.	The entire research team to receive mandatory education on the consenting process to include appropriate documentation; the acquired data cannot be utilized and must be turned over to the R&D Office; serious noncompliance is reported to the OHRP; and new Investigators and staff at the facility will be required to attend an educational session on performing research studies. CASE CLOSED.
160	21	VA Central California	H	**8/12/2014**	Facility reported the suicide of a subject in CSP Protocol #577: Colonoscopy vs Fecal Immunochemical Test (FIT).	The IRB will review the incident, but it appears unlikely that it was related to research participation. The case will be followed separately as an Unanticipated Human Death (Table 2F). CASE CLOSED.
161	04	Wilkes-Barre	S	**8/13/2014**	Facility reported a lapse in the annual review of two safety protocols.	Enrollment in the studies was temporarily halted until the annual SRS review of both protocols could occur. CASE CLOSED.
162	01	VA Boston	A	**8/14/2014**	Facility reported a noncompliance involving reporting procedures for animal welfare concerns.	Remedial Actions: Semiannual meeting between IACUC and PIs; dissemination of investigation results with animal users; offer mediation to resolve disputes; conduct follow-up survey to determine status at each campus. CASE CLOSED.
163	16	Houston (Michael DeBakey)	H	**8/14/2014**	Facility reported that international research on progressive transitional cell carcinoma (bladder cancer) was conducted without CRADO approval.	Remedial Actions: PI may not use the data from the one VA subject; none of the data may be used as long as the facility remains part of the study; R&DC requested that the protocol be amended to remove VA as a research site and close the project at the facility. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
164	21	San Francisco	A	8/15/2014	Facility reported two instances of animal protocol noncompliance involving the use of unapproved and, in one instance, expired analgesics.	Remedial Actions: Refresher training for all research staff; assurance that all staff have read current protocols; implementation of protocol performance worksheets for all surgical procedures; quarterly progress reports from PI's to the IACUC; random IACUC inspections and review of surgical records during semi-annual reviews. CASE CLOSED.
165	20	Portland	A	8/19/2014	Facility reported animal protocol noncompliance resulting in loss of mice due to administration of unapproved test article by unapproved personnel.	Development of a procedure checklist, approval of lithium chloride as a test substance, and addition of two trained staff members to the protocol. CASE CLOSED.
166	22	VA Long Beach	H	8/21/2014	Facility reported one informed consent document was not signed by the person obtaining consent.	The PI contacted the subject and arranged for re-consent, which has been completed. CASE CLOSED.
167	16	Southeast Louisiana Veterans	R	8/26/2014	Only 8 out of 41 RCO ICD audits were completed as required.	Complete all required regulatory and informed consent audits. CASE CLOSED.
168	03	VA New Jersey	A	8/27/2014	Facility reported a failed overheat test in the Veterinary Medical Unit (VMU).	Revision of procedures; equipment repair; testing initiated. CASE CLOSED.
169	10	Cleveland (Louis Stokes)	A	8/27/2014	Facility reported incomplete carbon dioxide euthanasia of a rat under a protocol which did not include this euthanasia method.	The PI must add carbon dioxide euthanasia to the protocol; the research team must complete euthanasia training; the PI and his technician must re-read the protocol and sign new certificates of understanding. CASE CLOSED.
170	21	San Francisco	H	8/27/2014	Facility reported one subject received a treatment plan that was not approved by the clinical trial headquarters per the requirements of the protocol.	IRB required additional training for the study staff as well as department-level training. CASE CLOSED.
171	16	Southeast Louisiana (New Orleans)	H	8/28/2014	CSP SMART audit revealed that a SAE was not reported to the CIRB as required, and there was a delay in reporting to the CSP.	Remedial Actions. RCO to provide re-training to all PIs and Study Coordinators on reporting of both Anticipated and Unanticipated SAEs.
172	17	Central Texas Veterans	E	8/29/2014	Facility reported the new IRB coordinator updated the facility IRB registration without first going through ORO CO for review.	Facility was requested to update their SOPs to ensure regulatory tracking duties are appropriately assigned and new employees are trained on ORO requirements for updating IRB registration. CASE CLOSED.
173	19	VA Eastern Colorado	S	8/29/2014	Facility reported a WOC employee potential exposure to paraformaldehyde. Employee sought medical care for potential exposure.	Discontinue formaldehyde use until Engineering Controls are in place and tested; use of a fume hood; fit test and medically clear all lab employees for respirator use; test the efficiency of the fume hood; training; suggest all employees visit Employee Health. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
174	17	Central Texas Veterans	R	**9/2/2014**	Notification was received that the facility did not seek ORO approval prior to expiration of its Federalwide Approval. The facility was instructed to contact the ORO's Executive Director for further instruction.	It was subsequently determined that the FWA was still in effect and no remedial actions are required. CASE CLOSED.
175	18	Southern Arizona VA	H	**9/2/2014**	Two protocol deviations occurred which resulted in the under-dosing of two subjects. One instance was identified during a monitoring visit and the second instance was identified by the research pharmacist. Both instances were reported to the IRB more than two months after each occurrence. Neither subject was harmed.	IRB required the indefinite suspension of study recruitment to complete remedial actions that included: PI must conduct a Strength, Weaknesses, Opportunities and Threats analysis, to identify threats to protocol execution and opportunities for improvement; a licensed nurse to serve as the project research coordinator to ensure that good clinical practice is maintained throughout the study's implementation; and SOP to enhance coordination between the research pharmacy, research teams and the ED. IRB Chair and RCO must observe consenting processes after suspension release; Research Pharmacist must report protocol deviations to the convened R&DC on a monthly basis; and the suspension must be reported to OHRP and FDA.
176	01	VA Boston	A	**9/3/2014**	Facility reported a protocol suspension following unapproved animal procedures and lack of analgesic administration in mice.	(1) PI to provide corrective action plan to IACUC to prevent future recurrences. (2) Submission of protocol amendment. (3) Research staff retraining. CASE CLOSED.
177	15	Columbia MO (Harry Truman)	A	**9/4/2014**	Facility reported use of an unapproved mouse strain on an approved protocol in involving treatment for prostate cancer. The incorrect strain was shipped by the vendor and the discrepancy was not noticed until after experiments began.	PI and animal facility staff will conduct additional checks to verify animal strains received match those ordered. CASE CLOSED.
178	04	VA Pittsburgh	H	**9/5/2014**	IRB suspended enrollment in a chemotherapy clinical trial for recurrent or metastatic head and neck cancer due to ICD not including ovarian failure and neutropenia under common risks section and thrombocytopenia under occasional risks section that may be serious.	Remedial Actions: The informed consent document revised to include the risks of ovarian failure, neutropenia and thrombocytopenia as risks that may be serious for Bevacizumab; re-consent not needed as the two subjects enrolled in the study had withdrawn from the study; enrollment suspension lifted. CASE CLOSED.
179	05	VA Maryland	R	**9/5/2014**	Facility identified (on 2014 FDC) RCO auditing deficiencies informed consent (0/128) and regulatory (122/151). Major factors included staff shortages, discrepant protocol totals, and diversion of the RCO to 9 months for non-audit initiatives: 'high-priority research related issues.'	RCEP (TA) & NERO (compliance case) are pursuing a joint approach. Facility submitted explanation and RAP including: hiring staff; auto-populating audit forms and auto-linking PI master lists, ICDs and CPRS.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
180	03	Bronx (James J. Peters)	H	**9/8/2014**	PI of a cardiovascular risk factor and cognitive aging study reported that alleged misconduct (fabrication linked RMOP case) also involving improper or failure to document informed consent and HIPAA authorizations.	Alleged informed consent and HIPAA noncompliance separated from research misconduct case and under review by IRB.
181	01	Providence	H	**9/9/2014**	Facility reported a protocol deviation on a study titled 'Veterans Coping Long-term with Active Suicide.' The study staff failed to have one significant other sign an ICD, as required by the approved protocol, before proceeding to complete the in-person session and first phone call.	Remedial Actions: No research involvement with the subject who was not consented, other than informing subject why research participation was suspended; PI may not use any data gathered from the participant prior to consenting; study staff member involved in the protocol deviation must be supervised by an experienced researcher in all interactions with participants to prevent other types of errors; RCO must monitor study procedures and progress for however long required.
182	10	Cleveland (Louis Stokes)	H	**9/9/2014**	Facility reported IRB actions to administratively close a PI's unfunded diabetic drug protocol due to multiple lapses in approvals, late/deficient submissions, uncertain and discrepant enrollment numbers, and failure to meet IRB required corrective actions timeline.	The investigator was reminded of his responsibilities, including provision of an accounting for the source of data used in publications. The Investigator will not serve as a PI, but can serve as study staff; will not participate in the consenting process; will not participate or be responsible for regulatory documents. The Investigator is required to re-take the basic CITI Human Subjects Protection/Good Clinical Practice training. If the Investigator participates in a human trial, a performance evaluation regarding his activity on the trial must be completed after 12 months. The IRB will review the evaluation to determine if the restrictions require alterations and/or adjustments. CASE CLOSED.
183	18	Phoenix VA	H	**9/16/2014**	A Senior Clinical Research Coordinator reported to the Privacy Officer that routine audit noncompliance identified a protocol deviation--screening research participants prior to consent and disposal of research records including possibly a VA flash drive.	The facility is to provide a plan to ensure all new study members who will be obtaining informed consent are appropriately trained; and a Research Compliance Officer audit to be completed if there had not been an audit in the past month by another oversight authority.
184	23	Iowa City	A	**9/24/2014**	Facility reported protocol deviations regarding the use of analgesics in mice.	Administration of analgesia following surgery; protocol amendment; training; supervision of procedures by animal care personnel. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
185	04	VA Pittsburgh	H	**9/25/2014**	Sponsor is halting enrollment on CALGB 80802-Phase III Randomized Study of Sorafenib plus Doxorubicin versus Sorafenib in patients with Advanced Hepatocelluar Carcinoma due to identification of new risks associated with Sorafenib.	Remedial Actions. No subjects have been enrolled in the study at this facility; PI has submitted amendment to the protocol to reflect the new/modified risks of Sorafenib and IRB has approved the amendment. CASE CLOSED.
186	16	Oklahoma City	I	**9/25/2014**	Facility reported a group text message using personally owned devices including the last name, last four SSN and health information of a research subject in a CSP vein graft angioplasty stent study was sent and received by a non-VA employee.	(1) The text messages containing VA research-related protected health information were removed from the personally owned devices. Facility PO made numerous attempts to talk with the one non-VA staff by phone but there were no responses. Facility has not received any further communication from the non-VA staff member. Credit/HIPAA notification letter Facility Director broadcasted to facility that use of personal devices to transmit PHI or other VASI is prohibited Retraining of staff. CASE CLOSED.
187	22	VA Greater Los Angeles	H	**9/25/2014**	Facility reported potential unapproved research	The HRPP Administrator is currently reviewing the research activities of individual providers to determine whether GLA is engaged in any unapproved human subject research.
188	16	Central Arkansas (Little Rock)	H	**9/26/2014**	Facility reported sponsor suspended enrollment in this study after new information on risks to subjects was obtained. Only one local subject was enrolled. PI contacted subject and notified the subject of the additional risks associated with Sorafenib (although subject could be assigned the placebo--study is blinded). The subject elected to continue in the study.	The revised protocol and informed consent documents will be reviewed by the full IRB at the next convened meeting. During this review, the IRB will document their determination as to whether the enrolled subject should provide informed consent on the updated informed consent document.
189	16	Central Arkansas (Little Rock)	H	**9/26/2014**	(1) The sponsor suspended enrollment in this study after new information on risks to subjects was obtained. New risks include treatment-related secondary malignancy, heart failure, and increase in risk attribution for anemia and chest pain.	(1) PI to submit Sponsor's revised protocol and ICD for review. CASE CLOSED.
190	12	Jesse Brown	H	**10/8/2014**	Facility reported IRB suspension of enrollment for this acute coronary syndrome investigational drug treatment study due to the upcoming transfer of IRB oversight.	Re-open upon transfer to new IRB. CASE CLOSED.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
191	16	Central Arkansas (Little Rock)	H	**10/8/2014**	Facility reported an IRB determination of serious non-compliance regarding a protocol violation in which a study staff member failed to properly to follow all the steps of the approved suicide prevention protocol. Case Closed.	The study PI conducted training with all study team members reviewing the steps in the suicide prevention protocol, and updated the computer assisted interview program so that once the suicide prevention protocol is triggered, every required question must have a response before the interviewer can advance past the page. The IRB determined serious non-compliance; however, the IRB also determined no further actions were required due to the PI's quick action. CASE CLOSED.
192	16	Central Arkansas (Little Rock)	H	**10/8/2014**	(1) Failure to obtain continuing review or close the study prior to IRB approval lapse.	(1) The PI must submit a closure application within 5 days of receipt of notification from the IRB, making sure to clearly describe the disposition of data and specimens. CASE CLOSED.
193	08	Tampa (Haley)	H	**10/9/2014**	Facility reported on the ORO's request to review studies initiated prior to VHA's Research Compliance Officer (RCO) audit program, in which investigators continue to obtain additional (new) identifiable private information about subjects. Five studies are still active, four of them were found to be in not serious or continuing noncompliance with current practices, however, the IRB determined 4 of the 5 studies to re-consent all subjects that are being followed up.	Remedial Actions: Re-consent all subjects being actively under follow up. CASE CLOSED.
194	19	Eastern Colorado (Denver)	A	**10/10/2014**	NA	Nonaffiliated IACUC members must complete all required training. CASE CLOSED.
195	16	Houston (DeBakey)	S	**10/22/2014**	(1) Controlled substances were improperly dispensed and secured.	(1) Standard operating procedure drafted to outline approved method for obtaining controlled substances. CASE CLOSED.
196	01	Boston	A	**10/27/2014**	(1) Conduct of research not approved by IACUC (inappropriate administration of post-operative analgesics).	(1) Refined communications with all research staff that work with animals; IACUC review of post-operative analgesic administration documentation; PI certification of time and dose of all analgesic administrations. CASE CLOSED.
197	11	Ann Arbor	H	**10/29/2014**	(1) PI use of prospective data collection/analysis for retrospective chart review without IRB approval.	(1) PI to report to IRB regarding protocol violation. PI to submit amendment to protocol to use data pulled from 2009-2014. IRB will send email reminder to all PIs concerning retrospective chart review protocols and what data use/analysis for these types of studies entails. IRB Chair to contact PI regarding issues of noncompliance.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
198	23	Minneapolis	A	**10/29/2014**	(1) Use of expired sedative in a pig.	(1) Discard expired drug; retrain investigator and staff; correctly label expiration dates. CASE CLOSED.
199	04	Pittsburgh	H	**10/30/2014**	(1) Research procedure conducted on two research subjects without IRB approval.	(1) The PI has put study on administrative hold. For the suspension of conducting MRI procedures to be lifted, the PI must submit a study closure for IRB approval.
200	08	Tampa (Haley)	A	**11/3/2014**	(1) 1) inappropriate suture use; 2) incomplete medical records; 3) presence of untrained staff; 4) inadequate documentation of post-operative analgesic administration; 5) use of uncalibrated equipment.	(1) For six months, PI and staff access to vivarium is restricted; PI must delegate support for all approved protocol procedures to vivarium staff. (2) Suspension and closure of protocol; revoked facility access privileges. CASE CLOSED.
201	16	Houston (DeBakey)	E	**11/5/2014**	(1) MOU expired.	(1) Amendment to extend MOU to be sent for signature.
202	07	Atlanta	I	**11/12/2014**	(1) Missing original ICD (1 of 33 subjects whose ICDs were kept at the affiliate).	(1) Additional fact-finding underway.
203	07	Atlanta	H	**11/14/2014**	(1) Unauthorized release of original ICDs to an affiliate colleague by the study PI. Missing original ICD (one subject). Inconsistent language for disclosure within ICD.	(1) Recovery of original ICDs (32 of 33 subjects); privacy officer review of unauthorized disclosures and missing ICD; IRB review.
204	09	Louisville (Rex)	I	**11/17/2014**	(1) Investigator files and 37 original ICDs and HIPAA authorizations were shredded when the study was closed. (2) The study records for 37 of 46 enrolled subjects which included original consents and HIPAA authorizations and investigator files were shredded when the protocol was closed. It does not appear that VA PHI was compromised.	(1) Human Studies Subcommittee determined the incident was serious noncompliance and requested a report be sent to the Office of Human Research Protection, instructed the Research and Development Office to remind studies at closure that data is required to be safeguarded and not destroyed. (2) Information pending whether an NSOC report was filed. (3) Study staff education related to records retention. CASE CLOSED.
205	21	San Francisco	A	**11/19/2014**	(1) Inadequate post-operative analgesia in mice.	(1) Voluntary suspension of surgical activities until staff retraining completed. (2) PI review of approved protocol procedures with research staff. (3) Order analgesic drugs for animal administration. (4) IACUC review of lab surgical notes and checklists. (5) IACUC review of staff training records. CASE CLOSED.
206	04	Pittsburgh	H	**11/20/2014**	(1) An individual accessed and used VA sensitive information without appropriate IRB approval.	(1) Amend protocol to add the data analyst to study staff on protocol. CASE CLOSED.
207	16	Central Arkansas (Little Rock)	H	**11/20/2014**	(1) ICD and HIPAA were not scanned into CPRS.	(1) ICDs and HIPAA documents scanned into CPRS. CASE CLOSED.
208	09	Lexington	A	**11/25/2014**	(1) Protocol suspension due to Inadequate aseptic surgical procedures in mice.	(1) Counseling and training.

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Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
209	04	Pittsburgh	A	**11/26/2014**	(1) Unanticipated loss of 3 mouse pups.	(1) Retraining research staff on breeding and weaning procedures; requiring PI to develop a corrective action plan to prevent similar future occurrences. CASE CLOSED.
210	04	Pittsburgh	S	**11/28/2014**	(1) Work-related chemical exposure.	(1) Training. CASE CLOSED.
211	21	Palo Alto	A	**12/2/2014**	(1) Unanticipated loss of animal life under an approved protocol.	(1) Reduction of sample size with two groups (drug and vehicle control); increasing the interval between drug administration; increasing monitoring; starting the experiment earlier in the day; and reporting results back to the IACUC. CASE CLOSED.
212	21	Palo Alto	A	**12/2/2014**	(1) Unanticipated loss of animal life (mice) due to installation of a new watering system.	(1) Provide supplemental fluids during transition to new watering system; enhanced animal monitoring; monthly updates to IACUC. CASE CLOSED.
213	17	North Texas (Dallas)	H	**12/4/2014**	(1) Use of an expired ICD to enroll 19 study participants.	Pending.
214	20	Portland	H	**12/5/2014**	(1) Identifiable information disclosed without authorization or encryption (or other secure manner).	(1) Case related remediation managed in the context of related information security case. CASE CLOSED.
215	12	Milwaukee (Zablocki)	S	**12/8/2014**	(1) Injury/exposure to technician from finger stick with pipette containing adeno-associated virus/green fluorescent protein gene and contaminating rat tissue.	(1) Assessment by employee health unit; send report to NIH-OBA; no further work on project until PI prepares new SOP and submits to IBC for review. CASE CLOSED.
216	04	Philadelphia	H	**12/9/2014**	(1) 32 subjects missing ICDs and HIPAA forms in a pre-2009 study for identifying mechanisms of clinical and biological outcomes in HCV, but 22/32 were documented in 2009 RCO audit to have had ICD/HIPAAs.	(1) Re-contact subjects to obtain ICDs and HIPAAs; PI to maintain biological specimens until all subjects re-contacted and IRB will then determine how to manage remaining samples of unconsented subjects.
217	11	Detroit (Dingell)	H	**12/12/2014**	(1) During continuing review the IRB discovered approval had lapsed for the second year in a row.	(1) PI required to submit an Unexpected Problem Form and the RCO will conduct a for-cause audit.
218	06	Richmond (McGuire)	H	**12/15/2014**	(1) PHI accessed on 30 subjects without HIPAA waiver or signed Authorization.	(1) Pending.
219	15	Columbia MO (Truman)	H	**12/15/2014**	(1) The ICD did not indicate that the subject will continue to be followed by the research team and their medical record accessed. (2) The study is a Cancer and Leukemia Group B (CALGB) study, yet the data is all being sent to Eastern Cancer Oncology Group (ECOG).	(1) Letter to all subjects regarding the collection of long term follow-up data. (2) Letter to subjects informing them of disclosure that data sent to ECOG is no longer protected from third party disclosure and the option to withdraw from the study. CASE CLOSED.

TABLE 2B. REMOTE REVIEWS OF FACILITY SELF-IDENTIFIED NONCOMPLIANCE

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
220	15	Columbia MO (Truman)	H	**12/15/2014**	(1) The ICD stated the follow-up would be a maximum of 5 years; there is no disclosure that the subject will be followed for survival and medical records will continue to be accessed.	(1) A letter to the subject regarding the collection and disclosure of long term follow-up data. Withdrawal from study form included should the subject wish to withdraw.
221	16	Central Arkansas (Little Rock)	H	**12/15/2014**	(1) No regulatory concerns--this was not research.	(1) None required. CASE CLOSED.
222	21	Palo Alto	S	**12/22/2014**	(1) Unauthorized personnel conducting research.	(1) Completion of VA appointment requirements and training.
223	22	Greater Los Angeles	H	**12/22/2014**	(1) Research screening procedures performed by academic affiliate without affiliate IRB approval.	(1) Pending.
224	10	Cincinnati	A	**12/23/2014**	(1) Protocol violation, rats given an unapproved analgesic.	(1) PI and staff training on protocol compliance; PI must ensure staff have access to approved protocol.
225	01	Boston	A	**12/24/2014**	(1) Failed overheat test and on-going HVAC issues.	(1) Re-code alarms in affected rooms as 'critical'; IACUC review of engineering SOPs concerning alarm systems and responses; increased temperature monitoring frequency in affected animal rooms.
226	16	Central Arkansas (Little Rock)	H	**12/30/2014**	(1) No regulatory concerns.	No remedial actions.
227	16	Central Arkansas (Little Rock)	H	**12/31/2014**	(1) Incorrect version of the ICD was signed by 3 subjects.	(1) Education of the study coordinator to notify RCO of study monitor visits and on using approved ICDs. (2) Re-consent subjects and update IRB on progress.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

VHA facility-based Research Compliance Officers (RCOs) must conduct annual informed consent audits and triennial regulatory audits of all research studies. The director of each research facility is required to report promptly to ORO any apparent serious or continuing noncompliance identified in these audits. ORO conducts remote reviews of these reports, requiring that the facility develop an acceptable remediation plan and monitoring implementation of the plan until remediation is complete.

Summary

- 46 = Cases Continuing from Previous Calendar Year *
- **79 = New Cases – January 1 through March 31 ***
- **82 = New Cases – April 1 through June 30**
- **56 = New Cases – July 1 through September 30**
- **30 = New Cases – October 1 through December 31**
- 247 = -Total New Cases in Calendar Year
- 293 = Total Cases (Continuing Plus New) in Calendar Year

***** Case #11 and Case #111 were inadvertently omitted from the 1st Quarter report.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
1	00	VA Central Office	H	05/22/2013	A routine RCO audit identified 12 serious adverse events at one study site that were not timely reported to the VA Central IRB for CSP 10-07, the SPRINT systolic blood pressure study.	Remedial Action: Training for local study site staff on reporting requirements, notice to all study sites of reporting requirements, audit of reportable events by local RCO after six months. CASE CLOSED.
2	21	San Francisco	H	07/15/2013	RCO audit found that 55 (out of 97) subjects had not signed HIPAA authorization forms and 12 (out of 99) subjects had not signed ICDs in an unfunded study of macular degeneration.	Remedial Actions: Obtain valid HIPAA authorization and documentation of informed consent; PI to provide explanation of how incident occurred and how future recurrence will be prevented; (re)training provided for PI and staff. CASE CLOSED.
3	16	Oklahoma City	H	07/24/2013	RCO Audit found 4 active VA researchers with a Contract appointment; 3 active VA researchers with a Fee Basis appointment; and 3 active VA researchers who were not Credentialed and Privileged.	Remedial Actions: Credentialing and privileging through VetPro; Fee Basis researcher obtaining a VA paid appointment; others will be converted to, or will obtain, a WOC appointment. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
4	16	Houston (Michael DeBakey)	H	07/25/2013	RCO Audit found the incorrect version of the ICD was used for 24 subjects. This study aims to set up a formal mechanism to prospectively contain consent to donate, collect and store human tissue.	Remedial Actions: PI to discard blood vials for 3 subjects and not use their data; remaining 21 subjects will be re-consented; if subjects are re-consented, tissue will be anonymized per the protocol. CASE CLOSED.
5	22	VA Greater Los Angeles HS	H	08/19/2013	RCO Audit found a HIPAA Authorization was not executed for one subject enrolled in a deep brain stimulation Parkinson's Disease follow-up study.	Remedial Actions: PI to submit modification requesting permission to continue non-Veteran/affiliate subject visits to the VA; follow subject transferred from another VA facility; submit SAEs involving non-Veteran subjects. CASE CLOSED.
6	12	James A. Lovell Federal Health Care Center	H	08/30/2013	RCO Audit of a study utilizing eye technology to assess PTSD found that no inclusion/exclusion criteria were used, no CPRS progress notes, wrong version of ICD used, wrong SSN on HIPAA and that patient data collected was neither de-identified nor placed on spreadsheets as outlined in protocol.	Remedial Actions: Education; update CPRS; determination of disposition of data collected; PIs to submit monthly enrollment reports to Research Department. CASE CLOSED.
7	03	VA New York Harbor HCS	H	09/17/2013	RCO Audit of an HIV study found seven missing HIPAA Authorizations.	Remedial Actions: PI and staff education; PI must obtain HIPAA authorizations from consent subjects or their data cannot be used. CASE CLOSED.
8	05	VA Maryland HCS	H	10/01/2013	RCO regulatory audit found that PI of a pulmonary study failed to submit amendments required by the IRB's Corrective action Plan in 2009 after a prior regulatory audit.	Remedial Actions: Modify the ICD to reconcile study description with procedures actually being performed, modify protocol to state that pulmonologist Co-Investigator will assess eligibility and document in the study records that participant has one of the chronic lung diseases in criteria. CASE CLOSED.
9	08	Miami	H	10/16/2013	RCO Audit found that the research team was administering 2 screening tools for 2 different studies, prior to obtaining Informed Consent, to determine whether or not the potential subject was eligible for the studies.	Remedial Actions: PI educated his study coordinators to follow the procedure outlined in the approved protocol. IRB requested follow-up with subjects that did not meet inclusion criteria to make sure appropriate follow-up is given thru clinical care. The PI developed a safety plan. CASE CLOSED.
10	04	Philadelphia	H	10/16/2013	RCO ICD Audit of study on adherence to long term oxygen therapy discovered 38 of 53 signed ICDs (dating back to 2007) missing.	Remedial Actions: Privacy Officer notified and NSOC completed; study closure; no use of data; inform local records management. CASE CLOSED.
11	04	*Philadelphia	I	10/17/2013	NSOC reported that during an RCO audit, 38 informed consent documents could not be located. PI confirmed that no research data has been disclosed outside of the VA.	Remedial Actions: Lost documents contained name only; subject or NOK notification not required; PI no longer using the research data; PI intends to close study. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
12	16	Houston (Michael DeBakey)	I	10/21/2013	RCO Audit found that a PI (stroke swallowing study) was unable to locate one research consent form and one HIPAA Authorization. PHI consisted of Veteran's full name; did not contain full or partial SSN. It was felt documents were likely lost within protected research space and not in public areas.	Remedial Actions: PI concluded subject has been lost to follow-up and will not use the data; credit protection services not required; study staff re-education. CASE CLOSED.
13	08	VA Caribbean HCS (San Juan)	I	10/21/2013	RCO Audit identified a missing original ICD and HIPAA authorization containing full name, full SSN for one subject enrolled in an antibiotic study.	Remedial Actions: Credit monitoring services were offered; subjects will sign consent documents in blue ink, copies made in black; coordinator to verify documents are correct, and then file original securely in research protocol office. CASE CLOSED.
14	05	VA Maryland HCS	H	10/23/2013	RCO Regulatory audit found a robotic rehabilitation protocol was not followed and study procedures varied among participants, 5 of 70 participants were enrolled twice; 1 student had no CITI training until after their involvement in the study, 2 staff had no Scopes of Practice.	Remedial Actions: PI will close this study and submit a new one consistent with how he was conducting the former study in order to reconcile his new protocol with IRB terms of approval. CASE CLOSED.
15	16	Houston (Michael DeBakey)	H	10/28/2013	RCO audit of this biorepository study designed to store and collect blood and serum for future studies revealed that 48/60 subjects signed ICDs with the wrong version date and 9 subjects signed expired ICDs.	Remedial Actions: PI to place a Note-to-File for each subject to document the irregularity and to re-consent the 9 subjects who signed the expired informed consent documents.
16	16	Houston (Michael DeBakey)	H	10/28/2013	RCO audit of this biorepository study designed to store and collect blood and serum for future studies revealed that 57 subjects did not sign HIPAA authorization and 13 subjects signed expired ICDs.	Remedial Actions: PI to contact the 57 study participants to obtain the signed HIPAA authorization form, place a Note-to-File for each subject consented on an incorrect version of the informed consent form to document the irregularity, and re-consent the 13 subjects.
17	09	Memphis	H	10/30/2013	RCO Audit of 21 ICDs (alcohol abuse and PTSD study) found no HIPAA authorizations 3/21; IRB did not approve enrollment of non-Veterans and health record documentation missing 21/21; enrollment and progress notes not entered 11/21; signed ICD and HIPAA were not scanned 4/21.	Remedial Actions: PI study enrollment was suspended; RCO audited all of the PI's studies; PI submitted waiver for ICD and HIPAA; PI received training from ACOS/R on SAE reporting requirements; HIPAA template revised; ISO/PO review procedures revised; IRB and PI was provided education on form 10-3203 (use of pictures). CASE CLOSED.
18	01	VA Boston Healthcare System	H	11/01/2013	RCO audit of a PTSD study found deviations from the protocol (extra assessment visits; patient data taken from another study, use of VA staff as pilot subjects).	Remedial Actions: Temporary suspension of study enrollment; PI must revise protocol to accurately reflect assessments performed and the assessment schedule; submit amendments as necessary. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
19	22	VA Greater Los Angeles HS	H	11/13/2013	RCO audit noted that documentation of HIPAA authorization had not been obtained for 3 of 6 enrolled study subjects. The RCA also noted that the available documentation indicated that 3 subjects, who had completed the study, had apparently not met the inclusion/exclusion criteria.	Remedial Actions: Additional IRB and PO reviews; data use permitted after HIPAA authorization; 1 of 3 inclusion errors was substantiated, no data use for that subject; refresher training and additional document review at enrollment. CASE CLOSED.
20	21	VA Palo Alto HCS	H	11/13/2013	RCO Audit of an early social development study found that data analysis related to children was being conducted without the required CRADO waiver.	Remedial Actions: Secure CRADO waiver. CASE CLOSED.
21	05	VA Maryland HCS	H	11/15/2013	RCO audit found failure to obtain a HIPAA authorization for one subject in a robot-assisted ankle training study of sub-acute stroke survivors.	Remedial Actions: IRB determined non-serious, not continuing noncompliance. No actions required. CASE CLOSED.
22	08	Bay Pines	H	11/20/2013	RCO informed consent audit found a subject was consented and dispensed study medication prior to verification of exclusion criteria in a dietary supplement and PTSD study.	Remedial Actions: All screening appointments will be scheduled as two separate visits. An Inclusion/Exclusion checklist was created. Protocol and ICD were updated and approved. CASE CLOSED.
23	02	Syracuse	H	11/20/2013	RCO audit on transitions intervention to improve medication adherence and reduce readmissions study found a sub-investigator conducted research follow-up visits on subjects without IRB approval, approved scope of practice, and was using ICD not stamped by IRB and HIPAA authorization not stamped.	Remedial Actions: PI education; RCO to provide research compliance education to all new residents. CASE CLOSED.
24	10	Cleveland (Louis Stokes)	H	11/25/2013	RCO audit found expired WOC appointment and missing scope of practice for one research staff member on this chart review and stool collection study.	Remedial Actions: Remove staff from the study under expedited review as minor changes by the IRB. CASE CLOSED.
25	10	Cleveland (Louis Stokes)	H	11/25/2013	RCO audit found person obtaining consent did not sign two consents for this Phase II blood draw and chart review study of Veterans at risk for Type 2 Diabetes.	Remedial Actions: PI create a note-to file in the investigator file documenting ICDs that were not properly signed and dates; decreased the approval period to 6 months for all this PI's studies; required the PI attend further education. CASE CLOSED.
26	16	Houston (Michael DeBakey)	H	11/26/2013	RCO audit revealed 3 participants were consented after a brain imaging study closed.	Remedial Actions: PI cannot utilize data collected; Research Service must educate investigators. CASE CLOSED.
27	08	Miami	H	11/26/2013	The RCO found a failure to obtain HIPAA authorization for one subject in a Vitamin D study.	Remedial Actions: Modification to the RCO's initial reporting, to include the PO. Education to the PI to disseminate understanding that a HIPAA waiver for initial screening does not apply when actively conducting research thru interventions. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
28	09	Memphis	H	12/02/2013	RCO audit found individually identifiable health information collected without a HIPAA authorization or waiver of HIPAA authorization.	Remedial Actions: NSOC filed; IRB requested RCO perform an audit of all studies being conducted by this investigator. Protocol suspension until completion of RCO for-cause audit. CASE CLOSED.
29	23	Minneapolis	H	12/02/2013	RCO audit of two knee arthroplasty studies found continuation of research past the IRB approval date, incomplete or absent ICDs, and unauthorized disclosure of PHI.	Remedial Actions: Notify affected subjects of unauthorized data disclosures; data may not be used that was obtained past IRB approval date and subject consent. CASE CLOSED.
30	17	VA North Texas HCS	H	12/02/2013	RCO audit found that two unauthorized study staff members of a melanoma study had obtained documentation of informed consent (3 subjects) and two subjects had been enrolled without HIPAA authorization.	Remedial Actions: Study suspended, PI submitted an action plan to ensure that only authorized individuals obtain consent and request permission to obtain HIPAA authorization from subjects who had not provided authorization. CASE CLOSED.
31	16	Central Arkansas (Little Rock)	H	12/04/2013	RCO audit of peripheral artery disease study found use of ICD without IRB approval stamp; failure to submit 2 deviation reports; randomization of an ineligible subject; failure to report SAEs; failure to document pharmacy activities in the medical record.	Remedial Actions: Deviations reported to IRB; SAE log updated; Pharmacy updated CPRS record; will mail page 15 of ICD to subject for signature and will withdraw subject if not returned within 14 days. CASE CLOSED.
32	21	San Francisco	H	12/04/2013	RCO audit found and NSOC reported that HIPAA authorizations were not obtained for four research participants and 20 HIPAA authorizations contained no expiration date.	Remedial Actions: PO submitted a VANSOC report; PI to re-consent subject with VA ICD; procedures implemented to ensure IRB approval prior to staff participation in research; revised HIPAA template used to document authorization. CASE CLOSED.
33	15	Columbia MO (Harry Truman)	H	12/10/2013	RCO conducted regulatory audit of a retrospective chart review of calcium and vitamin D. PI conducted unapproved prospective/retrospective research using PHI without IRB approvals or waivers.	Remedial Actions: IRB closed all PI's active protocols; PI instructed to submit protocol deviations for IRB review. CASE CLOSED.
34	05	VA Maryland HCS	H	12/10/2013	RCO audit found deviations on a movement & balance study for stroke & high fall risk patients - undocumented eligibility, used unapproved ICDs, enrolled participants under multiple ID numbers.	Remedial Actions: Revise ICDs to state that data will be shared; Confirm co-enrolled participants will be re-consented to use their data in all 3 studies; PI must attend additional training. Actions complete, CASE CLOSED.
35	05	VA Maryland HCS	H	12/10/2013	RCO regulatory audit found 2 of 10 subjects were enrolled with documented evidence that they met exclusion criteria on a motor learning study. Two study team members had no scopes for the duration of the study.	Remedial Actions: IRB determined not serious or continuing noncompliance, requested clarification of funding source, corrective actions accepted but not described. CASE CLOSED.
36	09	Louisville (Robley Rex)	H	12/12/2013	RCO regulatory audit found 1 research member with expired CITI training.	Remedial Actions: Employee to complete training upon return from medical leave. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
37	21	San Francisco	H	12/18/2013	RCO audit found programmatic failure to identify deficiencies in HIPAA authorizations for multiple protocols. The deficiencies consisted of the absence of an expiration date or event.	Remedial Actions: Re-review of all HIPAA authorizations approved during past year; responsible person relieved of responsibility pending trainer and refresher education; HIPAA authorization template review. CASE CLOSED.
38	21	VA Pacific Islands HCS	H	12/20/2013	NSOC reported use of ICD forms without the IRB approval stamp and HIPAA authorizations without local requirement for affirmation of PO review.	Remedial Actions: Remedial action plan to prevent recurrence accepted by the IRB. CASE CLOSED.
39	09	VA Tennessee Valley HCS	H	12/20/2013	RCO audit found that HIPAAs for 21 subjects in a lung cancer study did not completely document permissions for use and disclosure of 38 USC 7332 data to a non-VA entity.	Remedial Actions: Subjects to sign new HIPAA authorization form; VA NSOC to send notification to the subjects in question. CASE CLOSED.
40	16	Houston (Michael DeBakey)	I	12/23/2013	RCO audit found and NSOC reported one missing ICD.	Remedial Actions: Project placed on administrative hold; Study Coordinator's WOC appointment was not renewed due to severity of noncompliance issues; person whose consent was lost has been re-consented. CASE CLOSED.
41	21	San Francisco	H	12/23/2013	RCO Audit of a PTSD study found an outdated ICD version was used for enrollment of 43 of 192 subjects.	Remedial Actions: Mechanisms implemented to ensure use of current ICD forms. CASE CLOSED.
42	09	VA Tennessee Valley HCS	I	12/30/2013	RCO audit found one subject's case report form (including dates and subject initials) was missing.	Remedial Actions: The IRB and RDC reviewed the non-compliance and determined that there was no substantive harm or risk to the individual, that the non-compliance was not serious or continuing, and that no additional action was required. CASE CLOSED.
43	15	Columbia MO (Harry Truman)	A	12/31/2013	RCO audit discovered one animal protocol with a lapse in annual review and use of eight mice during the lapse.	Remedial Actions: The investigator submitted an annual review to the Subcommittee on Animal Studies; other actions Pending. CASE CLOSED.
44	15	Columbia MO (Harry Truman)	H	12/31/2013	RCO audit found that an expired cardiac stent had been placed in a patient for the VA CSP #571 device study.	Remedial Actions: Disclose to OHRP and FDA; confer with Regional Counsel about facility disclosure; technicians to perform inventory expiration audits; nurses to read out loud expiration dates at time of surgery. CASE CLOSED.
45	15	Columbia MO (Harry Truman)	R	12/31/2013	RCO audit found that the R&DC approved an ACORP involving mice prior to all subcommittee final approvals.	Remedial Actions: R&DC Chair to verify all approvals are in place prior to informing the ACOS/R. ACOS/R to verify all approvals are in place prior to sending initiation letter to PI. CASE CLOSE.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
46	18	Phoenix VA HCS	H	12/31/2013	RCO audit of research records for 9 of 76 enrolled subjects in a blood pressure intervention trial found multiple concerns including missing source documentation, discrepancies between source documents and CPRS entries, failure to obtain ICD for DNA sampling, and 1 subject running out of study med.	Remedial Actions: Sponsor notified; employment of one CRC terminated. CASE CLOSED.
47	21	San Francisco	H	**01/02/2014**	RCO audit found 2 of 65 subjects in a pulmonary study had not provided documentation of informed consent; 11 of 65 subjects had not provided HIPAA authorization; 2 of the HIPAA authorizations obtained were lacking the date of the participant's signature.	Remedial Actions: The PI assured that the study team had not enrolled subjects who provided incomplete ICDs. CASE CLOSED.
48	09	Memphis	H	**01/03/2014**	RCO audit found multiple ICD/HIPAA, regulatory violations for pre-2008 IRB approved social behavioral study suspensions resulting from an IRB-initiated for-cause audit; PI noncompliance of data collection without IRB approval.	Remedial Actions: OHRP notification; IRB initiated for-cause audit conducted; PI received education from ISO, PO, RCO, and ACOS/R; ISO and PO review procedures changed; it was determined that PI did have correct privileging; and procedures were modified accordingly. CASE CLOSED.
49	09	VA Tennessee Valley HCS	H	**01/03/2014**	RCO audit found misused 38USC 7332 data without appropriate HIPAA authorization along with missing source documents containing PHI.	Remedial Actions: No actions required. CASE CLOSED.
50	16	Houston (Michael DeBakey)	H	**01/06/2014**	RCO audit revealed that 3 subjects were enrolled into the study without signing an ICD, the ICD for 1 provider was missing, and a total of 162 individuals (125 subjects and 37 providers) were consented on an unapproved ICD. Minimal risk study looking at the relationship between patients and doctors.	Remedial Actions: Train study team; QA plan for review of ICDs/HIPAAs after signature by the subject and person obtaining consent; re-consent affected subjects. CASE CLOSED.
51	05	VA Maryland HCS	H	**01/07/2014**	RCO audit of a dementia study found 1 of 8 study team members had no documented scope of practice.	Remedial Actions: None, IRB found non noncompliance. CASE CLOSED.
52	15	St Louis	H	**01/08/2014**	RCO audit of a depression treatment study, funded by ORD, found that several study staff were not approved by the IRB and that an SAE was not reported to the IRB.	Remedial Actions: IRB did not find this was non-compliance. CASE CLOSED.
53	09	Memphis	H	**01/10/2014**	RCO audit of NIH funded OEF/OIF Veterans study found missing and unsigned HIPAAs, ICDs, and VA Form 10-3203 (picture and/or voice consent); use of outdated HIPAA; IRB approval issues; and missing scopes.	Remedial Actions: Study suspended to enrollment; NSOC reported for unauthorized disclosure of PHI. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
54	05	VA Maryland HCS	H	**01/10/2014**	RCO regulatory audit found 2 study team members had no documented scope of practice on a dementia outreach services evaluation.	Remedial Actions: PI will have both residents sign their scopes. IRB found continuing, but not serious, NC (no additional risk to participants) and accepted PI's CAP. CASE CLOSED.
55	05	VA Maryland HCS	H	**01/13/2014**	RCO audit of a Parkinson's Disease Exercise & Cognitive Training Intervention found: missing scopes of practice for 2 of 18 study team members; and one participant who was enrolled under two separate ID #s and not re-consented after he stopped participation and returned at a later date.	Remedial Actions: PI to develop an SOP to ensure adequate and consistent training for current & future staff. CASE CLOSED.
56	16	Houston (Michael DeBakey)	H	**01/16/2014**	RCO Audit revealed that one subject enrolled in a Parkinson's study did not have a signed HIPAA authorization, as required.	Remedial Actions: PI to enter a note to file in the research record of the subject to document that the volunteer did provide his/her HIPAA authorization via the information in signed VA Form 10-1086 and to note event reported to IRB; PI to obtain authorization if subject returns. CASE CLOSED.
57	01	Bedford (Edith Rogers)	H	**01/21/2014**	RCO audit of an alcohol dependence and PTSD study found the research team had enrolled subjects who did not meet the inclusion criteria.	Remedial Actions: IRB discussed with PI the importance that all inclusion/exclusion criteria are accurately detailed in the protocol. CASE CLOSED.
58	16	Central Arkansas (Little Rock)	H	**01/21/2014**	RCO audit of a chronic pain and suicidal ideation study found the PI continued research activity past expiration date of IRB approval; and 48 records were collected prospectively without the appropriate approvals in place.	Remedial Actions: PI to submit deviation report to IRB regarding: data collected prospectively instead of retrospectively; exceeding approval number of enrolled subjects; conducting research during lapse of approval; non-IRB-approved staff conducted research activities, and education. CASE CLOSED.
59	11	Ann Arbor HCS	H	**01/22/2014**	RCO audit found missing documentation of inclusion/exclusion criteria, waivers of ICD and HIPAA for recruitment, and time of enrollment for this osteoporosis study.	Remedial Actions: Instructions to investigator for documenting eligibility will be clarified; waiver of HIPAA authorization will be required for phone screenings prior to consent. CASE CLOSED.
60	09	Memphis	H	**01/22/2014**	RCO regulatory audit of a sleep disordered breathing study found continued work post IRB approval lapse, unauthorized IIHI collection, failure to re-consent, missing scope and valid VA appointment.	Remedial Actions: Protocol administratively closed; HIPAA template revised; PO review modified to ensure compliance; PI provided education by ACOS/R; -failure to re-consent was determined not to be noncompliance; PI resubmitted application for approval. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
61	21	San Francisco	H	**01/22/2014**	RCO audit found that 11 subjects were consented into a vascular pathology MRI study with an outdated ICD and 1 subject was enrolled by an unauthorized individual.	Remedial Actions: IRB determinations - neither serious nor continuing; corrective actions adequate; no further action required (no re-consenting needed). CASE CLOSED.
62	20	VA Puget Sound HCS	H	**01/29/2014**	RCO Audit found that scope of practice statement had not been developed for a sub-investigator of a colorectal cancer study.	Remedial Actions: Re-train staff; establish scope of practice. CASE CLOSED.
63	05	Washington DC	H	**01/30/2014**	RCO Audit found one HIPAA authorization was not signed by the subject on a study evaluating joint and tendon changes in asymptomatic hyperuricemia.	Remedial Actions: Subject must sign HIPAA authorization. CASE CLOSED.
64	16	Houston (Michael DeBakey)	H	**01/30/2014**	RCO Audit of a trauma recovery program outcomes study found that 16 subjects signed ICDs with the incorrect version date and 2 subjects did not sign the required HIPAA authorization.	Remedial Actions: ICD version control; PI placed note to file in all subjects files; data from 2 subjects who did not sign HIPAA will not be used. CASE CLOSED.
65	03	VA New York Harbor HCS	H	**02/03/2014**	RCO audit of an atrial fibrillation study found that two participants were consented by a non-approved individual (graduate student).	Remedial Actions: PI education; re-consenting two patients, report to sponsor and DSMB. CASE CLOSED.
66	04	VA Pittsburgh HCS	H	**02/03/2014**	RCO audit on study evaluating the impact of home monitoring guided anticoagulation on stroke risk in patients with ICD and CRT devices identified that admission of a subject to the hospital 11 times was not reported as apparent serious adverse event within the required five business days.	Remedial Actions: Education of investigator on documenting and reporting adverse events; PI provide a written plan describing how study team plans to adhere to complying with the SAE reporting requirements. CASE CLOSED.
67	04	Wilkes-Barre	H	**02/03/2014**	RCO Audit found that the IRB granted, but failed to document in the IRB minutes, IC and HIPAA waivers on an expedited pressure ulcer education study.	Remedial Actions: R&DC determined not serious or continuing programmatic noncompliance by the IRB, approved addendum to IRB minutes correcting error. CASE CLOSED.
68	16	Central Arkansas (Little Rock)	S	**02/05/2014**	RCO audit found a lapse in SRS annual review.	Remedial Actions: Improve communication with investigators; improve use of protocol tracking systems. CASE CLOSED.
69	23	Minneapolis	H	**02/06/2014**	RCO Audit of a leukemia tissue study found one subject was enrolled without documentation of informed consent of HIPAA authorization.	Remedial Actions: Clarify all study staff understand ICD process; notify affected subject of occurrence and provide option to withdraw tissue specimen; RCO consent audit. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
70	18	New Mexico VA HCS	H	**02/06/2014**	RCO audits of nine protocols found a lack of required IRB documentation related to expedited reviews of nine protocols.	Remedial Actions: 2013 IRB minutes audited for accuracy; IRB minutes and approval letters were amended to include correct and/or omitted information; supplemental staff training to prevent future deficiencies; review of procedures. CASE CLOSED.
71	21	VA Palo Alto HCS	H	**02/06/2014**	RCO audit of a study to improve visual aids for patients with TBI found that HIPAA authorization had not been obtained from one Veteran.	Remedial Actions: Disallow use of data obtained from Veteran who had not provided HIPAA authorization; increase RCO auditing frequency for this study. CASE CLOSED.
72	08	Tampa (James Haley)	H	**02/07/2014**	RCO Audit found an additional missing HIPAA authorization for the Homelessness Severity Index study, which already reported 80 missing HIPAAs under case # 0088-673-H. This previous case was satisfactorily remediated and closed.	Remedial Actions: No medical records were reviewed in this study, which is now closed. The final report for the study was submitted to the sponsor without access, review or analysis of any medical records for any participants. The reason for closing the study was insufficient staffing. CASE CLOSED.
73	21	San Francisco	H	**02/10/2014**	RCO (follow-up) audit of an unfunded macular degeneration study revealed recurring noncompliance in the use of an invalid HIPAA authorization form.	Remedial Actions: HIPAA authorization expiration date; IRB reporting requirements; PHI collected without valid HIPAA authorization excluded from research data sets. CASE CLOSED.
74	11	Indianapolis (Roudebush)	H	**02/11/2014**	RCO regulatory audit found one staff member without a valid scope of practice in this retrospective chart review study of carotid artery occlusions outcomes.	Remedial Actions: Ensure changes to staff lists are communicated to the R&DC. CASE CLOSED.
75	01	Providence	H	**02/11/2014**	RCO audit of an Aging Network Agency Coordinators study found that the PI consented 28 study participants on an unstamped Informed Consent Document that was modified by PI without IRB approval.	Remedial Actions: All activities on study suspended; PI must modify informed consent and re-consent participants; data from participants unwilling to re-consent cannot be used; PI provides monthly report to IRB on progress made in re-consenting. CASE CLOSED.
76	05	VA Maryland HCS	H	**02/11/2014**	RCO regulatory audit found that 1 of 3 study staff did not have Scope of Practice or CITI training for the duration of a postoperative pain management study.	Remedial Actions: IRB determined not serious, not continuing noncompliance and accepted PI's corrective actions. PI submitted a Scope for the staff member. CASE CLOSED.
77	16	Central Arkansas (Little Rock)	H	**02/12/2014**	RCO audit found 13 subjects CPRS flags were not initiated and six subjects did not have a pre-op EKG within 30 days prior to the surgical procedure in a study of postoperative nausea and vomiting.	Remedial Actions: Upload correct VHA Form 10-9012; confirm all PI essential documents are in regulatory binder; scan missing HIPAA and ICDs into CPRS; submit the six IRB requested deviations. CASE CLOSED.
78	07	Charleston (Ralph Johnson)	H	**02/13/2014**	Facility reported an RCA consent audit of a CSP depression study found that 2 of 5 enrolled did not sign a HIPAA Authorization.	Remedial Actions: Re-sign 2 HIPAA Authorizations. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
79	07	Charleston (Ralph Johnson)	H	**02/13/2014**	RCO audit on a diabetes outcome study discovered 84 consents signed on the incorrect version. IRB determined this not to be serious or continuing as the information in the ICF did not change. CASE CLOSED.	Remedial Actions: Plan introduced to QA the ICF versions prior to signature. CASE CLOSED.
80	17	VA North Texas HCS	H	**02/20/2014**	RCO audit of a heart failure device study found two SAEs had not been reported to the IRB.	Remedial Actions: PI to submit a plan to ensure future compliance with local reporting requirements. CASE CLOSED.
81	01	Providence	H	**02/21/2014**	RCO audit found six participants recruited on a study to determine feasibility and obstacles in implementation of a Shared Medical Appointment program for Heart Failure did not sign HIPAA Authorization.	Remedial Actions: PI cannot use collected data without re-consenting the participants using an IRB approved re-consenting version of the HIPAA authorization form. CASE CLOSED.
82	17	VA North Texas HCS	H	**02/21/2014**	RCO Audit of a PTSD study found that a subject signed an out of date ICD which was subsequently destroyed (shredded) after the subject signed the correct ICD version.	Remedial Actions: Study coordination education regarding records retention requirements. CASE CLOSED.
83	07	Columbia, SC (WJB Dorn)	S	**02/24/2014**	RCO audit identified a protocol with a lapse in SRS annual continuing review.	Remedial Actions: Review of incident. CASE CLOSED.
84	18	Phoenix VA HCS	H	**02/24/2014**	RCO audit identified electronic medical record deficiencies (9 subjects) that had not been reported to the IRB in a study of early lung cancer actions program.	Remedial Actions: Completion of follow-up CT scans; notations in CPRS; and study closure. CASE CLOSED.
85	23	Sioux Falls	H	**02/24/2014**	RCO regulatory audit found that R&DC approval was never recorded in 2010 for one study. Occurrence was an apparent oversight and an isolated event.	Remedial Actions: Institution of a tracking system in 2011 to prevent a recurrence; no further incidents noted subsequent to tracking system. CASE CLOSED.
86	01	VA Boston Healthcare System	H	**02/24/2014**	RCO audit of reported unauthorized research activity by a clinician researcher in a study of Alzheimer's disease.	Remedial Actions: Study suspended to new enrollment; sponsor notified; RCO for cause audit conducted. PI must work with sub-panel assigned by IRB to coach and mentor him; PI and study staff to complete education; ICDs, HIPAA Authorizations and protocol documentation must be revised.
87	11	Indianapolis (Roudebush)	H	**02/25/2014**	RCO ICD audit discovered 2/19 HIPAA authorizations were not obtained in a study of post-stroke patients with hypertension.	Remedial Actions: IRB determined the event did not constitute serious or continuing noncompliance. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
88	09	Memphis	I	**02/25/2014**	RCO for-cause audit identified 39 voice recordings were collected without the proper consent and apparently uploaded to the affiliate drive. Information subsequently obtained that recordings did not contain PHI. In addition, multiple instances of HRPP-related non-compliance are being followed in separate cases.	Remedial Actions: Private information access controls; storage of VA data on affiliate drives; definitive clarification received from the facility that only arbitrary participant study numbers were included on the voice recordings (no HIPAA identifiers). CASE CLOSED.
89	09	Memphis	H	**02/27/2014**	RCO audit of study comparing two interventions for alcohol use among OEF/OIF veterans identified issues with HIPAA documents, voice recordings and credentialing/scopes of practice.	Remedial Actions: Financial conflict of interest reporting; investigator privileges and scope of practice; documentation of informed consent waivers; initial telephone contact research requirements; study documentation. CASE CLOSED.
90	01	VA Connecticut HCS	H	**02/28/2014**	RCO audit found CPRS alerts were not being created and errors on ICD of signatures and SSN on an interviews outcomes study.	Remedial Actions: Education of PI and staff; PI to submit ICDs, HIPAA and CPRS alerts for next 10 enrollees to Research Office; and IRB to determine use of data already collected. CASE CLOSED.
91	04	VA Pittsburgh HCS	H	**03/01/2014**	RCO audit identified that amendments were done to a Prevention of Episodic Migraine study without submitting the amendments for FDA review and approval per 21CFR 312.30.	Remedial Actions: PI sponsor-investigator training; PI cannot collect additional data from the subjects; PI's privilege to submit proposals as a PI or Co-PI on future trials that engage facility has been rescinded. CASE CLOSED.
92	01	Central Western Massachusetts (Northampton)	R	**03/04/2014**	RCO Audit found two instances where the wrong version of the ICD was utilized to consent participants in a CSP study of the genetics of schizophrenia and bipolar disorder.	Remedial Actions: RDC to provide local oversight; PI and study staff education. CASE CLOSED.
93	07	Charleston (Ralph Johnson)	H	**03/05/2014**	RCO audit of a drug study to treat substance relapse found that the person obtaining consent for 32/52 subjects was a university researcher without a VA appointment.	Remedial Actions: Prohibition on "recruitment only" VA research; VA investigator requirements. CASE CLOSED.
94	05	VA Maryland HCS	H	**03/05/2014**	RCO audit found tissues stored in a non-VA site without ORD approval, and group session conducted at a non-VA site not described in the protocol. This is a study of weight loss for breast cancer survivors.	Remedial Actions: Tissue banking requirements; participation of non-Veterans requirements. CASE CLOSED.
95	10	Cleveland (Louis Stokes)	H	**03/06/2014**	RCO audit of a CSP colorectal cancer mortality study discovered person obtaining consent did not sign the ICD.	Remedial Actions: The person obtaining consent subsequently signed and dated the ICD. The patient was given a copy of the signed and dated ICD. A Note to File was completed and submitted to CIRB and copies maintained in the Regulatory Binder. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
96	09	Lexington	H	**03/06/2014**	RCO audit of an unfunded human factors study involving resuscitation found that the approved ICD did not contain the IRB approval stamp (53/53); HIPAA authorization was not obtained (53/53); and 2/53 subjects did not sign an ICD.	Remedial Actions: IRB revised the language of their approval memos to strongly suggest ICD and HIPAA authorization be immediately reviewed by the RCO. CASE CLOSED.
97	05	Washington DC	H	**03/07/2014**	RCO audit of a specimen banking project found that an unauthorized coordinator (not on study roster) used an unapproved ICD template; incomplete ICD (no genetic addendum) used to enroll subjects at secondary VA site using this IRB; IRB reviewed without a representative present from secondary site.	Remedial Actions: IRB suspended the study at other VA using this IRB; re-consent subjects with approved ICD; RCO must monitor consent process; investigate site staff's competence to conduct study procedures. CASE CLOSED.
98	04	Philadelphia	H	**03/07/2014**	RCO ICD Audit discovered 2 subjects' ICDs missing signature of person obtaining consent. This is a study of implementation challenges related to psychosocial issues within VA's largest homelessness joint initiative between VA and the Department of Housing and Urban Development.	Remedial Actions: Obtain signatures and dates of person obtaining consents; re-scan ICDs in CPRS. CASE CLOSED.
99	04	Philadelphia	H	**03/07/2014**	RCO ICD Audit of study of effect of family history on insomnia in subjects with alcoholism discovered HIPAA missing subject signature (1) and ICDs missing person's signature obtaining consent(4).	Remedial Actions: Obtain signed HIPAA and scan to CPRS; Obtain signatures of person obtaining consent and re-scan to CPRS; study coordinator training and PI monitoring of consent documents. CASE CLOSED.
100	04	Philadelphia	H	**03/07/2014**	RCO ICD Audit of study of effect of nitrates and hydralazine on heart failure subjects discovered ICD (1) without signature and date of person obtaining consent.	Remedial Actions: Obtain signature of person obtaining consent; re-scan ICD in CPRS CASE CLOSED.
101	21	VA Palo Alto HCS	H	**03/07/2014**	RCO Audit of a bipolar disorder study found unauthorized personnel (one individual) obtaining documentation of informed consent from four study subjects.	Remedial Actions: Document personnel authorized to obtain consent. CASE CLOSED.
102	06	Salisbury (Bill Hefner)	H	**03/07/2014**	RCO audits prior to OIG routine visit found seven instances where reporting to OHRP was not done.	Remedial Actions: New OHRP email address added to RCO reporting template. CASE CLOSED.
103	16	Houston (Michael DeBakey)	H	**03/12/2014**	RCO audit revealed that 13 subjects signed the affiliate's HIPAA authorization instead of the CIRB authorization. This study compares the effectiveness and safety of surgical treatment to medical treatment for veterans with heartburn that do not respond to proton pump inhibitors.	(1) PI should attempt to obtain HIPAA authorization from all 13 subjects. (2) PI made good faith effort, as determined by CIRB, to obtain authorization. The PI does not have to continue to contact the remaining 3 subjects to obtain authorization. Data can be used. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
104	05	VA Maryland HCS	H	**03/12/2014**	RCO audit found no scopes for 6/15 staff during the period the study was classified as VA research. PI said the study never qualified as VA research due to a misinterpretation of the VA rules. This is study of robotics for individuals with incomplete spinal cord injury.	Remedial Actions: Research scope of practice requirements; definition of VA research. CASE CLOSED.
105	09	Memphis	H	**03/13/2014**	RCO audit of an unfunded, malnutrition study found apparent noncompliance. A researcher consented 5 subjects, but did not have this duty documented in their scope of practice.	Remedial Actions: Study staff trained on ICD and HIPAA requirements; each has the appropriate scope of practice; IRB determined the events did not constitute noncompliance. CASE CLOSED.
106	01	VA Connecticut HCS	H	**03/13/2014**	RCO consent form audit found persons not approved on study obtained consent form 6 subjects; 6 subjects signed unstamped ICD; 2 subjects were on 2 consent logs; and 2 versions of a HIPAA authorization were used on a sleep apnea study.	Remedial Actions: Education; re-consent 6 subjects; and verify that wrong HIPAA authorization was not used. CASE CLOSED.
107	07	Columbia MO (Harry Truman)	H	**03/14/2014**	RCO audit of a heart failure biomarker study indicated that one subject printed his name on the consent form but did not sign it.	Remedial Actions: Change the annual review cycle; implement direct communication between the Subcommittee for Research Studies and the Principal Investigator; and document business items on meeting agendas and publish meeting calendars. CASE CLOSED.
108	15	Columbia MO (Harry Truman)	A	**03/14/2014**	RCO routine audit discovered a lapse in annual review of an animal protocol.	Remedial Actions: Change the annual review cycle; implement direct communication between the Subcommittee for Research Studies and the Principal Investigator; and document business items on meeting agendas and publish meeting calendars. CASE CLOSED.
109	05	Washington DC	H	**03/14/2014**	RCO audit found 19 participants were enrolled into a learning tool for nursing supervisors study using an IRB-approved ICD that omitted research-related injury text.	Remedial Actions: IRB determined not serious or continuing noncompliance, no further action required. CASE CLOSED.
110	08	VA Caribbean HCS (San Juan)	I	**03/14/2014**	NSOC reported that an RCO noticed during an audit that a copy of an ICF was scanned into Veteran's CPRS record, instead of the original ICF. The whereabouts of the original ICF is not determined.	Remedial Actions: Notification letter sent to participant; PI action plan required to facilitate proper ICD and HIPAA authorization retention. CASE CLOSED.
111	07	*Columbia SC (WJB Dorn)	H	**03/14/2014**	RCO audit of a heart failure biomarker study indicated that one subject printed his name on the consent form but did not sign it.	Remedial Actions: Subject provided new consent. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
112	09	Memphis	H	**03/18/2014**	RCO audit found that the unfunded, interventional study providing a nutritional supplement to gastrointestinal surgical patients was missing a Scope of Practice for 1 research team member.	Remedial Actions: IRB determined that none of the events constituted noncompliance; PI moved data to correct location. CASE CLOSED.
113	09	Memphis	H	**03/18/2014**	RCO audit of an unfunded, spinal cord injury and nutrition study found no record of ISO or PO review of this study. Study is now closed.	Remedial Actions: ISO/PO reviews must be documented; ISO/PO must review where study data is being retained. CASE CLOSED.
114	09	Memphis	H	**03/18/2014**	RCO regulatory and ICD audit of a closed comparative study of tinnitus management found ICD and HIPAA information omissions, scopes of practice deficiencies, SAE reporting delays and inaccuracies, as well as IRB errors of documentation and review procedures.	Remedial Actions: HIPAA template modified; lack of scopes of practice was determined to not be noncompliance; ISO/PO reviews were not required when study initiated so determined to not be noncompliance by the IRB; lack of scopes of practice was also determined to not be noncompliance; SAE reporting delays was determined to not be noncompliance. CASE CLOSED.
115	16	Houston (Michael DeBakey)	H	**03/20/2014**	RCO Audit found one subject in a cocaine dependence treatment study began study procedures prior to signing the informed consent document.	Remedial Actions: The ICD was later located that showed the subject was consented prior to starting study procedures. CASE CLOSED.
116	19	VA Salt Lake City HCS	H	**03/21/2014**	RCO audit of a prostate biopsy study found 31 out of 131 subjects were consented using expired ICDs.	Remedial Actions: IRB determination of neither serious nor continuing noncompliance; PI plan to prevent recurrence (identify current form) accepted by IRB. CASE CLOSED.
117	22	VA San Diego HS	H	**03/25/2014**	RCO audit of a treatment study comparing yoga to standard of care treatment of chronic back pain found that 27 ICDs did not include an IRB approval stamp.	Remedial Actions: Informed consent obtained using approved ICDs for all affected subjects. IRB determination of neither serious nor continuing noncompliance. All identified concerns resolved. CASE CLOSED.
118	09	Memphis	H	**03/26/2014**	RCO audit of an unfunded, Deep Vein Thrombosis Prophylaxis study found that the CoPI did not complete a financial COI form, the ISO/PO reviews did not occur prior to IRB review, PHI was collected without an authorization or waiver. Study is closed, PI no longer at facility.	Remedial Actions: Lack of financial COI form for CoPI was determined not to constitute noncompliance by IRB; ISO/PO review process has been modified; HIPAA template has been modified to capture all PHI. CASE CLOSED.
119	10	Cincinnati	H	**03/27/2014**	RCO audit of a pharma-sponsored diabetes drug study found that 3 subjects were provided study drug after the study had expired.	Remedial Actions: PI was provided education on the requirements for continuing review and study expiration; a new PI will take over the study; pharmacy relabeled protocol binders to clearly exhibit the IRB approval/expiration dates of all current protocols; training was provided to research staff on using the electronic IRB application system. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
120	04	Philadelphia	R	**03/27/2014**	RCO ICD Audit of a CSP colorectal screening study discovered one subject had not signed a HIPAA authorization.	Remedial Actions: Obtain signature; delete existing scanned ICD/HIPAA document in CPRS; re-scan signed HIPAA; complete note to file. CASE CLOSED.
121	07	Tuscaloosa	H	**03/27/2014**	RCO routine regulatory audit of a survey study discovered that a Pharmacy Resident was listed as a CoPI however a supervisory PI was not noted in the submission.	Remedial Actions: The Board agreed with the corrective actions recommended by the Chair to add a VA appointee as a CoPI; scan all records into CPRS; add a student checkbox on the IRB submission form; revise research SOP's to prohibit student/trainee PI's; reminder to IRB reviewers to affirm PI qualifications; PI responsibility letter sent to new VA co-PI. CASE CLOSED.
122	09	Memphis	I	**03/28/2014**	RCO audit of a liver cancer study found and facility reported that VA network access to research related PHI was not limited to approved study staff and information related to the security of collected data was not listed in the protocol. Other items followed in H case.	Remedial Actions: Closed protocol study data transferred to research service archived folders; research staff reminded to store all human subjects' data in assigned research folders. CASE CLOSED.
123	04	VA Pittsburgh HCS	H	**03/28/2014**	RCO regulatory audit of Omega-3 Fatty Acid Supplementation on CAD risk in Schizophrenia study identified seven subjects underwent interaction or intervention prior to consenting and multiple subjects appeared to have deficiencies with HIPAA authorization procedures.	Remedial Actions: Investigator education; the IRB Chair determined appropriate outcomes for those subjects who did not meet eligibility criteria. CASE CLOSED.
124	09	Memphis	H	**03/31/2014**	RCO audit of an unfunded study of cancer survival predictors found 2/7 financial COI forms weren't completed; ISO/PO reviews did not occur; HIPAA/ICD waivers were incomplete; PHI was used without authorization; and the IRB application did not include data security descriptions.	Remedial Actions: NSOC was filed; RCO will review PI's regulatory records; lack of scopes, missing financial COI statements, and deficient HIPAA waiver were all determined to not constitute noncompliance; procedures have been implemented to ensure ISO/PO review; the IRB application has been amended to incorporate data security concerns; remedial actions complete, CASE CLOSED.
125	08	VA Caribbean HCS (San Juan)	H	**03/31/2014**	RCO audit found lack of required HIPAA for one subject and numerous discrepancies in 27 ICDs audited for a pilot study monitoring blood glucose levels after joint injections.	Remedial Actions: The IRB determined the issues to be serious, continuing noncompliance. The IRB requested numerous actions from the PI which included: suspension of all research activities after completion of a risk assessment on all active participants; a plan on resources and time availability to conduct this study; a roster of the research team members and re-training on obtaining proper informed consent and documenting the process. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
126	23	Iowa City	H	**04/01/2014**	RCO audit of a post-surgical pain study found that HIPAA authorizations were not requested from the 3 enrolled subjects.	Remedial Actions: PI must obtain valid HIPAA authorization from the subjects or may not use data associated with the subjects; study staff must complete supplemental Privacy and HIPAA related training. CASE CLOSED.
127	23	Iowa City	H	**04/01/2014**	RCO audit of an anticoagulation study found that HIPAA authorizations were not requested from 4 of 7 enrolled subjects.	Remedial Actions: Valid HIPAA authorization obtained from all subjects; study staff completed HIPAA and Privacy related training. CASE CLOSED.
128	04	Philadelphia	H	**04/01/2014**	RCO ICD Audit of study evaluating radiographic joint damage in Rheumatoid Arthritis discovered two subjects' ICDs missing signature of person obtaining consent and date.	Remedial Actions: IRB comparison of approved and unapproved ICDs; obtain signature of subjects and current date on ICDs (2); delete scanned ICD/HIPAA document in CPRS; re-scan ICD/HIPAA; complete note to file explaining the date discrepancy. CASE CLOSED.
129	17	VA North Texas HCS	H	**04/03/2014**	RCO audit found that 5 subjects enrolled in a study to assess the safety and efficacy of a device used in conjunction with renal replacement therapy in patients with acute kidney injury did not provide HIPAA authorization.	Remedial Actions: PI attempting to obtain HIPAA authorization. Two have been obtained. I subject has died. PI will submit protocol amendment to extend coverage of HIPAA waiver for the deceased subject and remaining 2 subjects if contact attempts fail. CASE CLOSED.
130	05	Washington DC	H	**04/3/2014**	RCO audit found 12 of 12 subjects enrolled on an HSR&D sponsored study using a CIRB-approved ICD that did not include the VA research-related injury text.	Case is being followed by ORO CO (#0080-101-H). CIRB found not serious or continuing, no further action required. CASE CLOSED.
131	16	Central Arkansas (Little Rock)	H	**04/09/2014**	RCO audit found one subject missing HIPAA authorization.	Remedial Actions: Obtain the HIPAA authorization from the participant. If unable to obtain the HIPAA authorization, the PI must withdraw the patient and his or her data from the study. CASE CLOSED.
132	06	Durham	H	**04/09/2014**	RCO audit of brain imaging study for PTSD discovered that HIPAA Authorization was not signed.	Remedial Actions: Retrain staff; subject to sign at next study visit. CASE CLOSED.
133	21	San Francisco	H	**04/11/2014**	RCO Audit found missing HIPAA authorization for one subject.	Failure to obtain HIPAA authorization at enrollment. PI unsuccessfully attempted to obtain HIPAA authorization. Subject's file sealed until authorization or waiver obtained. CASE CLOSED.
134	16	Central Arkansas (Little Rock)	A	**04/15/2014**	RCO Audit found a lapse in IACUC and SRS annual reviews.	Remedial Actions: Annual review of protocol; internal audit of electronic files to generate automatic reminders for annual reviews; development of SOP for annual reviews. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
135	07	Tuscaloosa	H	**04/16/2014**	RCO routine audit of a pet therapy study found multiple consent documentation errors on four consent forms.	Remedial Actions: Re-consent all subjects under the supervision of the IRB Vice-Chair; - appropriately enter consent progress notes on all re-consented; allow the screening/recruitment data to be used no additional subjects enrolled so a new waiver of for screening/recruitment is moot; an experienced VA researcher required as PI for all student/trainee studies; IRB checklist drafted to determine qualification/experience of PI. CASE CLOSED.
136	04	Coatesville	H	**04/17/2014**	RCO ICD Audit of study on predicting treatment process through personality inventory assessment discovered that the investigator did not use the IRB-approved informed consent document (9 subjects) and HIPAA authorization did not include expiration date for use of identifiable information.	Remedial Actions: RCO education of study team; IRB determined that the ICDs matched those approved for use but data could not be used as study has ended and subjects can no longer be contacted to sign revised HIPAA forms; recently published HIPAA forms have been implemented and disseminated to research community. CASE CLOSED.
137	01	Bedford (Edith Rogers)	H	**04/17/2014**	RCO audit found that a jail diversion study enrolled 3 (of 34 subjects) without a HIPAA authorization.	Remedial Actions: retrain the study team; and obtain HIPAA authorizations or sequester (not use/disclose) data. All corrective actions completed (HIPAA authorizations obtained). CASE CLOSED.
138	19	VA Eastern Colorado HCS	H	**04/17/2014**	RCO audit found that all 5 subjects enrolled in an ALS upper extremity orthosis study lacked VA HIPAA authorizations.	PI has contacted the three living subjects; one has signed HIPAA authorization and decisions are pending from two subjects; clarify whether a HIPAA waiver will be requested to use data from deceased subjects; PI to review internal processes to prevent future occurrences. IRB waived HIPAA and determined that PI may use all collected data. CASE CLOSED.
139	21	San Francisco	H	**04/21/2014**	RCO audit of three studies (one PI) found one unsigned ICD in a neurocognitive performance study; use of an outdated ICD (10 of 14 subjects) in a PTSD and aging brain study; and lack of documentation of HIPAA authorization for one subject in a women and PTSD study.	Remedial Actions: Corrective actions (in response to IRB and PO reviews) completed, retraining for study staff, no use/disclosure without compliant HIPAA for any of the 3 studies. CASE CLOSED.
140	08	Orlando	H	**04/23/2014**	RCO audit found 20 ICDs containing incorrect treatment of research related injuries statement and those ICDs were inconsistent with the HIPAA authorization in the protocol titled: Oral tongue versus tongue base movement during speech and swallowing.	Remedial Actions: PI to send a letter to each subject explaining and apologizing for the error; additional training in the review of ICD and HIPAA documents was provided for the IRB members, ISO, and PO with copies of the training materials made available to absent members and alternates; IRB will establish periodic retraining in review procedures for IRB members, ISO, and PO. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
141	05	Washington DC	H	**04/23/2014**	RCO audit found subjects enrolled using a non-VA ICD; missing 1 Scope of Practice; recruiting non-Vets without PI justification or IRB approval.	(1) Scope was developed, submitted and approved by IRB. No further action required. (2) ORO consulted OGC/STAR group and OIG, confirmed noncompliance, but no criminal prosecution was warranted. NERO counseled facility management (MCD, COS and ACOS/R) on oversight of agreements, MOU was revised and signed by authorized representatives of both institutions. CASE CLOSED.
142	07	Columbia SC (WJB Dorn)	H	**04/23/2014**	RCO audit of biofeedback study discovered that that the PI used the wrong consent form version for 26 subjects. Further information is Pending.	Remedial Action: Investigator may only serve as a subinvestigator on studies for the next calendar year. At that time the investigator can petition the Board for full PI responsibilities. CASE CLOSED.
143	18	New Mexico VA HCS	H	**04/25/2014**	RCO audits found multiple instances when the (affiliate) IRB used expedited review procedures to conduct review and approve protocol amendments and continuing review applications for five protocols, but did not document the approvals in the IRB minutes.	Remedial Actions: Staff retraining R&DC will verify required content in the IRB minutes and approval letters. CASE CLOSED.
144	18	New Mexico VA HCS	H	**04/25/2014**	RCO auditing found seven protocols had expired within a one-year period.	Remedial Actions: Staff retraining; the Research and Development Committee will verify required content in the IRB minutes and approval letters. CASE CLOSED.
145	17	Central Texas Veterans HCS	H	**04/28/2014**	RCO closure audit found that a study of different vascular graft substrates had expired prior to release of continuing review approval and unapproved research (follow-up interactions) continued during the lapse.	Remedial Actions: The root of the problem was identified as an administrative error by the IRB. The IRB has established processes to prevent a recurrence. CASE CLOSED.
146	05	VA Maryland HCS	H	**04/28/2014**	RCO attempted to audit a closed protocol; however, PI and study staff were unable or unresponsive to repeated requests for access to the study files. The Human Protections Administrator reported to the NSOC and RISP without informing the RCO. RISP is following the issues.	Remedial Actions: The protocol was initially an affiliate-only study with the VA facility added later as a recruitment site for Veterans. Shortly after the VA facility approved the study, the PI terminated his VA employment and Veterans were not recruited into the study. All approval documents related to the study are maintained in hardcopy at the R&DC office or accessible electronically through the affiliate IRB e-protocol system (CICERO). RISP case closed. CASE CLOSED.
147	18	New Mexico VA HCS	H	**04/29/2014**	RCO audit found an informed consent waiver for recruitment into a cancer screening study was granted without receipt of a request for the waiver.	Remedial Actions: IRB determined the incident did not constitute serious or continuing noncompliance. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
148	09	Memphis	H	**05/01/2014**	RCO audit found missing informed consents, missing CPRS notes, initiation of study interactions prior to informed consent, lack of expedited review documentation, and lack of study record documentation for this minimal risk study whose aim is to teach cooking techniques to veterans in an effort to improve health and decrease weight.	Remedial Actions: PI cannot use data unless informed consent is obtained; IRB updated expedited review process to ensure that all reviews include a designated reviewer. CASE CLOSED.
149	07	Columbia SC (WJB Dorn)	H	**05/01/2014**	RCO audit of a PTSD biofeedback study found that 26 participants signed an incorrect consent form. This was the second such case for the PI, the first which involved cytokine measurement in PTSD subjects of which 25 also signed the incorrect consent. Enrollment and recruitment are suspended for both.	Remedial Action: Investigator may only serve as a subinvestigator on studies for the next calendar year. At that time the investigator can petition the Board for full PI responsibilities. CASE CLOSED.
150	04	VA Pittsburgh Healthcare System	H	**05/02/2014**	RCO audit found on a study of Auditory Steady State Responses Modulation Rate Effects Across Adult Life Span that PI maintained information on 131 subjects to contact them for future research participation without them signing the HIPAA authorization which would allow PI to contact them for future research project participation.	Remedial Actions: The logbook to be turned over to the ACOS/R&D immediately. The ACOS/R&D will assume responsibility for determining disposition of the logbook; use of contact information from the 131 affected individuals is prohibited; PI may only use IRB approved methods of recruitment for identification of potential subjects, and if PI would like to include additional recruitment procedures, a modification to protocol must be submitted for IRB review and approval. CASE CLOSED.
151	19	VA Eastern Colorado HCS	H	**05/05/2014**	RCO audit found one subject had initialed, but not signed, a HIPAA authorization form for a study exploring the effects of insulin sensitivity, cardiovascular function, and exercise in non-insulin dependent diabetes.	Remedial Actions: Obtain subject signature during the next scheduled study visit (data relevant to this subject will not be used for research purposes unless the signature is obtained), and improve ICD compliance verification procedures during the informed consent process. CASE CLOSED.
152	19	VA Eastern Colorado HCS	H	**05/05/2014**	RCO audit found one subject enrolled without documentation of HIPAA authorization.	Remedial Actions: IRB determinations that the noncompliance was not serious or continuing, that the subject may be contacted and asked to provide valid HIPAA authorization, and that no data obtained from the subject may be used without valid authorization. CASE CLOSED.
153	04	VA Pittsburgh Healthcare System	H	**05/06/2014**	RCO regulatory audit found PI using invalid HIPAA authorizations missing subjects full SSN, signature, or printed name for an aphasia study. The PI also did not have proper signature approval to transfer identifiable information off-site.	Remedial Actions: Data of affected individuals cannot be used without the individuals re-signing the HIPAA authorization; PI must submit amendment to protocol describing the method of collection and transfer of data off-site; PI must obtain appropriate authorizations to transfer and utilize data outside of the protected environments. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
154	04	VA Pittsburgh Healthcare System	H	**05/06/2014**	RCO regulatory audit found PI using invalid HIPAA authorizations missing subjects full SSN signature, or printed name for a second stroke study (in addition to the previously identified study). The PI also did not have proper signature approval to transfer identifiable information off-site.	PI advised that data use for those participants whose HIPAA authorizations are considered invalid is not permitted until appropriate actions are approved; protocol was amended to remove all references to collection of data at off-site locations with justification that this procedure was no longer occurring obviating the need for an Authorization to Transport and Utilize VA Sensitive Information outside Protected Environment. CASE CLOSED.
155	23	Minneapolis VA HCS	H	**05/07/2014**	RCO audits confirmed that ICDs containing noncompliant injury compensation language had been approved by the IRB and used to enroll (at least) 1539 subjects into 73 human subject research studies.	Remedial Actions: ICD template revised. CASE CLOSED.
156	20	VA Puget Sound HCS	H	**05/07/2014**	RCO close-out audit found that one Co-Investigator did not have an approved Scope of Work.	Remedial Actions: Enhanced administrative procedures for ensuring at continuing review that staff has Scopes of Work, and for determining the research engagement of non-responsive staff; and PI's newly approved project to receive increased monitoring by the RCO. CASE CLOSED.
157	16	Houston (Michael DeBakey)	I	**05/12/2014**	NSOC reported that the facility Research Compliance Officer reports that five HIPAA authorizations were missing during a routine audit. It was later clarified that five ICDs were missing (not HIPAA authorizations) and that four of the five had been located.	Remedial Actions: Five Veterans were sent HIPAA notification letters; RCO, Assistant RCO, and the Director of Quality Assurance and Regulatory Affairs provided compliance re-training to all staff responsible for consenting subjects on this research protocol.; PI and staff revised document storage procedures within work area so all approved staff have a central access. CASE CLOSED.
158	16	Houston (Michael DeBakey)	I	**05/13/2014**	NSOC reported that an RCO Audit identified that one ICD is missing. The Research Coordinator believes it might have been placed in the shredding container. No partial or full SSN was on the form.	Remedial Actions: NSOC determined criteria for credit protection or HIPAA notifications were not met. CASE CLOSED.
159	16	Oklahoma City	I	**05/13/2014**	NSOC reported that an RCO audit noted a missing ICF and HIPAA authorization for one research participant. The participant was contacted by a research nurse and remembered being consented for the research, signing the documents and receiving a copy and told the research nurse he normally maintains copies of these documents and will try to locate copies.	Remedial Actions: Participant unable to locate his copies and agrees to be re-consented during his next visit; credit protection services letter mailed to participant. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
160	15	Columbia MO (Harry Truman)	A	**05/14/2014**	RCO audit found a lapse in approval for Subcommittee for Animal Studies (SAS) mouse protocol.	Remedial Actions: Improved communication between subcommittee and PI; modification of the annual review cycle; integration of monthly meeting agendas with the subcommittee calendar. CASE CLOSED.
161	11	Richard L. Roudebush	H	**05/14/2014**	RCO audit of a retrospective chart review of colon cancer therapy sponsored by a foundation; found that one study staff member did not have a scope of practice. However, this individual was qualified to conduct the respective study procedures and was approved by the IRB to participate in this study. The individual is no longer actively participating in the study.	Remedial Actions: The PI is going to conduct periodic reviews of regulatory documents to ensure that all study members have appropriate scopes of practice; the Research Service has adopted a tracking process for scopes of practice to mitigate future occurrences; IRB determined the event was not noncompliance. CASE CLOSED.
162	08	Tampa (James Haley)	H	**05/16/2014**	RCO found a Principal Investigator's failure to obtain HIPAA authorization for two subjects while obtaining informed consent.	Remedial Actions: The remedial actions approved were to inform the subjects of the oversight and to request a signature on the HIPAA authorization during their next study visit. The PO will monitor until both HIPAA authorizations are signed. CASE CLOSED.
163	18	New Mexico VA HCS	H	**05/16/2014**	RCO audit found an informed consent waiver for recruitment into a testosterone study was granted without documented justification and there was no IRB communication regarding IRB required modifications to an amendment.	Implementation of an application form that allows the PI to unambiguously indicate when HIPAA and informed consent waivers are requested for recruitment only; and improved monthly summary reporting of IRB exempt and expedited actions. CASE CLOSED.
164	22	VA Loma Linda Healthcare System	H	**05/19/2014**	RCO audit found 18/18 subjects did not sign the HIPAA authorization. IRB had approved enrollment of 15 subjects but 18 were enrolled. 13 business days elapsed between the Medical Center Director being notified of the apparent serious noncompliance and the initial report to ORO.	Remedial Actions: PI can use collected data; 16 subjects subsequently signed HIPAA authorization; HIPAA waiver obtained for two deceased subjects; PI submitted amendment to IRB to increase enrollment to 18; facility re-worked process for MCD notifications to ORO. CASE CLOSED.
165	22	VA San Diego Healthcare System	H	**05/19/2014**	RCO audit found 18 subjects signed an outdated ICD in cardiovascular study.	Remedial Actions: PI and Research Service staff members have been reminded that investigators must use the most recently approved ICD version. CASE CLOSED.
166	16	Houston (Michael DeBakey)	I	**05/20/2014**	RCO audit found one consent and HIPAA authorization was missing. PHI included the subject's full SSN and full name.	Remedial Actions: Veteran will be offered credit protection services; credit protection letter mailed to subject. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
167	04	Philadelphia	H	**05/20/2014**	RCO ICD Audit of study on managing memory retention and problem solving abilities discovered that scanned informed consent documents for three subjects did not have the IRB approval stamp and were not signed by the IRB Vice Chair.	Remedial Actions: IRB compared unapproved signed ICDs with currently approved ICDs to determine similarities and if ICDs are consistent with each other; PI re-consented the two remaining subjects using the approved, stamped ICD forms; entered in CPRS with note to file. CASE CLOSED.
168	06	Salem	H	**05/20/2014**	RCO closeout audit found that a retrospective chart review study has a co-I from the University who did not have a WOC appointment and no MOU was in place for storing VA de-identified data on an off-site computer	Remedial Actions: The lack of a WOC for the University employee was determined to be serious noncompliance. This study has been closed with the IRB and the University Investigator is not involved with any other VA studies. The IRB has approved a series of corrective and preventative actions including an immediate study personnel review for all active VA studies to confirm required appointments. CASE CLOSED.
169	05	Washington DC	I	**05/20/2014**	RCO audit identified that three original ICDs and HIPAA authorizations are missing for the Veterans Aging Cohort Study and 27 original ICDs and HIPAA authorizations are missing in a PTSD study. The documents had been scanned into CPRS and the PHI consisted of names, full SSNs and dates of birth.	Remedial Actions: The missing forms for both protocols have been found; the PI of one study implemented a plan to prevent the loss of PHI and study documentation in the future, including storing documents in locked cabinets in a locked room, maintaining an inventory of records, and educating study personnel on maintaining consistent files of study documents. CASE CLOSED.
170	08	Tampa (James Haley)	S	**05/21/2014**	RCO Audit found that two staff members were not approved to work on an SRS approved protocol.	Remedial Actions: Protocol is closed; SRS SOPs revised to require amendments for the addition of personnel. CASE CLOSED.
171	23	Minneapolis VA HCS	H	**05/23/2014**	RCO audit found that documentation of informed consent and HIPAA Authorization was not available for approximately 11 study subjects	Oversight of remediation transferred to for-cause onsite review cases opened 04/25/2013. CASE CLOSED.
172	11	VA Ann Arbor Healthcare System	H	**05/23/2014**	RCO audit of a NIH funded, pain study, found that 16/78 subjects were consented with an outdated version of the ICD. It appears the only difference with the outdated version and the current version is the element that lists the number of subjects to be enrolled in the study.	Remedial actions: PI requested to provide an Action Plan or Standard Operating Procedure for preventing the use of outdated consent forms in the future; IRB determined the events did not constitute noncompliance. The IRB current practice is NOT to include a version date on approved consent forms. A plan for remediation will accompany the response to the ORO site visit report. CASE CLOSED.
173	03	Northport	I	**05/29/2014**	Facility reported that an RCO audit discovered that a PI transferred PHI with samples to a collaborator for analysis; per protocol, the PI was only approved to transfer de-identified data. In addition, the facility did not report the incident to the VA-NSOC within the required timeframe.	Remedial Actions; RCO re-educated the PI; PI required to submit protocol amendment and promptly create a DUA; PO to review future data sets prior to transfer to and use at the affiliate. PI required to submit a Memo to Transport VA Sensitive Information to the University. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
174	05	Washington DC	I	**05/29/2014**	RCO audit found research files were destroyed as a result of data being stored on a desktop computer. The PI subsequently indicated that no PHI or Federal records were included in the data that was deleted.	Remedial Actions: A plan has been put in place to prevent deletion of study records in the future that includes establishing a network drive for data storage; the temporary protocol suspension was lifted once the CAP was put into place. CASE CLOSED.
175	07	Columbia SC (Wm. Jennings Bryan Dorn)	H	**05/30/2014**	RCO audit of an eyelid surgery study found that 8 subjects signed an unstamped consent form and did not sign a HIPAA Authorization.	Remedial Actions: 7 of 8 subjects re-consented. The eighth chose to revoke consent and not participate. CASE CLOSED.
176	16	Houston (Michael DeBakey)	H	**06/02/2014**	RCO audit found that 12 participants signed an ICD that was not expired; however, it was not updated with the current amendment version. This greater than minimal risk study investigates the potential association of chronic acid suppressive therapy from proton pump inhibitors and reduced levels of immunologic recovery in HIV-1-infected patients who have experienced Highly Active Antiretroviral Therapy-induced virologic suppression.	Remedial Actions: Study member completed the required human subjects training. CASE CLOSED.
177	18	New Mexico VA HCS	H	**06/02/2014**	RCO audit found consent-related noncompliance in each of the two identified studies.	Remedial actions: Corrective action plan for both Principal Investigators (PIs) includes retraining on Informed Consent Requirements and providing them with a consent checklist tool. CASE CLOSED.
178	16	Central Arkansas (Little Rock)	H	**06/04/2014**	RCO audit found that 2 Veteran subjects who underwent the consent process did not sign a HIPAA Authorization.	Data collected from the 2 subjects in question may not be used and must be surrendered to the RCO's office; PI and study staff must complete education regarding HIPAA authorization requirements. CASE CLOSED.
179	18	Phoenix VA HCS	I	**06/04/2014**	RCO audit found there were inappropriate disclosures of PHI for two research subjects. During the consent process, Subject 1 saw name, last 4 SSN, and date of birth of Subject 2, and Subject 2 possibly seeing the name/signature of Subject 1. No loss of the information in hardcopy since both Veterans declined copies of documents. The completed ICD and HIPAA authorization documents were uploaded into the incorrect subject's CPRS record.	Remedial actions: Health Information Management Service removed erroneous documents from CPRS; credit monitoring was offered to Subject 2; Subject 1 and 2 Subject 2 will be re-consented; PI submitted corrective action plan including a revised before and after informed consent process document verification; IRB approved corrective action plan. CASE CLOSED
180	23	Sioux Falls VA HCS	H	**06/04/2014**	RCO audit found multiple consent-related irregularities (e.g., missing signatures and dates, unauthorized signatures), errors in CPRS notations, and personnel-related noncompliance (e.g., expired training, missing scopes).	Assessment and identification of deficiencies; resolution of deficiencies. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
181	11	VA Ann Arbor Healthcare System	H	**06/04/2014**	RCO audit found that the R&DC was not consistently conducting annual continuing review of IRB exempt protocols. Of 38 exempt protocols reviewed: 14 received an annual continuing review beyond 12 months, 1 may not have received an initial review, 3 may not have had any continuing review, and 15 may not have had all annual continuing reviews performed.	Remedial Actions: The R&DC will conduct continuing reviews of IRB exempt projects that were previously only reviewed by the SRS; the research office identified a gap in documenting these reviews and worked to address it; research office also improved tracking system of IRB exempt protocols; ORO identified similar issue during the R&DCP routine review and will incorporate further remedial actions into that report. CASE CLOSED.
182	12	Hines IL (Edward Hines)	H	**06/05/2014**	RCO ICD audit of study of fluid collection (normally discarded) following cataract surgery found 3 resident physicians, un-authorized as study team members, consenting subjects with a non IRB approved version of the ICD, the subjects not dating the informed consent documents themselves, and not obtaining required multiple HIPAA Authorizations for subjects.	Remedial Actions: The IRB determined this to be continuing non-compliance. Investigator was instructed her that these individuals may not continue to enroll participants until they have been added to the study team, complete required training, and approved by the IRB. Many individuals need to be reconsented and provide new HIPAA Authorization.
183	08	Tampa (James Haley)	H	**06/06/2014**	RCO audit found 13 research subjects consented to the study, using an outdated informed consent document (ICD) version. The PI submitted the reportable event to IRB with a corrective action plan.	Remedial Actions: IRB requested the study team not to pre-print copies of informed consents; only to print from eIRB when needed to ensure current version. CASE CLOSED
184	08	Tamps (James Haley)	H	**06/06/2014**	RCO audit found unauthorized personnel participating in research activities without required scope of practice and personnel obtaining informed consent without prospective designation in writing by the Pl to do so.	Remedial Actions: The staff member was asked to cease all activities until approval is obtained; the IRB approved an amendment adding the study staff member; subjects did not need to be re-consented, a new consent form version was also approved updating study staff. CASE CLOSED.
185	22	VA San Diego Healthcare System	H	**06/06/2014**	RCO audit found 133 cases of ICDs containing photocopied signatures of the person obtaining consent and 5 instances of failure to obtain documentation of HIPAA authorization.	Remedial Action: Additional training for staff. Attempt to obtain HIPAA authorization. Internal audit of consent documents. CASE CLOSED.
186	16	Houston (Michael DeBakey)	H	**06/09/2014**	RCO audit found that one study member did not complete the required human subject protection training. This minimal risk study is aimed at assessing the patterns of testing for vitamin D deficiency and its management at the Houston VA HIV Clinic and compare characteristics of patients grouped according to their vitamin D levels.	Remedial Action: The study staff member completed the required training. CASE CLOSED.
187	20	VA Puget Sound HCS	H	**06/09/2014**	RCO audit found that an outdated ICD had been used to consent 20 subjects into a lung cancer screening study.	Remedial Actions: IRB required implementation of quality assurance procedures. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
188	20	Portland	H	**06/11/2014**	RCO audit of an alcohol use reduction drug study found some study procedures were conducted prior to informed consent.	IRB determined noncompliance was neither serious not continuing. CASE CLOSED.
189	10	Columbus (Chalmers Wylie)	H	**06/12/2014**	RCO ICD audit found four ICDs were signed after their expiration date. The most recent IRB-approved ICD had no changes from the expired version.	Required actions: RCO provided education to the PI on expiration dates on ICDs and ensured that the PI had the most recent IRB-approved ICDs for future enrollments the 4 subjects will be re-consented using correct ICDs. CASE CLOSED.
190	08	VA Caribbean HCS (San Juan)	H	**06/13/2014**	RCO found two informed consent documents (ICDs) signed by a legally authorized representative (LAR) when the protocol did not have IRB approval to use a LAR. The RCO found two HIPAA authorizations signed by the subject's family members without verification from the PI that they met the requirements of a personal representative in HIPAA and the Privacy Act of 1974.	Remedial Actions: The PI must re-consent the subjects that are competent to sign. PI re-consented subjects, corrected the errors in the Master List, and completed all required actions. The IRB lifted the study suspension for enrollment. CASE CLOSED.
191	08	VA Caribbean HCS (San Juan)	H	**06/13/2014**	RCO found discrepancies in the level of risk of the study. The PI's records were marked as more than minimal risk while MIRB records were marked as minimal risk. The RCO was unable to ascertain if the documentation for WOC appointment was current, training for team members or even if the list of research team member was current, accurate and complete. The inclusion/exclusion criteria were not correctly applied for two subjects.	Remedial Actions: The study was suspended to further enrollment until the audit findings are corrected; correct risk level in the IRB database; correct the delegated responsibilities form for site personnel; remove staff no longer active in the study; PI to provide a resources report for the study; clarify approved versions of the CITI training; PI to submit protocol amendment and HIPAA authorization if desiring to re-open enrollment. All RAs completed, suspension lifted. CASE CLOSED.
192	19	VA Eastern Colorado HCS	H	**06/13/2014**	(1) The PI allowed individuals who did not have VA appointments to conduct VA research. (2) The enrollment of non-Veterans was not appropriately justified and documented. (3) Investigational drug was delivered to a non-VA pharmacy (after apparent receipt by the study team, with subsequent dispensing by a non-VA pharmacist), without reference to the presumably required Letter of Understanding (LOU). (4) The PI appeared to lack a Chief Research and Development Officer (CRADO) waiver for the exclusive off-site conduct of the ORD funded study.	(1) It was clarified that two of the five study staff had all required appointments, credentialing and scopes of practice. Of the remaining three staff, one staff member lacked a VA appointment, one staff member lacked VA privileges, and one staff member lacked a VA appointment, VA privileges, and a research scope of practice. (2) Explain, justify and document approval for the enrollment of non-Veteran. (3) The current practice in the VAECHCS Research Pharmacy is to require a LOU for any non-VA receipt/dispensing of investigational drugs associated with VA-funded research. (4) Request a secure a CRADO off-site waiver. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
193	08	Tampa (James Haley)	H	**06/17/2014**	RCO audit found no original or copies of signed informed consent documents (ICD) and HIPAA authorizations for two subjects. In addition, the RCO found an outdated version of the ICD used for 28 subjects.	Remedial Actions: To ensure current versions are utilized, Research Assistant to confirm that the study team will not pre-print a stack of ICDs, but instead will print each ICD when required. CASE CLOSED.
194	18	New Mexico VA HCS	H	**06/17/2014**	RCO reported apparent serious noncompliance because the IRB had not reviewed 20 audit reports of noncompliance that was neither serious nor continuing.	Remedial Actions: Improved IRB submission and IRB review processes to prevent further delays reviewing RCO audit reports. CASE CLOSED.
195	22	VA San Diego Healthcare System	H	**06/19/2014**	RCO audit found that HIPAA authorization was not obtained from one subject and 15 subjects had signed outdated ICDs for enrollment into a study of the effect of continuous positive airway pressure therapy for obstructive sleep apnea on PTSD Symptoms.	Remedial Actions: PI will ensure most current ICD is in enrollment materials. Data from subject with missing HIPAA will not be used. CASE CLOSED.
196	05	Washington DC	H	**06/19/2014**	RCO audit found several missing documents from PI regulatory binders and AEs were reported without dates of the event or of IRB review on the forms. In addition, some documents were missing from IRB files.	Remedial Actions: IRB Administrator and chair reviewed regulatory requirements with the PI and provided education on maintaining complete files; RCO to conduct monthly audits of the three studies for the next six months. Follow-up audits showed all required documentation in study binders, training up to date for all study staff. CASE CLOSED.
197	09	Memphis	H	**06/22/2014**	RCO ICD audit found the HIPAA authorization form for this cardiac stent study did not include all required information. Errors noted on 123 of 123 HIPAA forms audited.	Remedial Actions: Further review determined that the HIPAA authorization form complied with HIPAA and VA requirements. CASE CLOSED.
198	09	Memphis	H	**06/22/2014**	RCO ICD audit found HIPAA form lacked required elements and enrollment of a subject by personnel not approved for this medical intensive care community acquired pneumonia study. Errors noted on 12 of 12 forms audited.	Education of study staff regarding appropriate scopes of practice. Further review determined that the HIPAA authorization form complied with HIPAA and VA requirements. CASE CLOSED.
199	04	Philadelphia	H	**06/22/2014**	RCO Triennial audit of study to analyzed blood or tissue for Hepatocellular carcinoma cells (HCC) initially reviewed as an expedited minimal risk study in 2007, was changed to greater than minimal risk in 2010 following IRB determinations on increased blood draws, but continued to receive expedited, rather than full board review in 2011.	Remedial Actions: Programmatic issues and all submission material at the time of expedited CR reviewed by convened IRB; determined not to adversely impact subjects or conduct of study; not serious nor continuing noncompliance. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
200	04	Philadelphia	H	**06/22/2014**	RCO Triennial Audit of retrospective study on Genetic and Environmental Factors in Prostate Cancer Etiology and Severity discovered that PI did not have WOC status updated by completing all required paperwork.	Remedial Actions: IRB closed study; PI contacted upon return from travel and will not be renewing WOC status and will not be completing training requirements for VA; study data remains within the VA Firewall. CASE CLOSED.
201	11	VA Ann Arbor Healthcare System	H	**06/22/2014**	RCO ICD audit found errors on the signature date and social security boxes of executed ICDs and HIPAA forms for this data review study of National Guard Veterans needing mental health care. Errors were noted on 54 of the 66 ICDs audited.	Remedial Actions: PI developed an action plan to prevent future occurrences of these issues, including the use of an ICD checklist; study team to fix dates on ICDs and document the change; IRB determined the events did not constitute noncompliance. CASE CLOSED.
202	01	VA Boston Healthcare System	H	**06/23/2014**	RCO audit found that PI used an ICD without the IRB approval stamp for 14 participants in a study of cognitive impairment among veterans in anticoagulation clinic. In addition, errors were found in the subject master log that made it impossible to confirm the number of study participants.	Remedial Actions: Education of PI and study staff. SOP developed to clarify research component of pharmacy residency program and how these students are supervised and mentored in their research work.
203	06	Durham	H	**06/24/2014**	RCO routine audit of cardiac drug study found two SAE's not reported to the IRB on time.	IRB determined occurrence did not constitute noncompliance. CASE CLOSED.
204	11	VA Ann Arbor Healthcare System	H	**06/24/2014**	RCO audit found the Investigator's Research Record was disorganized and missing required documents.	Remedial Actions: PI corrected the deficiencies and submitted the regulatory binder to the RCO who issued a revised regulatory audit stating the PI had satisfied all correction action requests. PI confirmed that all other active research projects have appropriate Regulatory Binder available for review. CASE CLOSED.
205	12	Hines IL (Edward Hines)	H	**06/26/2014**	RCO ICD Audit of study on computerized job interview skill training discovered PI did not obtain HIPAA authorizations and VA Form 3203 voice and/or photo consents for 10 veteran subjects.	Remedial Actions: IRB required PI to obtain signed VA Form 3203 and HIPAA authorizations for all subjects. CASE CLOSED.
206	08	Tampa (James Haley)	H	**06/26/2014**	Facility reported that a routine RCO audit of an ACE Inhibitor drug study found that 3 SAE's were not reported within the prescribed timeframe	Remedial Actions: The IRB determined this issue to be serious noncompliance and accepted the remedial action plan submitted by the PI. The PI indicated that CPRS will be monitored more closely for study subjects' hospitalizations CASE CLOSED.
207	21	San Francisco	H	**06/26/2014**	RCO audit found that the study was initiated without identification of the facility as a performance site; R&DC approval; or ACOS/R approval.	Remedial Actions: Research program improvements to the project processing system; improved documentation of collaborative research distinctions; and development of collaborative research policies to guide research staff. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
208	20	Portland	H	**7/1/2014**	RCO audit found that 6 subjects had been enrolled by an individual who was not authorized to work on the study in question.	Remedial Actions: The IRB requested the PI to review all scope of work documents for each of his approved protocols and report back whether all personnel have an approved scope of work consistent with their assigned duties. CASE CLOSED.
209	16	Houston (Michael DeBakey)	H	**7/3/2014**	RCO audit found that none of the 95 subjects enrolled in the study signed the required HIPAA authorization in a study to identify the reasons that Veterans leave the HUD-VASH (VA Supportive Housing) program prematurely.	(1) Authorization must be obtained and/or IRB must waive requirement per HIPAA privacy rule. CASE CLOSED.
210	22	VA San Diego	H	**7/3/2014**	RCO audit found that (IRB required) CPRS entries were lacking for the 11 enrolled study subjects.	CPRS entries completed for the one remaining active subject. IRB determinations of noncompliance (not serious or continuing) and data use permitted. CASE CLOSED.
211	22	VA San Diego	H	**7/3/2014**	RCO audit found 24 subjects had been enrolled using ICDs without the IRB stamp of approval; 45 additional subjects had been enrolled using ICDs that lacked the IRB stamp on the first 3 pages; and one subject had been enrolled without HIPAA authorization.	Remedial Actions: The PI will attempt to re-consent (with RCO monitoring) the subjects that signed outdated ICDs; the data obtained from these subjects will not be used without the proper consent; and the RCO trains the staff on the importance of using IRB approved consent documents. CASE CLOSED.
212	05	Washington DC	H	**7/7/2014**	RCO regulatory audit found PI had no documentation of having completed mandatory research compliance training.	IRB determined not serious or continuing, took no corrective actions. CASE CLOSED.
213	21	San Francisco	H	**7/8/2014**	RCO audit found that informed consent was obtained from one participant (out of three) by unauthorized study personnel.	Remedial Actions: Withdrawing the subject from the study, and adding the individual who obtained the ICD to the study staff. CASE CLOSED.
214	19	VA Eastern Colorado HCS	H	**7/9/2014**	RCO audit found one individual had not signed and dated the HIPAA authorization.	Remedial Actions: IRB required that the subject sign and date the VA HIPAA form, without which, the subject's data cannot be used or disclosed. The Privacy Officer recommended the research team reevaluate their processes and retrain staff as necessary to ensure consent and HIPAA forms are filled out correctly before a patient is entered into the study. CASE CLOSED.
215	12	Hines IL (Edward Hines)	H	**7/10/2014**	RCO audit found 29 missing HIPAA authorizations on a study surveying Veterans experiences on communal dining for Veterans with spinal cord injuries.	Remedial Actions: Education and re-contact the 29 participants for HIPAA authorizations.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
216	16	Houston (Michael DeBakey)	H	**7/14/2014**	RCO audit found that 23 participants in a PTSD study signed expired consent forms. Study staff re-consented all subjects; however, 5 subjects were consented on an incorrect version of an ICD, which was also back dated. The audit also revealed that 4 study participants signed an ICD that was not expired; however, it did not have the current amendment version. In addition, one ICD was not signed by participant or person obtaining consent.	(1) Ensure legally effective informed consent for all subjects. (2) IRB required PI to place a note-to-file in all subject's records.
217	16	Houston (Michael DeBakey)	H	**7/14/2014**	RCO audit found two participants in a leukemia study did not sign the required separate written HIPAA authorization form.	Authorization must be obtained and/or IRB must waive requirement per HIPAA privacy rule.
218	16	Houston (Michael DeBakey)	H	**7/14/2014**	RCO audit found that 11 of the study participants in a treatment trial for advanced liver cancer did not sign a separate written HIPAA authorization form. In addition, one study participant was consented prior to written notification from the ACOS/R that research may begin.	(1) IRB must determine remedial action. (2) Research Service staff re-educated study staff on the importance of waiting for R&DC approval and ACOS/R written notification prior to initiating research. (3) Authorization must be obtained and/or IRB must waive requirement per HIPAA privacy rule. CASE CLOSED.
219	16	Houston (Michael DeBakey)	H	**7/15/2014**	RCO audit found two study participants in an advanced lung cancer clinical trial did not sign a separate written HIPAA authorization form. One study participant was consented prior to written notification from the ACOS/R that research may begin.	(1) Ensure legally effective informed consent for all subjects. (2) Ensure that research does not begin prior to ACOS/R notification. CASE CLOSED.
220	07	Birmingham	H	**7/17/2014**	Facility reported that an RCO consent audit of a cancer biomarker study discovered that 5 of 5 subjects signed an informed consent however a signed HIPAA Authorization for the five could not be located.	Remedial actions: All five have been located; consent observation and audit uncovered no additional issues. CASE CLOSED.
221	11	Indianapolis (Richard Roudebush)	H	**7/17/2014**	RCO audit of a focus group study on substance abuse intervention found that 12/12 subjects did not sign a HIPAA authorization, and that 12/12 subjects signed an ICD that did not have the IRB approval stamp. It was subsequently determined the study did not use or disclose PHI so a HIPAA authorization was not needed.	Remedial Actions: Study team was provided education on the importance of using ICDs with the approval stamp; PI to submit protocol amendment removing the HIPAA authorization request. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
222	15	Columbia MO (Harry Truman)	A	**7/17/2014**	RCO audit found a lapse in annual approval for a study involving mice.	Remedial Actions: Revise annual review mechanism; review and revise SOP regarding use of designated member review; direct communication with PI regarding expiration dates for protocol approvals. CASE CLOSED.
223	16	Jackson MS (Sonny Montgomery)	H	**7/17/2014**	RCO audit of a teleconference hypertension education class effectiveness study found 1 HIPAA Authorization was not signed by the subject and the PI; ICDs for all 18 subjects were missing the date of IRB approval; and miscellaneous consent irregularities within all 18 ICDs (e.g., missing subject's name, date, and subject's initials on some pages, also SSN on some pages). PI has submitted closure documents for this study.	PI is required to complete informed consent training with the RCO, and the PI will be assigned to work closely with an experienced investigator to learn consenting techniques and to be further educated. CASE CLOSED.
224	08	Miami VA	S	**7/21/2014**	RCO audit found lapse in safety approval.	Remedial Actions: Audit all safety studies requiring 2012 annual reviews. CASE CLOSED.
225	01	White River Junction	H	**7/22/2014**	RCO audit of polyp prevention study identified that an unauthorized person obtained consent from one participant for the follow up portion of the study. Although the appropriate VA consent form was used, the individual was not on the VA protocol, only on the academic affiliate's protocol for this study.	Education provided to PI and study staff; regulatory differences between academic affiliate and VA were reviewed; IRB at the academic affiliate determined that the event did not constitute serious or continuing non-compliance. CASE CLOSED.
226	08	VA Caribbean HCS (San Juan)	H	**7/22/2014**	RCO audit found that this study on chronic diabetic foot ulcers does not have IRB approval to use a Legally Authorized Representative (LAR) to sign the ICD on behalf of the subject. The RCO found one ICD and HIPAA with a LAR signature.	Remedial Actions: IRB determined this issue to be serious noncompliance and the data must not be used. The research team was re-educated regarding obtaining proper consent for research. Training was requested by the principal investigator and provided by the RCO. CASE CLOSED.
227	08	VA Caribbean	H	**7/22/2014**	RCO audit found programmatic noncompliance with following the IRB SOP.	Remedial Actions: The IRB determined this issue to be a serious programmatic noncompliance. The IRB remedial actions were to make changes to the reviewers' checklist and remind the IRB members not to approve studies without SRS committee approval. The IRB committee was trained on the use of the new checklist through an Education Capsule. CASE CLOSED.
228	16	Houston (Michael DeBakey)	I	**7/22/2014**	RCO audit found two research consent forms containing full SSN for the same Veteran subject were missing. The subject did not meet criteria for participating in the study; therefore the subject will not be contacted to sign another consent.	Remedial Actions: The Veteran will receive a letter offering credit protection services; credit monitoring letter mailed to one subject; incident documented in subject's medical record; study staff re-education completed. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
229	05	Washington DC	H	**7/23/2014**	RCO regulatory audit of an HIV dose-delivery (prepared pillboxes) study found no documentation of research-specific training or a scope of practice for the study coordinator.	Scope of practice identified. CASE CLOSED.
230	21	VA Northern California HCS	H	**7/29/2014**	RCO audit found that one subject in an ultramarathon visual disturbance study initialed each page, but did not sign the ICD. The IRB was unable to convene a meeting the following month to review the audit report due to not having an unaffiliated member.	An unaffiliated member was appointed to the IRB and the RCO audit report was reviewed at the next convened meeting; no specific corrective actions were required of the PI due to PI's lack of previous compliance-related issues. CASE CLOSED.
231	01	VA Boston	H	**7/30/2014**	RCO audit of a spinal cord injured study found that the PI had not adhered to IRB approved protocol procedures. Three participants were entered into the study prior to VA IRB approval for recruitment at VA. One participant was entered into the protocol despite having met exclusionary criteria.	PI and study team education; PI must provide lists of SAEs and protocol deviations to the IRB.
232	05	Washington DC	H	**7/30/2014**	RCO regulatory audit found three co-investigators had no scopes of practice and two had expired CITI training on a retrospective review of transnasal upper endoscopy in veterans.	IRB determined non-serious, not continuing noncompliance; no corrective actions taken. CASE CLOSED.
233	08	Tampa (James Haley)	I	**7/30/2014**	RCO audit found that signed informed consent documents and HIPAA authorizations for two participants in a sleep study are missing. Case linked with SRO 673-0010-H.	PI cannot use the data for the two subjects for whom the Informed Consent and HIPAA could not be located. The PI confirmed that this data will not be used. The corrective action plan to print current informed consent and HIPAA documents when needed instead of stockpiling them was accepted. Two Veterans will receive offers of credit monitoring. CASE CLOSED.
234	16	Houston (Michael DeBakey)	H	**7/30/2014**	RCO audit found that 35 subjects (out of 118) in a tissue resource study signed an ICD that was not expired; however, it did not contain the correct amendment version. The only change to the amended ICD was the addition of a co-investigator.	(1) IRB required the PI to locate and destroy all copies of the outdated ICDs. (2) Study staff must be re-educated by the research service. CASE CLOSED.
235	16	Houston (Michael DeBakey)	H	**7/30/2014**	RCO audit found that 2 out of 27 subjects in an alcohol dependence treatment study did not sign the required separate HIPAA authorization.	Remedial Actions. Pending.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
236	16	Houston (Michael DeBakey)	H	**7/30/2014**	(1) 24 subjects signed an old version of the ICD. The only change to the amended ICD was to add that a flyer would be used during VA Research Week. (2) Study staff re-consented a subject, but backdated the ICD to the original consent date.	(1) The IRB did not require re-consenting, because they determined there were no significant differences in the language in either version of the consent documents with regard to the information provided to subjects. (2) The IRB required the PI to place a note-to-file in subjects' records. CASE CLOSED.
237	16	Houston (Michael DeBakey)	H	**7/30/2014**	RCO audit found that 12 subjects out of 55 in a cocaine dependence study signed an old amendment version of the ICD. The content of the ICD was changed during the amendment.	Remedial Actions: The 12 subjects will be re-consented on the correct version of the ICD.
238	11	VA Ann Arbor	H	**7/31/2014**	RCO audit found a molecular marker in gastroesophageal cancer study that did not have the designated 6 month IRB review.	Remedial Actions: Investigator will complete paperwork for continuing review at the August IRB meeting; IRB Coordinators will review Primary Reviewer checklist notating proper risk level and interval between reviews; risk level and review interval will be carefully documented in the minutes; IRB Coordinators will contact software manager regarding default to 12 month review. CASE CLOSED.
239	16	Oklahoma City	H	**7/31/2014**	RCO found for one subject, a non-IRB approved version of the ICD used to obtain consent, the PI failed to obtain a signed HIPAA Authorization, the consent progress note in the participant's CPRS was missing required VA language, and the IRB-approved ICD and HIPAA authorization contained minor deficiencies.	Remedial Actions: The PI and study nurse provided education to the sub-investigators on the correct ICD and HIPAA paperwork, and the correct consenting and documenting process. The PI obtained a signed IRB-approved ICD and HIPAA authorization from the relevant participant. PI submitted a protocol violation/deviation to the IRB; amended the ICD and HIPAA authorization with recommended revisions; and obtained required approvals. CASE CLOSED.
240	04	Philadelphia	H	**8/5/2014**	RCO Triennial Audit found that a respiratory technician who was a member of the research team for a study on remote ambulatory management of veterans with sleep apnea did not have certification of CITI training or a research scope of practice/functional statement.	PI submitted updated scope of practice; respiratory tech functioning within scope of usual clinical practice and PI clarified he is not engaged in informed consent of participants and training verified; records control schedule guidance and language reviewed with PI. CASE CLOSED.
241	17	VA North Texas HCS (Dallas)	S	**8/5/2014**	RCO audit found lapsed annual approvals for eight safety protocols.	Remedial Actions: Training of SRS administrator; inclusion of impending protocol expirations on SRS agenda until review by subcommittee; enhanced communications with PIs including the use of alternate emails addresses as needed; maintenance of accurate protocol database. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
242	04	Coatesville	H	**8/12/2014**	RCO audit of study using Personality Assessment Inventory to predict treatment process variables for Veterans found investigators did not maintain regulatory binder documentation including copies of submissions for study modifications, continuing review documents, approval letters, waivers of informed consent and waiver of HIPAA Authorization documents.	PI educated regarding documentation requirements for regulatory binder; copies of missing documentation retrieved and filed, verified by audit. CASE CLOSED.
243	06	Hampton	H	**8/12/2014**	RCO audit of the MVP Study (CSPG002) discovered that the wife of an enrollee signed his HIPAA Authorization, while he signed the informed consent. The facility confirmed that the wife does not have power-of-attorney or is his Personal Representative.	No remedial actions required as Virginia law permits this practice. CASE CLOSED.
244	19	VA Salt Lake City HCS	H	**8/12/2014**	RCO audit found 8 participants in a cognitive support for shared decision making study with signed Informed Consent Documents, but no HIPAA authorizations.	The IRB approved the Principal Investigator's corrective action plan. The research staff is in the process of obtaining signed HIPAA authorization forms; data will not be used for subjects whose signatures are not obtained. The IRB and the R&DC determined that the non-compliance did not represent serious or continuing non-compliance. CASE CLOSED.
245	15	Kansas City	H	**8/14/2014**	RCO ICD audit found that the consent signed by one subject was on an incorrect ICD (consent for a different study). Study Coordinator mistakenly provided the subject an ICD for a study going through the IRB approval process but did not have IRB approval. Subject had provided verbal consent to the Study coordinator prior to signing the mistaken ICD. During follow-up the IRB Chair also found the subject also signed an incorrect HIPAA Authorization. PO was notified.	Subject signed the correct ICD; PI to reduce number of study staff so training can be better managed; study team received training on ICD process; study team developed process to easily identify ICDs for the appropriate study. CASE CLOSED.
246	20	Portland	I	**8/14/2014**	A local VA Research study was found to have disclosed data to a non-VA statistician for analysis (5000 Veterans). The data had been obtained from the VA Corporate Data Warehouse under an approved waiver of informed consent or HIPAA Authorization. The IRB had approved analysis of coded de-identified data; PHI was included (dates of birth and other subject-specific dates) but contained no names or contact information.	(1) The affiliate deleted all VA data from email and network folders except emails left on the server after 90 days going into an affiliate permanent archive, the IRB approved the request to add a VA research data analyst to the study, data will no longer be sent to the affiliate university bio-statistician, the ISO provided education on sharing identifiable data. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
247	08	Tampa (James Haley)	H	**8/18/2014**	RCO audit found that a sensory processing disorder in PTSD/TBI study HIPAA authorization did not include an expiration date as required. The PI clarified that 8 of 9 enrolled subjects signed the invalid version; however, no identifiable information had been disclosed.	The IRB made a determination of non-serious, non-continuing noncompliance and that the PI could use the data previously collected. No further action was required by the IRB. The R&DC reviewed the IRB's determination and unanimously approved the IRB's determinations and determined no additional reporting was required. The R&DC also reported that the PI decided to close the study and that the IRB approved closure. CASE CLOSED.
248	05	Washington DC	H	**8/20/2014**	RCO audit found an informed consent informant was unauthorized to obtain consent on an exercise, nutrition and stress management intervention study for Veterans with type 2 diabetes; IRB to review informant's functional statement.	IRB determined serious noncompliance; PI submitted a revised investigator roster and scope for sub investigator. IO sent letter to OHRP; acknowledged and closed. CASE CLOSED.
249	06	Durham	H	**8/20/2014**	RCO audit of a recruitment study found that an unauthorized person entered the consent note in CPRS.	Investigator chose to close the study rather than provide IRB with a corrective action plan. As a consequence, the IRB has stipulated that no new studies may be opened by this investigator until a corrective & preventative action plan for future studies has been approved. CASE CLOSED.
250	16	Southeast Louisiana Veterans HCS (New Orleans)	H	**8/21/2014**	RCO audit found that an ICD for a Vitamin D and prostate cancer study was signed by someone else other than the subject.	RCO informed the study staff that only the subject's legally authorized representative were allowed to sign consent documents for the subject and noted that the data for this subject cannot be used in the study. The PI acknowledged the non-compliance and agreed not to use the subject's data in the research. CASE CLOSED.
251	11	Indianapolis (Richard Roudebush)	I	**8/27/2014**	RCO audit found that a signed original ICD containing full name and full SSN is missing for one participant who is now deceased.	Current PI will store all research consents in a locked secure cabinet at the VA; because this subject is deceased, the VA-NSOC approved the PO's appeal for a NOK notification rather than an offer of credit monitoring services. CASE CLOSED.
252	21	San Francisco	H	**8/27/2014**	RCO audit found use of incorrect ICD and failure of person obtaining consent to sign and date the ICDs in a study of simulated emergency removal of jaw wires.	Investigator to initiate training for his study staff regarding VHA regulatory requirements. CASE CLOSED.
253	21	San Francisco	H	**8/27/2014**	RCO audit found multiple consent-related deficiencies in a magnetic resonance scanner pulse sequencing study consisting of use of an outdated consent (18), person obtaining consent did not date the ICD (4) and use of an incorrect ICD version (2).	All issues addressed and resolved (refresher training, new procedures to ensure use of most current ICD), IRB determination of neither serious nor continuing. No further action required. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
254	09	Louisville (Robley Rex)	H	**8/28/2014**	RCO audit found one participant was enrolled using the incorrect informed consent document in this CSP trial evaluating the use of methylprednisolone in the treatment of severe, community-acquired pneumonia.	Participant will be re-consented. CASE CLOSED.
255	22	VA Greater Los Angeles	H	**9/3/2014**	RCO audit found one instance of unapproved enrollment of a subject with a conservator.	(1) The PI acknowledged the enrollment error with 3 subjects, and proposed a protocol modification applicable to all participation of subjects with conservators. CASE CLOSED.
256	22	VA Greater Los Angeles	H	**9/3/2014**	RCO found that 10 subjects had been enrolled by personnel not authorized to obtain informed consent.	(1) PI provided the CIRB a report verifying that all study personnel have met local VA facility requirements and have completed applicable training governing human subject research. CASE CLOSED.
257	17	South Texas Veterans HCS (San Antonio)	H	**9/4/2014**	RCO found that the ICD and HIPAA authorization had been combined into a single form for this study (i.e., instead of separate documents as required by VA).	Remedial Actions: Submitting updated separate ICD and HIPAA forms. CASE CLOSED.
258	12	Hines IL (Edward Hines)	H	**9/5/2014**	RCO audit on a sight imaging study identified noncompliance of missing information on consent forms, deviations from study procedures, and data not being stored in the research drive.	Remedial Actions: Stop enrolling new subjects until required actions are completed: Provide a process plan to ensure consenting is done correctly; move all data into a research drive folder; update all forms and protocol (if appropriate) to accurately reflect current study procedures; clarify in the consent which procedures are research vs. standard of care; and resubmit consent copies to Medical Records for scanning into CPRS.
259	16	Houston (Michael DeBakey)	H	**9/8/2014**	RCO audit found RCO that a study was initiated prior to written notification from ACOS/R. Eight out of 9 subjects were consented prior to the notification, and three of the 8 had study procedures done during this time.	1) R&DC allowed use of the data for the 3 subjects who received procedures prior to ACOS/R written notification. (2) The IRB required the research service to re-educate study staff on when research can be initiated. CASE CLOSED.
260	18	Southern Arizona HCS (Tucson)	A	**9/8/2014**	RCO audit found initiation of animal research without ACOS/R notification and implementation of significant changes (change in species from canine to swine) without IACUC approval.	New IACUC staff to manage protocol tracking; review and revision of local policies to ensure proper notifications, subcommittee review and documentation. CASE CLOSED.
261	10	Cleveland (Louis Stokes)	H	**9/10/2014**	RCO regulatory audit found Initial Conflicts of Interest, VA Form 10-1313-14, missing for two Co-Investigators.	Pending.
262	22	VA San Diego	H	**9/24/2014**	RCO observation of informed consent process found that subjects were not always provided copies of the signed ICD and HIPAA authorization.	(1) The study team will explain to Veterans the reasons for providing the documents, and whenever necessary, enter a research note that the documents were offered and refused. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
263	01	VA Central Western Mass	H	**9/30/2014**	RCO audit found that the local approval letter to the PI, notifying the PI that research can be initiated was missing from the file of this CSP/CIRB approved study.	CIRB determined that this was not serious or continuing non-compliance; facility developed SOP to ensure that COS signs approval documents when the ACOS is also the PI. CASE CLOSED.
264	23	Iowa City	H	**10/1/2014**	RCO audit found that all four subjects enrolled lacked an IRB approval date stamp, and one lacked the subject's signature and date signed.	The study team to re-contact subjects for the purposes of seeking compliant informed consent documentation. CASE CLOSED.
265	23	Minneapolis	H	**10/1/2014**	(1) Apparent R&DC approval of research in advance of CIRB approval.	(1) CIRB determination regarding noncompliance and clarification of local approval process. CASE CLOSED.
266	17	North Texas (Dallas)	H	**10/2/2014**	(1) A HIPAA authorization form, used with 117 subjects, did not inform of all potential disclosures. (2) 64 instances of incomplete documentation of either inclusion or exclusion criteria. (3) 1 ineligible subject enrolled; and 3 non-Veterans without authorization.	(1) The PO determined that unauthorized disclosures had not occurred. (2) Staff training concerning recordkeeping requirements as they pertain to maintenance of study data and the regulatory binder. (3) Implement improved team communication protocol. CASE CLOSED.
267	16	Houston (DeBakey)	H	**10/16/2014**	RCO audit found that all 35 subjects were consented using a version of the consent form that, although identical in content, was not the most recent IRB approved version of the ICD.	Remedial actions. PI placed a note-to-file in subjects' records.
268	22	Long Beach	H	**10/16/2014**	RCO pre-audit found that unauthorized surrogate consent was used for enrollment of one study subject.	IRB determinations: the noncompliance was not serious or continuing; PI corrective actions (data from subject in question will not be used, staff will receive refresher training) are sufficient. CASE CLOSED.
269	09	Louisville (Rex)	H	**10/17/2014**	(1) A person who was not approved as a member of the research team consented 4 subjects for 2 separate studies.	(1) PI added study coordinator to the two protocols with an amendment to the IRB. This item was approved by the IRB. CASE CLOSED.
270	08	Miami	H	**10/28/2014**	(1) During an informed consent audit, the RCO found a person obtaining consent that was not approved by the IRB and R&DC.	(1) The IRB informed the principal investigator (PI) to assure that the individual in question does not consent other research subjects prospects. The IRB determined this issue to be serious noncompliance. The PI sent to the IRB remedial actions to include re-consenting of the subject in question and to submit an amendment to the IRB adding this person to the study staff. The IRB accepted the remedial actions submitted by the PI. The R&DC with the determinations of the IRB with no additional actions. CASE CLOSED.
271	08	Miami	H	**10/28/2014**	(1) The RCO found a sub-investigator actively working on a study without a Research Scope of Practice. He was added to the project via amendment and approved by the CIRB on April 17, 2014.	(1) Scope completed; Internal checklist developed to track these activities. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
272	16	Houston (DeBakey)	H	**10/30/2014**	RCO audit found that that one study member had not completed the initial 'VA Human Subjects Protection and Good Clinical Practices' training course prior to participating in human subjects research.	Individual completed training. CASE CLOSED.
273	04	Pittsburgh	H	**10/31/2014**	(1) Conduct of research activity by one or more members of research team without the required credentialing, privileging, or scopes of practice, or engaging in activities outside the approved scope of practice.	(1) IRB2 determined that serious non-compliance had occurred. The IRB2 took into consideration that the study team did not adhere to the data security and privacy procedures outlined in the IRB approved protocol when making its determination. IRB2 determined the data can be used in accordance with the protocol since the use of the data was described in the protocol and this individual has access to the data as part of her clinical work, so the privacy of the patients was not violated. CASE CLOSED.
274	09	Memphis	H	**10/31/2014**	RCO audit found that PI and research staff used invalid ICD and HIPAAs for 67 of 71 subjects, noting various discrepancies of documentation related to completion of the ICD and HIPAA forms as well as missing required elements from the study's IRB-approved ICD and HIPAA templates.	The IRB determined that the findings did represent serious and continuing noncompliance.
275	21	Palo Alto	H	**11/7/2014**	(1) HIPAA authorization was not requested from 39 enrolled study subjects.	(1) HIPAA authorization must be obtained in order to use data collected. HIPAA has been obtained from subjects enrolled. CASE CLOSED.
276	18	New Mexico (Albuquerque)	A	**11/14/2014**	(1) Lapse in annual protocol review during which research was conducted.	(1) Conduct annual review. CASE CLOSED.
277	08	Bay Pines	S	**11/17/2014**	(1) Failure to obtain SRS approval for protocol involving collection, packaging, and shipping of samples.	(1) Investigators and Coordinators will take refresher training on document submission to the SRS. CASE CLOSED.
278	15	Columbia MO (Truman)	A	**11/17/2014**	(1) Lapse in IACUC annual review.	(1) Revision of IACUC annual review procedures; Communication with investigators.
279	21	Palo Alto	H	**11/17/2014**	(1) One study subject was enrolled under the supervision of a clinical student who had not completed all required VA training, was not registered with the Research Administration, and had not been specifically authorized to participate in the study in question.	(1) Review, assessment and corrective action by the IRB. (2) Privacy officer provided training to the PI. CASE CLOSED.
280	21	Palo Alto	H	**11/17/2014**	(1) Enrollment of 12 study subjects using an inappropriate HIPAA authorization; i.e., a form that described a different project.	(1) Review, assessment, and recommendation of actions by the IRB and the PO, regarding the identified noncompliance. CASE CLOSED.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
281	11	Indianapolis (Roudebush)	H	**11/19/2014**	(1) Two participants signed expired ICDs. (2) One subject was consented by an individual who was yet to be added as key personnel on the study.	IRB determined the report of noncompliance to be neither serious nor continuing. The IRB recommended the study team consider additional IRB training in an attempt to preclude technical issues leading to noncompliance. The R&DC agreed with the IRB determination. The RCO will follow up with the study on the additional training. CASE CLOSED.
282	17	North Texas (Dallas)	H	**11/25/2014**	(1) A research participant enrolled on November 12, 2014, signed and dated a HIPAA authorization but not the consent form; the individual obtaining consent also did not sign or date the consent form.	Pending.
283	04	Philadelphia	H	**12/3/2014**	(1) Twenty-two subjects missing signed HIPAA authorizations in a study surveying OIF/OEF veterans with and without PTSD. Study team thought a waiver of HIPAA for recruitment only applied to the full study.	(1) Study team requesting subjects sign HIPAA forms.
284	10	Cincinnati	H	**12/4/2014**	(1) WOC study staff obtained informed consent and entered study notes into CPRS without being approved by the IRB to conduct study procedures. (2) The PI did not provide study documents to the research pharmacy as required, including a copy of the signed ICD for one subject.	(1) WOC study staff must be approved by the IRB to conduct study procedures. (2) Subject must be re-consented by study staff authorized to obtain consent. (3) The ACOS/R and the affiliate's Clinical Trials Director will provide education to all oncology PIs and research staff on requirements for use of the VA research pharmacy.
285	21	Palo Alto	H	**12/4/2014**	(1) Failure to obtain HIPAA authorization from three subjects.	Pending.
286	22	Greater Los Angeles	H	**12/4/2014**	(1) Failure to obtain HIPAA authorization from eight subjects.	Pending.
287	11	Indianapolis (Roudebush)	H	**12/5/2014**	(1) One ICD was missing the subject's signature and date.	(1) IRB determined no serious/continuing noncompliance. CASE CLOSED.
288	15	Columbia MO (Truman)	S	**12/12/2014**	(1) Lapse in continuing review of protocol.	(1) Modification of local policies for annual reviews; publication of the SRS meeting schedule and agendas for tracking purposes; alignment of SRS and R&DC review schedules and approval dates. CASE CLOSED.
289	23	Minneapolis	H	**12/16/2014**	(1) The informed consent form used with 22 subjects did not include documentation of IRB approval and the IRB approval date.	Pending.

TABLE 2C. REMOTE REVIEWS OF RESEARCH COMPLIANCE OFFICER (RCO) AUDITS

Case	VISN	Facility	Focus	Date	Issue of Noncompliance	Remedial Actions
290	01	White River Junction	H	**12/18/2014**	(1) Audit of study on effectiveness of rTMS in depressed veterans found a consented subject did not meet exclusionary criteria (medications). Subject was withdrawn from study after screening failure.	Pending.
291	22	Loma Linda	H	**12/19/2014**	(1) The study close-out reported stated 40 subjects were enrolled, RCO found 46 ICDs, and master list contained 44 entries. Lack of a password did not allow access to final master list. (2) Three subjects were missing HIPAA authorizations.	(1) A full accounting of all subjects who signed an ICD must be accomplished. (2) IRB must determine if data gathered without a valid HIPAA authorization can be used by the investigator.
292	11	Indianapolis (Roudebush)	H	**12/22/2014**	(1) PI cannot locate informed consent and HIPAA for one deceased participant.	(1) Educate study staff; revise process of copying ICD/HIPAA forms.
293	23	Iowa City	H	**12/22/2014**	(1) RCO identified a regulatory audit was not performed.	(1) Complete regulatory audit and identify if any others need to be completed. Audits were completed. CASE CLOSED.

TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT

The director of each VHA research facility must lead an annual program-wide self-assessment of research compliance and provide ORO with a certification of research oversight based on this self-assessment in July of each year. The program requires that the facility director's certification include an action plan to remediate any deficiencies identified by the self-assessment. ORO monitors implementation of these remedial actions.

Summary

- 12 = Cases Continuing from Calendar Year 2013 *
- **0 = New Cases – January 1 through March 31**
- **1 = New Cases – April 1 through June 30**
- **269 = New Cases – July1 through September 30**
- **3 = New Cases – October 1 through December 31**
- 273 = New Cases in Calendar Year 2014
- 285 = Total Cases (Continuing Plus New) in Calendar Year

* Item #1 was inadvertently omitted from previous reports.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
1	12	Hines, IL (Edward Hines)	H	2012	Remedial Actions: CRADO denied facility request for waiver to conduct a children's study. At the direction of ORD, the study is to be kept open while the facility explores options for transferring the study to another institution. University affiliate has tentatively agreed to accept and continue conduct of the study.
2	16	Houston (Michael DeBakey)	A	2012	Remedial Actions: Ensure SRS approval of protocols; ensure personnel training is current; complete annual reviews of IACUC protocols; ensure HVAC enhancements are completed. CASE CLOSED.
3	08	Tampa (James Haley)	A	2012	Remedial Actions: Develop standard operating procedures for RSSP and ACUP; complete SRS review of protocols; complete SRS annual review of protocols. CASE CLOSED.
4	20	Boise	A	2013	Remedial Actions: Ensure IACUC annual review of protocols; review and update policies for SRS/RSSP and noncompliance reporting; ensure adequate resources and personnel. CASE CLOSED.
5	05	Washington DC	A	2013	Remedial Actions: Fill administrative positions; complete MOU. CASE CLOSED.
6	12	Hines IL (Edward Hines)	E	2013	Remedial Actions: RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
7	09	Memphis	A	2013	Remedial Actions: Review and document training; complete MOU signatures; complete occupational health and safety risk assessments for applicable personnel; update SOPs. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
8	23	Minneapolis	I	2013	Remedial Actions: A risk based assessment for each laptop has been prepared and was provided to the CIO for review; attempts to encrypt the laptop are still underway.
9	16	Muskogee (Jack Montgomery)	H-R	2013	Remedial Actions: Clarify Program Status Hold; Clarify that a study requiring the USH authorization is being conducted at the facility; and Update MOUs. CASE CLOSED.
10	16	Muskogee (Jack Montgomery)	I	2013	Remedial Actions: Clarify Program Status Hold; clarify that a study requiring the USH authorization is being conducted at facility; and update MOUs. Due to non-response, ORO restricted human subject research until a functional and effective HRPP is in place.
11	23	VA Black Hills HCS	H-R	2013	Remedial Actions: R&DC conducted an annual review of the IRB. CASE CLOSED.
12	19	VA Salt Lake City HCS	H-R	2013	Remedial Actions: Ensure report to ORO and follow-up of RCO audit reports of apparent serious noncompliance; functional statements and scopes of practice for all research staff; completion of required investigator training. CASE CLOSED.
13	12	Hines IL (Edward Hines)	H	**2014**	Remedial Actions: CRADO denied 2012 request for waiver for participation in a children's study; facility exploring other options (including transferring study to another institution).
14	02	Albany (Samuel Stratton)	R	**2014**	No new deficiencies identified. CASE CLOSED.
15	02	Albany (Samuel Stratton)	A	**2014**	No new deficiencies identified. CASE CLOSED.
16	02	Albany (Samuel Stratton)	S	**2014**	No new deficiencies identified. CASE CLOSED.
17	06	Asheville	S	**2014**	No new deficiencies identified. CASE CLOSED.
18	06	Asheville	R	**2014**	No new deficiencies identified. CASE CLOSED.
19	07	Atlanta	R	**2014**	Three studies lapsed in their annual R&DC reviews. No human or animal research involved. No research was conducted during the lapses. Operating procedures under review.
20	07	Atlanta	A	**2014**	No new deficiencies identified. CASE CLOSED.
21	07	Atlanta	S	**2014**	No new deficiencies identified. CASE CLOSED.
22	07	Augusta (Charlie Norwood)	A	**2014**	No new deficiencies identified. CASE CLOSED.
23	07	Augusta (Charlie Norwood)	S	**2014**	No new deficiencies identified. CASE CLOSED.
24	02	Bath	R	**2014**	No new deficiencies identified. CASE CLOSED.
25	02	Bath	S	**2014**	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
26	11	Battle Creek	R	2014	No new deficiencies identified. CASE CLOSED.
27	08	Bay Pines VA HCS	A	2014	No new deficiencies identified. CASE CLOSED.
28	08	Bay Pines VA HCS	S	2014	No new deficiencies identified. CASE CLOSED.
29	08	Bay Pines VA HCS	R	2014	No new deficiencies identified. CASE CLOSED.
30	01	Bedford (Edith Nourse Roger)	A	2014	No new deficiencies identified. CASE CLOSED.
31	01	Bedford (Edith Nourse Roger)	S	2014	No new deficiencies identified. CASE CLOSED.
32	01	Bedford (Edith Nourse Rogers)	R	2014	Although multiple deficiencies and concerns were noted in the Certification, each and all have either been reported to ORO (with tracking of corrective actions in referenced ORO cases) or addressed with satisfactory local corrective actions. CASE CLOSED.
33	07	Birmingham	R	2014	No new deficiencies identified. CASE CLOSED.
34	07	Birmingham	A	2014	No new deficiencies identified. CASE CLOSED.
35	07	Birmingham	S	2014	No new deficiencies identified. CASE CLOSED.
36	20	Boise	R	2014	No new deficiencies identified.
37	03	Bronx (James Peters)	R	2014	No new deficiencies identified. CASE CLOSED.
38	03	Bronx (James Peters)	A	2014	No new deficiencies identified. CASE CLOSED.
39	03	Bronx (James Peters)	S	2014	No new deficiencies identified. CASE CLOSED.
40	02	Canandaigua	R	2014	No new deficiencies identified. CASE CLOSED.
41	12	Captain James A. Lovell FHCC	R	2014	No new deficiencies identified. CASE CLOSED
42	12	Captain James A. Lovell FHCC	R	2014	PI obtained 14 missing HIPAA authorizations. CASE CLOSED.
43	12	Captain James A. Lovell FHCC	S	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
44	16	Central Arkansas (Little Rock)	R	2014	Ensure no lapses in IRB continuing review; ensure correct ICD used; ensure participant dates when signing an ICD; ensure; include clinicaltrials.gov statement for FDA regulated studies.
45	16	Central Arkansas Veterans HCS	A	2014	No new deficiencies identified. CASE CLOSED.
46	16	Central Arkansas Veterans HCS	S	2014	No new deficiencies identified. CASE CLOSED.
47	17	Central Texas Veterans HCS	R	2014	Certification identified multiple deficiencies and concerns. Each had been addressed and resolved (or had resolution pending) locally or had been reported to, or identified by, ORO and tracked in the context of specific ORO cases. CASE CLOSED.
48	17	Central Texas Veterans HCS	A	2014	No new deficiencies identified. CASE CLOSED.
49	17	Central Texas Veterans HCS	S	2014	No new deficiencies identified. CASE CLOSED.
50	07	Charleston (Ralph Johnson)	R	2014	No new deficiencies identified. CASE CLOSED.
51	07	Charleston (Ralph Johnson)	A	2014	No new deficiencies identified. CASE CLOSED.
52	07	Charleston (Ralph Johnson)	S	2014	No new deficiencies identified. CASE CLOSED.
53	07	Charlie Norwood	R	2014	No new deficiencies identified. CASE CLOSED.
54	10	Chillicothe	S	2014	No new deficiencies identified. CASE CLOSED.
55	10	Chillicothe	R	2014	No new deficiencies identified. CASE CLOSED.
56	10	Cincinnati	A	2014	No new deficiencies identified. CASE CLOSED.
57	10	Cincinnati	S	2014	No new deficiencies identified. CASE CLOSED.
58	10	Cincinnati	R	2014	No new deficiencies identified. CASE CLOSED.
59	04	Clarksburg (Louis Johnson)	R	2014	No new deficiencies identified. CASE CLOSED.
60	10	Cleveland (Louis Stokes)	A	2014	No new deficiencies identified. CASE CLOSED.
61	10	Cleveland (Louis Stokes)	S	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
62	10	Cleveland (Louis Stokes)	R	2014	Completion of IRB/HRPP annual review; completion of ACOS quality assurance review of publications.
63	04	Coatesville	A	2014	No new deficiencies identified. CASE CLOSED.
64	04	Coatesville	S	2014	No new deficiencies identified. CASE CLOSED.
65	15	Columbia MO (Harry Truman)	S	2014	No new deficiencies identified. CASE CLOSED.
66	15	Columbia MO Harry Truman)	A	2014	No new deficiencies identified. CASE CLOSED.
67	15	Columbia MO Harry Truman)	R	2014	No new deficiencies identified. CASE CLOSED.
68	07	Columbia SC (Wm. Jennings Bryan Dorn)	A	2014	No new deficiencies identified. CASE CLOSED.
69	07	Columbia SC (Wm. Jennings Bryan Dorn)	S	2014	Remedial Action: conduct and review 2014 multidisciplinary vulnerability assessment. CASE CLOSED.
70	07	Columbia SC (Wm. Jennings Bryan Dorn)	R	2014	No new deficiencies identified. CASE CLOSED.
71	10	Columbus (Chalmers Wylie)	R	2014	No new deficiencies identified. CASE CLOSED.
72	10	Columbus (Chalmers Wylie)	S	2014	No new deficiencies identified. CASE CLOSED.
73	10	Dayton	R	2014	No new deficiencies identified. CASE CLOSED.
74	11	Detroit (John Dingell)	A	2014	No new deficiencies identified. CASE CLOSED.
75	11	Detroit (John Dingell)	S	2014	No new deficiencies identified. CASE CLOSED.
76	11	Detroit (John Dingell)	R	2014	No new deficiencies identified. CASE CLOSED.
77	06	Durham	R	2014	No new deficiencies identified. CASE CLOSED.
78	06	Durham	A	2014	No new deficiencies identified. CASE CLOSED.
79	06	Durham	S	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
80	23	Fargo	S	2014	No new deficiencies identified. CASE CLOSED.
81	23	Fargo	R	2014	No new deficiencies identified.
82	06	Hampton	R	2014	No new deficiencies identified. CASE CLOSED.
83	12	Hines IL (Edward Hines)	R	2014	No new deficiencies identified. CASE CLOSED
84	12	Hines IL (Edward Hines)	A	2014	No new deficiencies identified. CASE CLOSED.
85	12	Hines IL (Edward Hines)	S	2014	No new deficiencies identified. CASE CLOSED.
86	16	Houston (Michael DeBakey)	A	2014	No new deficiencies identified. CASE CLOSED.
87	16	Houston (Michael DeBakey)	S	2014	No new deficiencies identified. CASE CLOSED.
88	16	Houston (Michael DeBakey)	R	2014	Remedial actions. Research and RCO will continue to educate researchers; facility will engage the affiliate IRB's Office of Research and IRB #4 to help solve the problem; facility will send email reminders to PIs' VA accounts instead of only the affiliate email; RCO will hold start-up meetings with PIs who obtain consent; a pop-up reminder has been implemented in the system that PIs use to submit IRB protocols reminding them that a separate HIPAA authorization is required. CASE CLOSED.
89	09	Huntington	A	2014	No new deficiencies identified. CASE CLOSED.
90	09	Huntington	S	2014	No new deficiencies identified. CASE CLOSED.
91	09	Huntington	R	2014	No new deficiencies identified. CASE CLOSED.
92	11	Indianapolis (Richard Roudebush)	A	2014	No new deficiencies identified. CASE CLOSED.
93	11	Indianapolis (Richard Roudebush)	S	2014	No new deficiencies identified. CASE CLOSED.
94	11	Indianapolis (Richard Roudebush)	R	2014	Facility to address lapses in IRB continuing review approvals.
95	23	Iowa City	A	2014	No new deficiencies identified.
96	23	Iowa City	S	2014	No new deficiencies identified.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
97	23	Iowa City	R	**2014**	The FDC identified no previously unreported deficiencies for which reporting was required; and additional communication resolved referenced concerns involving IRB expiration of approval and minor informed consent process deficiencies. CASE CLOSED.
98	16	Jackson MS (Sonny Montgomery)	R	**2014**	Remedial Actions: Affiliate IACUC proceedings related to VA protocols are now copied to the VA R&DC for review at their regularly scheduled meetings; ACOS/R&D will be provided with computer access and complete training requirements; annual reports will be reported to the R&DC and forwarded to the MCD in a timely manner.
99	16	Jackson MS (Sonny Montgomery)	A	**2014**	No new deficiencies identified. CASE CLOSED.
100	16	Jackson MS (Sonny Montgomery)	S	**2014**	No new deficiencies identified. CASE CLOSED.
101	12	Jesse Brown	A	**2014**	No new deficiencies identified. CASE CLOSED.
102	12	Jesse Brown	S	**2014**	No new deficiencies identified. CASE CLOSED.
103	12	Jesse Brown	R	**2014**	No new deficiencies identified. CASE CLOSED.
104	15	Kansas City	A	**2014**	No new deficiencies identified. CASE CLOSED.
105	15	Kansas City	S	**2014**	No new deficiencies identified. CASE CLOSED.
106	09	Lexington	A	**2014**	No new deficiencies identified. CASE CLOSED.
107	09	Lexington	S	**2014**	No new deficiencies identified. CASE CLOSED.
108	09	Lexington	R	**2014**	No new deficiencies identified. CASE CLOSED.
109	09	Louisville (Robley Rex)	A	**2014**	No new deficiencies identified. CASE CLOSED.
110	09	Louisville (Robley Rex)	S	**2014**	No new deficiencies identified. CASE CLOSED.
111	09	Louisville (Robley Rex)	R	**2014**	Facility identified personnel shortage due to two vacant FTEs.
112	12	Madison (William Middleton)	A	**2014**	No new deficiencies identified. CASE CLOSED.
113	12	Madison (William Middleton)	S	**2014**	No new deficiencies identified. CASE CLOSED.
114	12	Madison (William Middleton)	R	**2014**	Facility identified that consents were obtained by a person not listed on the protocol. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
115	01	Manchester	R	2014	Affiliate IRB review has been completed and all other reviews have been scheduled with summaries provided to the Director upon the conduct/completion of each review. The remaining reviews will be conducted as scheduled. CASE CLOSED.
116	01	Manchester	S	2014	No new deficiencies identified. CASE CLOSED.
117	05	Martinsburg	R	2014	No new deficiencies identified. CASE CLOSED.
118	09	Memphis	A	2014	Several animal research protocols initiated prior to completion of all committee reviews/approvals. Remedial actions pending.
119	09	Memphis	S	2014	Several safety protocols initiated prior to completion of all committee reviews/approvals. Remedial actions pending.
120	09	Memphis	R	2014	No new deficiencies in the R&DC or HRPP portions of the FDC were identified. RSAW made aware of several deficiencies listed in the animal and safety portions. CASE CLOSED.
121	08	Miami VA HCS	A	2014	Ensure all protocols are reviewed on time; ensure all ACORP individuals have approved scopes of practice.
122	08	Miami VA HCS	S	2014	No new deficiencies identified.
123	08	Miami VA HCS	R	2014	No new deficiencies identified. CASE CLOSED.
124	12	Milwaukee (Clement Zablocki)	R	2014	No new deficiencies identified. CASE CLOSED.
125	12	Milwaukee (Clement Zablocki)	A	2014	No new deficiencies identified. CASE CLOSED.
126	12	Milwaukee (Clement Zablocki)	S	2014	No new deficiencies identified. CASE CLOSED.
127	23	Minneapolis VA HCS	A	2014	No new deficiencies identified.
128	23	Minneapolis VA HCS	S	2014	No remedial actions required.
129	23	Minneapolis VA HCS	R	2014	No unreported deficiencies; resolution of referenced training deficiencies with 6 staff members confirmed. CASE CLOSED.
130	09	Mountain Home (James Quillen)	A	2014	No new deficiencies identified. CASE CLOSED.
131	09	Mountain Home (James Quillen)	S	2014	No new deficiencies identified. CASE CLOSED.
132	09	Mountain Home (James Quillen)	R	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
133	16	Muskogee (Jack Montgomery)	S	2014	No new deficiencies identified. CASE CLOSED.
134	16	Muskogee (Jack Montgomery)	R	2014	No new deficiencies identified. CASE CLOSED.
135	18	New Mexico VA HCS	R	2014	Expired informed consent documents for enrollment in two studies; miscellaneous consent-related errors such as incorrect dates and missing dates. CASE CLOSED.
136	18	New Mexico VA HCS	A	2014	Upgrades to heating, ventilation, and air conditioning (HVAC) system. CASE CLOSED.
137	18	New Mexico VA HCS	S	2014	No new deficiencies identified. CASE CLOSED.
138	08	North Florida/South Georgia Veterans Health System	R	2014	No new deficiencies identified. CASE CLOSED.
139	08	North Florida/South Georgia Veterans Health System	A	2014	No new deficiencies identified. CASE CLOSED.
140	08	North Florida/South Georgia Veterans Health System	S	2014	No new deficiencies identified. CASE CLOSED.
141	03	Northport	R	2014	No new deficiencies identified. CASE CLOSED.
142	03	Northport	A	2014	No new deficiencies identified. CASE CLOSED.
143	03	Northport	S	2014	No new deficiencies identified. CASE CLOSED.
144	16	Oklahoma City	A	2014	No new deficiencies identified. CASE CLOSED.
145	16	Oklahoma City	S	2014	No new deficiencies identified. CASE CLOSED.
146	16	Oklahoma City	R	2014	Ensure no lapses in IRB continuing review; ensure correct ICD used; ensure statement on clinicaltrials.gov is included with FDA regulated studies; ensure staff training requirements are met. CASE CLOSED.
147	08	Orlando	R	2014	No new deficiencies identified. CASE CLOSED.
148	04	Philadelphia	R	2014	No new deficiencies identified. CASE CLOSED.
149	04	Philadelphia	A	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
150	04	Philadelphia	S	2014	No new deficiencies identified. CASE CLOSED.
151	18	Phoenix VA HCS	A	2014	No new deficiencies identified. CASE CLOSED.
152	18	Phoenix VA HCS	S	2014	No new deficiencies identified. CASE CLOSED.
153	18	Phoenix VA HCS	R	2014	One unreported compliance deficiency (inadequate resources and administrative support from the MCD), addressed and resolved (or being resolved). CASE CLOSED.
154	20	Portland	A	2014	No new deficiencies identified. CASE CLOSED.
155	20	Portland	S	2014	No new deficiencies identified. CASE CLOSED.
156	20	Portland	R	2014	ORO notes that the Certification identified multiple deficiencies and concerns and that each had been addressed and resolved (or had resolution pending) locally or reported to, or identified by ORO, and tracked in the context of specific ORO cases. CASE CLOSED.
157	01	Providence	R	2014	No new deficiencies identified. CASE CLOSED.
158	01	Providence	A	2014	No new deficiencies identified. CASE CLOSED.
159	01	Providence	S	2014	No new deficiencies identified. CASE CLOSED.
160	06	Richmond (HH McGuire)	R	2014	No new deficiencies identified. CASE CLOSED.
161	06	Richmond (HH McGuire)	A	2014	No new deficiencies identified. CASE CLOSED.
162	06	Richmond (HH McGuire)	S	2014	No new deficiencies identified. CASE CLOSED.
163	11	Saginaw (Aleda Lutz)	R	2014	No new deficiencies identified. CASE CLOSED.
164	06	Salem	S	2014	No new deficiencies identified. CASE CLOSED.
165	06	Salem	R	2014	No new deficiencies identified. CASE CLOSED.
166	06	Salisbury (Bill Hefner)	A	2014	No new deficiencies identified. CASE CLOSED.
167	06	Salisbury (Bill Hefner)	S	2014	No new deficiencies identified. CASE CLOSED.
168	06	Salisbury (Bill Hefner)	R	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
169	21	San Francisco	A	2014	No new deficiencies identified. CASE CLOSED.
170	21	San Francisco	S	2014	No new deficiencies identified. CASE CLOSED.
171	21	San Francisco	R	2014	No new deficiencies identified. CASE CLOSED.
172	16	Shreveport (Overton Brooks)	R	2014	No new deficiencies identified.
173	23	Sioux Falls VA HCS	A	2014	No new deficiencies identified.
174	23	Sioux Falls VA HCS	S	2014	No RSSP deficiencies identified.
175	23	Sioux Falls VA HCS	R	2014	A process was implemented to ensure research committee members complete required training prior to the issuance of an appointment letter. CASE CLOSED.
176	17	South Texas Veterans HCS	R	2014	Identified multiple deficiencies and concerns, each and all had been addressed and resolved locally. CASE CLOSED.
177	17	South Texas Veterans HCS	A	2014	No new deficiencies identified. CASE CLOSED.
178	17	South Texas Veterans HCS	S	2014	No new deficiencies identified. CASE CLOSED.
179	16	Southeast Louisiana Veterans HCS	A	2014	No new deficiencies identified. CASE CLOSED.
180	16	Southeast Louisiana Veterans HCS	S	2014	No new deficiencies identified. CASE CLOSED.
181	16	Southeast Louisiana Veterans HCS	R	2014	No new deficiencies identified.
182	18	Southern Arizona VA HCS	A	2014	No new deficiencies identified. CASE CLOSED.
183	18	Southern Arizona VA HCS	S	2014	No new deficiencies identified. CASE CLOSED.
184	18	Southern Arizona VA HCS	R	2014	No new deficiencies identified. CASE CLOSED.
185	23	St. Cloud VA HCS	R	2014	No new deficiencies identified.
186	15	St. Louis	R	2014	Facility has requested extensions for completion of the 2014 FDC.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
187	15	St. Louis	R	2014	No new deficiencies identified. FDC once again identified lack of documentation of RCO audits for human ICD and regulatory, animal, and safety. The R&DC review of subcommittees did not appear to include the VA Central IRB. CASE CLOSED.
188	02	Syracuse	R	2014	No new deficiencies identified. CASE CLOSED.
189	02	Syracuse	A	2014	No new deficiencies identified. CASE CLOSED.
190	02	Syracuse	S	2014	No new deficiencies identified. CASE CLOSED.
191	08	Tampa (James Haley)	R	2014	No new deficiencies identified. CASE CLOSED.
192	08	Tampa (James Haley)	A	2014	No new deficiencies identified. CASE CLOSED.
193	08	Tampa (James Haley)	S	2014	No new deficiencies identified. CASE CLOSED.
194	09	Tennessee Valley HCS	A	2014	No new deficiencies identified. CASE CLOSED.
195	09	Tennessee Valley HCS	S	2014	No new deficiencies identified. CASE CLOSED.
196	09	Tennessee Valley HCS	R	2014	No new deficiencies identified. CASE CLOSED.
197	01	Togus	R	2014	No new deficiencies identified. CASE CLOSED.
198	01	Togus	S	2014	No new deficiencies identified. CASE CLOSED.
199	07	Tuscaloosa	S	2014	No new deficiencies identified. CASE CLOSED.
200	07	Tuscaloosa	R	2014	No new deficiencies identified. CASE CLOSED.
201	11	VA Ann Arbor HCS	R	2014	No new deficiencies identified. CASE CLOSED.
202	11	VA Ann Arbor HCS	A	2014	Remedial Actions: IACUC review of protocol lapses; finalize pending MOU.
203	11	VA Ann Arbor HCS	S	2014	No new deficiencies identified. CASE CLOSED.
204	01	VA Boston HCS	H	2014	Facility IRB must review protocol from the VA National Center for PTSD that was identified to involve children without the required CRADO waiver. PI to stop recruitment of children until ORD policy issue is addressed.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
205	01	VA Boston HCS	A	2014	No new deficiencies identified. CASE CLOSED.
206	01	VA Boston HCS	S	2014	No new deficiencies identified. CASE CLOSED.
207	08	VA Caribbean HCS	S	2014	No new deficiencies identified. CASE CLOSED.
208	08	VA Caribbean HCS	R	2014	No new deficiencies identified. CASE CLOSED.
209	21	VA Central California HCS	S	2014	No new deficiencies identified. CASE CLOSED.
210	21	VA Central California HCS	R	2014	No new deficiencies identified. CASE CLOSED.
211	01	VA Central Western Massachusetts HCS	R	2014	No new deficiencies identified. CASE CLOSED
212	01	VA Central Western Massachusetts HCS	S	2014	No new deficiencies identified. CASE CLOSED.
213	01	VA Connecticut HCS	R	2014	No new deficiencies identified. CASE CLOSED.
214	01	VA Connecticut HCS	A	2014	No new deficiencies identified. CASE CLOSED.
215	01	VA Connecticut HCS	S	2014	No new deficiencies identified. CASE CLOSED.
216	19	VA Eastern Colorado HCS	I	2014	Previous Information Security Agreement currently being revised.
217	19	VA Eastern Colorado HCS	R	2014	Update HRPP SOPs; remediation of Scope of Research Practice deficiencies.
218	19	VA Eastern Colorado HCS	A	2014	No new deficiencies identified. CASE CLOSED.
219	19	VA Eastern Colorado HCS	S	2014	No new deficiencies identified. CASE CLOSED.
220	15	VA Eastern Kansas HCS	R	2014	No new deficiencies identified. CASE CLOSED.
221	22	VA Greater Los Angeles HCS	A	2014	No new deficiencies identified. CASE CLOSED.
222	22	VA Greater Los Angeles HCS	S	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
223	22	VA Greater Los Angeles HCS	R	2014	Four individuals involved in human subject protocols were not current with all required training. Eight individuals involved in animal protocols were not current with all required training. PIs sent listing of deficient employees who must cease research activities. Research Office confirms training completion before employee can resume.
224	16	VA Gulf Coast Veterans HCS	R	2014	No new deficiencies identified. CASE CLOSED.
225	03	VA Hudson Valley HCS	R	2014	No new deficiencies identified. CASE CLOSED.
226	22	VA Loma Linda HCS	A	2014	No new deficiencies identified. CASE CLOSED.
227	22	VA Loma Linda HCS	S	2014	No new deficiencies identified. CASE CLOSED.
228	22	VA Loma Linda HCS	R	2014	RDC membership and research staff to complete missing training; update expired MOU with VA facility using this facility's IRB; update local SOPs.
229	22	VA Long Beach HCS	R	2014	No new deficiencies identified. CASE CLOSED.
230	22	VA Long Beach HCS	A	2014	No new deficiencies identified. CASE CLOSED.
231	22	VA Long Beach HCS	S	2014	No new deficiencies identified. CASE CLOSED.
232	05	VA Maryland HCS	R	2014	Failure of RCO program to complete all required audits is being followed separately. CASE CLOSED.
233	05	VA Maryland HCS	A	2014	No new deficiencies identified. CASE CLOSED.
234	05	VA Maryland HCS	S	2014	No new deficiencies identified. CASE CLOSED.
235	23	VA Nebraska-Western Iowa HCS	A	2014	No new deficiencies identified. CASE CLOSED.
236	23	VA Nebraska-Western Iowa HCS	S	2014	No new deficiencies identified. CASE CLOSED.
237	23	VA Nebraska-Western Iowa HCS	R	2014	No new deficiencies identified.
238	03	VA New Jersey HCS	R	2014	No new deficiencies identified. CASE CLOSED.
239	03	VA New Jersey HCS	A	2014	No new deficiencies identified. CASE CLOSED.
240	03	VA New Jersey HCS	S	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
241	17	VA North Texas HCS	R	2014	Director's Certification identified the following deficiencies. (a) Nine HIPAA authorizations were not obtained. (b) One protocol was suspended/terminated by the Institutional Review Board. (c) Six protocols had a lapse in Institutional Animal Care and Use Committees (IACUC) annual or triennial review (two had research activities during the lapse). (d) Eight protocols had a lapse in Subcommittee on Research Safety (SRS) annual review (three had research activities during the lapse). Remedial actions implemented. CASE CLOSED.
242	17	VA North Texas HCS	A	2014	No new deficiencies identified. CASE CLOSED.
243	17	VA North Texas HCS	S	2014	Remedial Actions: Complete required research-specific drills.
244	21	VA Northern California HCS	A	2014	No new deficiencies identified. CASE CLOSED.
245	21	VA Northern California HCS	S	2014	No new deficiencies identified. CASE CLOSED.
246	21	VA Northern California HCS	R	2014	No new deficiencies identified. CASE CLOSED.
247	03	VA NY Harbor HCS	A	2014	No new deficiencies identified. CASE CLOSED.
248	03	VA NY Harbor HCS	S	2014	No new deficiencies identified. CASE CLOSED.
249	21	VA Pacific Islands HCS	R	2014	No new deficiencies identified. CASE CLOSED.
250	21	VA Palo Alto HCS	A	2014	No new deficiencies identified. CASE CLOSED.
251	21	VA Palo Alto HCS	S	2014	No new deficiencies identified. CASE CLOSED.
252	21	VA Palo Alto HCS	R	2014	ACOS/R now responsible for written approval of authorizations and annual review of Research Scopes. All concerns clarified and/or resolved. CASE CLOSED.
253	04	VA Pittsburgh HCS	R	2014	No new deficiencies identified. CASE CLOSED.
254	04	VA Pittsburgh HCS	A	2014	No new deficiencies identified. CASE CLOSED.
255	04	VA Pittsburgh HCS	S	2014	No new deficiencies identified. CASE CLOSED.
256	20	VA Puget Sound HCS	I	2014	VA approved Federal Information Processing Standard (FIPS) 140-2 validated encryption package was installed in FIPS mode on six of the eight laptops identified as requiring encryption, if technically possible, or a risk based decision; two laptops were withdrawn by facility management decision from service in lieu of requesting a risk based decision from the VA Office of Information Security. CASE CLOSED.
257	20	VA Puget Sound HCS	A	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
258	20	VA Puget Sound HCS	S	2014	No new deficiencies identified. CASE CLOSED.
259	20	VA Puget Sound HCS	R	2014	No unreported deficiencies for which reporting was required; however, the FDC referenced 5 deficiencies without sufficient description; further information pending. All concerns were addressed and resolved. CASE CLOSED.
260	19	VA Salt Lake City HCS	R	2014	Informed consent deficiencies were previously reported to ORO and handled in separate cases. Training noncompliance has been corrected. CASE CLOSED.
261	19	VA Salt Lake City HCS	A	2014	No new deficiencies identified. CASE CLOSED.
262	19	VA Salt Lake City HCS	S	2014	No new deficiencies identified. CASE CLOSED.
263	22	VA San Diego HCS	A	2014	No new deficiencies identified. CASE CLOSED.
264	22	VA San Diego HCS	S	2014	No new deficiencies identified. CASE CLOSED.
265	22	VA San Diego HCS	R	2014	No remedial actions required.
266	21	VA Sierra Nevada HCS	S	2014	No new deficiencies identified. CASE CLOSED.
267	21	VA Sierra Nevada HCS	R	2014	No new deficiencies identified. CASE CLOSED.
268	22	VA Southern Nevada HCS	S	2014	No new deficiencies identified. CASE CLOSED.
269	22	VA Southern Nevada HCS	R	2014	No new deficiencies identified. CASE CLOSED.
270	02	VA Western New York HCS	R	2014	No new deficiencies identified. CASE CLOSED.
271	02	VA Western New York HCS	A	2014	No new deficiencies identified. CASE CLOSED.
272	02	VA Western New York HCS	S	2014	No new deficiencies identified. CASE CLOSED.
273	16	Veterans HCS of the Ozarks	R	2014	No new deficiencies identified. CASE CLOSED.
274	05	Washington DC	R	2014	No new deficiencies identified. CASE CLOSED.
275	05	Washington DC	A	2014	No new deficiencies identified. CASE CLOSED.
276	05	Washington DC	S	2014	No new deficiencies identified. CASE CLOSED.

Case	VISN	Facility	Focus	Year	TABLE 2D. REVIEWS OF ANNUAL FACILITY DIRECTOR CERTIFICATIONS OF RESEARCH OVERSIGHT
277	01	White River Junction	R	2014	No new deficiencies identified. CASE CLOSED.
278	01	White River Junction	A	2014	No new deficiencies identified. CASE CLOSED.
279	01	White River Junction	S	2014	No new deficiencies identified. CASE CLOSED.
280	15	Wichita (Robert Dole)	R	2014	No new deficiencies identified. CASE CLOSED.
281	04	Wilkes-Barre	R	2014	No new deficiencies identified. CASE CLOSED.
282	04	Wilkes-Barre	S	2014	No new deficiencies identified. CASE CLOSED.
283	11	Ann Arbor	R	2014	No new deficiencies identified. CASE CLOSED.
284	11	Ann Arbor	A	2014	Remedial Actions: IACUC review of protocol lapses; finalize pending MOU.
285	11	Ann Arbor	S	2014	No new deficiencies identified. CASE CLOSED.

TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS

ORO remote technical assistance reviews constitute an additional prospective approach to assist research programs at VA facilities in fulfilling their responsibilities to conduct research with adequate protections for human subjects, laboratory animal welfare, research safety, research laboratory security, research information protections, and the responsible conduct of research. Remote technical assistance reviews may be conducted at the request of the facility or initiated by ORO as a follow up action to a for-cause or routine onsite review, as a targeted review to address specific areas of concern, or as a supplementary review opportunity.

Summary

- 24 = Cases Continuing from Previous Calendar Year *
- **70 = New Cases – January 1 through March 31**
- **64 = New Cases – April 1 through June 30**
- 100 **= New Cases – July 1 through September 30**
- **67 = New Cases – July 1 through September 30**
- 301 = Total New Cases in Calendar Year
- 325 = Total Cases (Continuing Plus New) in Calendar Year

* Case #11 and Case #23 were inadvertently omitted from the 1st Quarter Report.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
1	23	VA Black Hills HCS	E	10/17/2012	Technical Assistance: New RCO support program. Evaluated and addressed auditing plan and progress on 2013 triennial human subjects' auditing requirements. CASE CLOSED.
2	23	Fargo	E	10/22/2012	Technical Assistance: New RCO support program including coaching and education through first 12 months. CASE CLOSED.
3	21	San Francisco	E	11/19/2012	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
4	01	VA Central Western Massachusetts (Northampton)	E	11/28/2012	Technical Assistance: New RCO support program. Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office. CASE CLOSED.
5	01	Maine HCS (Togus)	E	01/24/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
6	09	Huntington	E	02/25/2013	Technical Assistance: New RCO support program. Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
7	21	VA Central California HCS	E	04/15/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
8	21	VA Pacific Islands HCS	E	06/03/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
9	01	Togus	E	07/08/2013	Technical Assistance: RCO Part Time Waiver Program: Follow-Up Survey. Continuing assistance. CASE CLOSED.
10	16	Central Arkansas (Little Rock)	E	07/16/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
11	07	Charleston (Ralph Johnson)	E	08/19/2013	Technical Assistance: Part Time RCO Waiver request. Approved. CASE CLOSED.
12	06	Salisbury (Bill Hefner)	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
13	01	White River Junction	S	08/28/2013	Technical Assistance: IBC review and approval of multi-site study. CASE CLOSED.
14	15	*St. Louis	E	11/15/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
15	23	VA Nebraska/West Iowa HCS	E	11/18/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.
16	16	Gulf Coast HCS	E	11/20/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
17	16	Southeast Louisiana (New Orleans)	E	11/20/2013	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources. CASE CLOSED.
18	16	Oklahoma City	E	11/20/2013	Technical Assistance: MOU consultation and review. CASE CLOSED.
19	16	Shreveport (Overton Brooks)	E	11/26/2013	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
20	06	Salem	E	12/03/2013	Technical assistance: New RCO support program including coaching and educational needs assessment and resources.
21	09	Memphis	H	12/08/2013	Technical Assistance: Monitor additional IRB meetings; QA of lapsed studies; process to ensure data collected during lapse is not used; increased support for IRB Chair. CASE CLOSED.
22	23	VA Black Hills HCS	H	12/10/2013	Technical Assistance: Provided information concerning required Central Office notifications, and the establishment of documents reflecting closure of the research program. CASE CLOSED.
23	18	*New Mexico HCS	H	12/18/2013	Technical Assistance: Facility planning creation of a local IRB; provided information concerning timelines and required steps before implementation. CASE CLOSED.
24	01	VA Connecticut HCS	E	12/30/2013	Technical Assistance: MOU review and consultation. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
25	03	VA New York Harbor HCS	H	01/05/2014	Technical Assistance: SRS reviews for appropriate human subj. studies; IRB deliberation and review of lapsed study; use of VA Form 10-3203. CASE CLOSED.
26	16	Shreveport (Overton Brooks)	E	01/06/2014	Technical Assistance: MOU consultation and review. CASE CLOSED.
27	22	VA Greater Los Angeles HS	E	01/07/2014	Technical Assistance: MOU consultation and document review. CASE CLOSED.
28	16	Muskogee (Jack Montgomery)	E	01/08/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
29	15	Wichita (Dole)	E	01/14/2014	Technical assistance: New RCO support program including coaching and educational needs assessment and resources.
30	21	VA Pacific Islands HCS	E	01/15/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
31	10	Cincinnati	E	01/16/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
32	03	Northport	E	01/21/2014	Technical Assistance: MOU consultation and document review. CASE CLOSED.
33	01	Providence	E	01/24/2014	Technical Assistance: MOU and document review. CASE CLOSED.
34	15	Columbia MO (Harry Truman)	E	01/27/2014	Technical Assistance: MOU consultation and review. CASE CLOSED.
35	11	Detroit (John Dingell)	A	01/29/2014	Technical Assistance: Assisted facility with affiliate IACUC meeting minutes. CASE CLOSED.
36	04	Philadelphia	S	01/29/2014	Technical Assistance: Assisted facility with question about reporting requirements. CASE CLOSED.
37	12	Chicago (Jesse Brown)	E	01/30/2014	Technical Assistance: FWA modification approved for new facility Director. CASE CLOSED.
38	05	Martinsburg	E	01/30/2014	Technical Assistance: FWA modification approved. New signatory official Timothy Cooke. CASE CLOSED.
39	01	Togus VA Medical and Regional Office Center	E	01/30/2014	Technical Assistance: FWA modification approved to add IRB. CASE CLOSED.
40	03	VA New Jersey HCS	E	01/30/2014	Technical Assistance: FWA renewal approved. CASE CLOSED.
41	20	Portland	E	01/31/2014	Technical Assistance: FWA modification approved deactivation of IRB #2. CASE CLOSED.
42	23	Sioux Falls	E	01/31/2014	Technical Assistance: FWA modification approved new signatory official and new HPA. CASE CLOSED.
43	02	Syracuse	E	01/31/2014	Technical Assistance: FWA modification approved new signatory official. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
44	01	Manchester	E	01/31/2014	Technical Assistance: MOU consultation and review. CASE CLOSED.
45	08	Miami	S	02/03/2014	Technical Assistance: Question regarding use of affiliate IBC. CASE CLOSED.
46	03	VA New York Harbor HCS	H	02/03/2014	Technical Assistance: IRB demonstrates improvement in identifying discrepancies between protocol, ICD and HIPAA authorizations, New SOPs are appropriately developed and approved. CASE CLOSED.
47	06	Hampton	E	02/05/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
48	08	VA Caribbean HCS (San Juan)	E	02/05/2014	Technical Assistance: MOU and document review. CASE CLOSED.
49	08	VA Caribbean HCS (San Juan)	E	02/05/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
50	06	Asheville	S	02/06/2014	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
51	06	Salem	S	02/06/2014	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
52	21	San Francisco	S	02/06/2014	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
53	06	Salisbury (Bill Hefner)	S	02/06/2014	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
54	10	Dayton	S	02/11/2014	Technical Assistance: Provided information on research safety. CASE CLOSED.
55	23	Fargo	S	02/11/2014	Technical Assistance: Provided information on research safety. CASE CLOSED.
56	16	Shreveport (Overton Brooks)	S	02/11/2014	Technical Assistance: Provided information on research safety. CASE CLOSED.
57	01	Manchester	S	02/11/2014	Technical Assistance: Provided information on research safety. CASE CLOSED.
58	12	Hines (Edward Hines)	E	02/12/2014	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
59	21	VA Palo Alto HCS	S	02/12/2014	Technical Assistance: Provided information on chemical safety. CASE CLOSED.
60	09	Huntington	E	02/14/2014	Technical Assistance: MOU and document consultation and review. CASE CLOSED.
61	11	Detroit (John Dingell)	A	02/18/2014	Technical Assistance: Assisted facility with question about affiliate IACUC and R&D Committee's role. CASE CLOSED.
62	04	Philadelphia	S	02/18/2014	Technical Assistance: Assisted facility with question about SRS Appointment Letters. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
63	08	VA Caribbean HCS (San Juan)	S	02/18/2014	Technical Assistance: Provided information on research safety. CASE CLOSED.
64	08	Tampa (James Haley)	A	02/18/2014	Technical Assistance: Assisted facility with question about semiannual animal welfare checklists. CASE CLOSED.
65	20	VA Puget Sound HCS	E	02/18/2014	Technical Assistance: MOU and document consultation and review. CASE CLOSED.
66	01	Providence	E	02/25/2014	Technical Assistance: Document consultation and review. CASE CLOSED.
67	07	Columbia SC (WRB Dorn)	A	03/07/2014	Technical Assistance: Assisted facility with question regarding Animal Component of Research Protocol (ACORP). CASE CLOSED.
68	07	Columbia SC (WJB Dorn)	A	03/13/2014	Technical Assistance: Assisted facility with question about off-site waivers and WOC appointments. CASE CLOSED.
69	16	Houston (Michael DeBakey)	S	03/13/2014	Technical Assistance: Assisted facility with query about combining laboratory safety inspections and multi-disciplinary vulnerability assessments. CASE CLOSED.
70	08	Tampa (James Haley)	A	03/13/2014	Technical Assistance: Assisted facility with query about IACUC random reviews of 5% of the total active projects each year. CASE CLOSED.
71	17	VA Central Texas HCS	A	03/13/2014	Technical Assistance: Assisted facility with question about retention of research records. CASE CLOSED.
72	19	VA Eastern Colorado HCS	S	03/13/2014	Technical Assistance: Reviewed draft MOU for the academic affiliate institution. CASE CLOSED.
73	04	VA Pittsburgh HCS	A	03/13/2014	Technical Assistance: Assisted facility with question about retention of research records. CASE CLOSED.
74	02	VA Western New York HCS	E	03/13/2014	Technical Assistance: Will review audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
75	05	Washington DC	H	03/14/2014	Technical Assistance: Study approved without discussion; amendment submitted to compare two databases PI presented analysis last year; IRB determined that fabrication of an 'IRB approved' ICD was neither serious nor continuing noncompliance. Strategic discussions between ORO CO, ORD and MCD, COS, and other facility leadership led to agreement (going forward) to conduct conference call 'debriefings' after IRB meetings to discuss observations and best practices. CASE CLOSED.
76	20	Portland	A	03/14/2014	Technical Assistance: Question regarding IACUC reporting of adverse event. CASE CLOSED.
77	17	VA Central Texas HCS	S	03/14/2014	Technical Assistance: Question Subcommittee on Research Safety suspension of research safety protocol. CASE CLOSED.
78	01	VA Connecticut HCS	S	03/14/2014	Technical Assistance: Question regarding Research Safety Officer duties and approvals. CASE CLOSED.
79	01	Bedford (Edith Rogers)	E	03/17/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
80	07	Atlanta	E	03/18/2014	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
81	16	Southeast Louisiana (New Orleans)	A	03/18/2014	Technical Assistance: Reviewed draft MOU for the academic affiliate institution. CASE CLOSED.
82	16	Shreveport (Overton Brooks)	A	03/18/2014	Technical Assistance: RSAW revised draft MOU with academic affiliate. CASE CLOSED.
83	04	Pittsburgh HCS	A	03/18/2014	Technical Assistance: Question regarding research training. CASE CLOSED.
84	07	Columbia SC (WJB Dorn)	A	03/19/2014	Technical Assistance: Assisted facility with IACUC membership question. CASE CLOSED.
85	06	Richmond (HH McGuire)	S	03/19/2014	Technical Assistance: Assisted facility with a question about training requirements. CASE CLOSED.
86	09	Memphis	S	03/19/2014	Technical Assistance: Assisted facility with question regarding storage of materials in research labs. CASE CLOSED.
87	04	Philadelphia	S	03/19/2014	Technical Assistance: Assisted facility with questions about subcommittee composition, continuing review requirements and recordkeeping practices. CASE CLOSED.
88	08	Tampa (James Haley)	S	03/19/2014	Technical Assistance: Assisted facility with a question about biosecurity training. CASE CLOSED.
89	22	VA Long Beach HS	A	03/19/2014	Technical Assistance: Assisted facility with question about shipping requirements. CASE CLOSED.
90	09	Memphis	H	03/20/2014	Technical Assistance: Monitor additional IRB meetings; QA of lapsed protocols; provide support of newly appointed IRB Chair. CASE CLOSED.
91	03	VA New York Harbor HCS	T	03/20/2014	Technical Assistance: Assisted facility BSL3 design query. CASE CLOSED.
92	10	Chillicothe	E	03/21/2014	Technical Assistance: RCEP Remote Technical assistance for HRPP review. CASE CLOSED.
93	10	Columbus (Chalmers Wylie)	E	03/21/2014	Technical Assistance: RCEP Remote Technical assistance for HRPP review. CASE CLOSED.
94	11	Indianapolis (Roudebush)	S	03/26/2014	Technical Assistance: RSAW reviewed revised VA Form 10-0398 (Research Protocol Safety Survey). CASE CLOSED.
95	08	Bay Pines VA Healthcare System	A	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
96	16	Central Arkansas (Little Rock)	A	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
97	08	Miami VA Healthcare System	S	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
98	16	Overton Brooks	A	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
99	01	Providence	A	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
100	01	White River Junction	S	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
101	01	White River Junction	S	04/01/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
102	20	Portland	S	04/02/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
103	22	VA San Diego Healthcare System	A	04/02/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
104	02	VA Western New York Healthcare System	S	04/02/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
105	07	Columbia SC Wm. Jennings Bryan Dorn	A	04/02/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
106	05	Washington DC	E	04/07/2014	ORO Remote Technical assistance for RCEP. CASE CLOSED.
107	04	VA Pittsburgh Healthcare System	E	04/08/2014	ORO Remote Technical assistance for RCEP. CASE CLOSED.
108	16	Central Arkansas (Little Rock)	A	04/09/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
109	17	Central Texas Veterans HCS	A	04/09/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
110	05	VA Maryland HCS	S	04/09/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
111	03	VA New Jersey HCS	S	04/09/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
112	03	Northport	S	4/17/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
113	16	Overton Brooks	A	4/17/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
114	07	Tuscaloosa	E	04/17/2014	ORO Remote Technical assistance for RCEP. CASE CLOSED.
115	05	VA Maryland HCS	I	04/17/2014	Inquiry into the need for additional RISP reporting based on an NSOC complaint (not an incident, reporting not required). CASE CLOSED.
116	01	VA Central Western Massachusetts (Northampton)	S	04/18/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
117	03	VA New Jersey HCS	A	04/18/2014	ORO remote technical assistance for RSAW. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
118	20	Boise	A	04/29/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
119	05	VA Maryland HCS	S	04/29/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
120	07	Charlie Norwood	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
121	23	Iowa City	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
122	09	Lexington	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
123	08	North Florida/South Georgia Veterans Health System	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
124	01	VA Boston Healthcare System	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
125	03	VA NY Harbor Healthcare System	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
126	19	VA Salt Lake City HCS	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
127	12	Madison (William Middleton)	A	04/30/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
128	17	Central Texas Veterans HCS	S	05/06/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
129	18	Phoenix VA HCS	S	05/06/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
130	03	VA NY Harbor Healthcare System	S	05/06/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
131	12	Hines IL (Edward Hines)	A	05/14/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
132	03	Bronx (James J. Peters)	S	05/14/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
133	17	VA North Texas HCS	A	05/14/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
134	03	VA NY Harbor Healthcare System	S	05/14/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
135	10	Cincinnati	S	06/02/2014	ORO remote technical assistance for RSAW. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
136	04	Clarksburg (Louis Johnson)	E	06/02/2014	New RCO support program including coaching and educational needs assessment and resources.
137	07	Charleston (Ralph Johnson)	A	06/02/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
138	03	VA New Jersey HCS	S	06/04/2014	ORO Remote Technical Assistance for RSSP. CASE CLOSED.
139	07	Columbia (Wm. Jennings Bryan Dorn)	A	06/06/2014	ORO remote technical assistance for ACUP. CASE CLOSED.
140	01	Bedford (Edith Rogers)	R	06/09/2014	ORO Remote Technical Assistance for R&DC. CASE CLOSED.
141	23	Fargo	S	06/09/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
142	18	New Mexico VA HCS	S	06/09/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
143	01	Bedford (Edith Rogers)	H	06/10/2014	ORO remote Technical Assistance for HRPP. CASE CLOSED.
144	07	Birmingham	S	06/17/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
145	07	Charleston (Ralph Johnson)	A	06/17/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
146	21	San Francisco	S	06/20/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
147	21	VA Palo Alto HCS	S	06/20/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
148	11	Battle Creek	E	06/23/2014	ORO On-Site Technical Assistance visit for RCEP. CASE CLOSED.
149	08	Bay Pines VA Healthcare System	S	06/25/2014	ORO remote technical assistance for RSSP. CASE CLOSED.
150	16	G.V. (Sonny) Montgomery	S	06/25/2014	ORO remote technical assistance for RSSP. CASE CLOSED.
151	23	Iowa City	A	06/25/2014	ORO remote technical assistance for RSAW. CASE CLOSED.
152	09	Memphis	S	06/25/2014	Remote technical assistance for RSSP. CASE CLOSED.
153	18	New Mexico VA HCS	A	06/25/2014	ORO remote technical assistance for ACUP. CASE CLOSED.
154	15	St. Louis	E	06/27/2014	ORO Remote Technical assistance for RCEP to new RCO.
155	10	Cincinnati	E	06/30/2014	ORO Remote Technical Assistance for RCEP CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
156	09	Lexington	A	06/30/2014	ORO remote technical assistance for ACUP. CASE CLOSED.
157	18	New Mexico VA HCS	S	6/30/2014	ORO remote technical assistance for RSSP. CASE CLOSED.
158	04	Philadelphia	S	06/30/2014	ORO remote technical assistance for RSSP. CASE CLOSED.
159	21	VA Sierra Nevada HCS	E	7/2/2014	Technical Assistance: New RCO support program including coaching and educational needs assessment and resources.
160	07	Charleston (Ralph Johnson)	A	7/7/2014	Technical Assistance: Assisted facility with a question regarding electronic storage of subcommittee meeting minutes. CASE CLOSED.
161	08	Miami VA HCS	S	7/7/2014	Technical Assistance: Assisted facility with a question regarding FDC reporting of subcommittee approval lapses. CASE CLOSED.
162	07	Charleston (Ralph Johnson)	A	7/8/2014	Technical Assistance: Assisted facility with query regarding scopes of practice documentation. CASE CLOSED.
163	17	Central Texas Veterans HCS	A	7/9/2014	Technical Assistance: Assisted facility with question regarding notification of IACUC in amendment approval. CASE CLOSED.
164	08	Tampa (James Haley)	E	7/10/2014	Technical Assistance: Document review. CASE CLOSED.
165	21	San Francisco	M	7/14/2014	Technical Assistance: VHA Handbook 1058.02 'Research Misconduct' (with an emphasis on the requirements pertaining to research misconduct Inquiries); and conducting witness interviews. CASE CLOSED.
166	08	Tampa (James Haley)	E	7/15/2014	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
167	11	Saginaw (Aleda Lutz)	E	7/15/2014	Technical assistance by RCEP in support of onsite HRPP review. CASE CLOSED.
168	11	VA Ann Arbor HCS	E	7/15/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
169	23	Iowa City	E	7/15/2014	Technical Assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
170	08	Bay Pines VA HCS	S	7/18/2014	Technical Assistance: Assisted facility with questions regarding SRS review procedures. CASE CLOSED.
171	21	VA Palo Alto HCS	A	7/18/2014	Technical Assistance: Assisted facility with a question regarding triennial / de novo protocol reviews. CASE CLOSED.
172	23	VA Nebraska-Western Iowa HCS	A	7/18/2014	Technical Assistance: provided guidance to the facility regarding external agency reporting. CASE CLOSED.
173	16	Houston (Michael DeBakey)	E	7/23/2014	Technical assistance: New RCO support program will include coaching and educational needs assessment and resources.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
174	02	Syracuse	A	7/31/2014	Technical Assistance: Assisted facility with question about IACUC Chair. CASE CLOSED.
175	17	Central Texas Veterans HCS	A	7/31/2014	Technical Assistance: Assisted facility with question on offsite waivers. CASE CLOSED.
176	17	Central Texas Veterans HCS	A	7/31/2014	Technical Assistance: Assisted facility with question about controlled substances. CASE CLOSED.
177	18	New Mexico VA HCS	A	7/31/2014	Technical Assistance: Assisted facility with questions about animal holding protocols. CASE CLOSED
178	12	Hines IL (Edward Hines)	H	8/5/2014	The issues discussed during this remote visit were the recording of guests in IRB minutes, verification of final quorum count from yesterday's meeting, IRB members' role in ratifying expedited approvals by the Chair or designee, set-up and use of repositories, clarifying why studies have to remain open when they are only in manuscript preparation phase, and the use of a Systems of Records Notice (SORN) with data repositories. CASE CLOSED.
179	01	Providence	A	8/7/2014	Answered question regarding the need for a new ACORP versus an amendment. CASE CLOSED.
180	01	White River Junction	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
181	04	Coatesville	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
182	04	Philadelphia	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
183	08	Tampa (James Haley)	A	8/7/2014	Answered question about requirement for protocol audits during IACUC semiannual program review. CASE CLOSED.
184	10	Cleveland (Louis Stokes)	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
185	15	Columbia MO (Harry Truman)	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
186	15	St. Louis	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
187	18	New Mexico VA HCS	A	8/7/2014	Answered question on reporting of lapses in annual IACUC reviews. CASE CLOSED.
188	19	VA Eastern Colorado HCS	A	8/7/2014	Technical Assistance: Suggestions for improvement in preparation for AAALAC site visit. CASE CLOSED.
189	04	Coatesville	S	8/11/2014	Answered question about SRS reviews of lapsed protocols. CASE CLOSED.
190	10	Cincinnati	A	8/11/2014	Answered question about protocol audits during IACUC semiannual program reviews. CASE CLOSED.
191	08	Tampa (James Haley)	A	8/14/2014	ORO assisted facility with question regarding ACORP versions. CASE CLOSED.
192	19	VA Eastern Colorado HCS	A	8/14/2014	Answered question about use of an RSAW Onsite Review as part of an IACUC semiannual facility inspection. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
193	06	Richmond (HH McGuire)	A	8/15/2014	Answered question about transportation of dogs from the VA to an affiliate. CASE CLOSED.
194	19	VA Eastern Colorado HCS	S	8/15/2014	Assisted facility with question on frequency of emergency shower testing and what is involved in testing. CASE CLOSED.
195	19	VA Eastern Colorado HCS	S	8/15/2014	Answered question on reciprocation with affiliate safety training. CASE CLOSED.
196	21	VA Central California HCS	S	8/19/2014	Assisted facility with question about SRS membership. CASE CLOSED.
197	16	Houston (Michael DeBakey)	E	8/25/2014	Technical assistance: New RCO support program including coaching and educational needs assessment and resources. Duplicate Entry. CASE CLOSED.
198	01	VA Central Western Massachusetts HCS	S	8/27/2014	RSAW assisted facility with a question regarding Biological Material Survey Attestation. CASE CLOSED.
199	03	VA NY Harbor HCS	S	8/27/2014	RSAW assisted facility with a question regarding modifications to the Research Protocol Safety Survey Form 10-0398. CASE CLOSED.
200	03	VA NY Harbor HCS	S	8/27/2014	RSAW assisted facility with a question regarding Subcommittee on Research Safety (SRS) review of exempt protocols. CASE CLOSED.
201	03	VA NY Harbor HCS	S	8/27/2014	RSAW assisted facility with a question regarding re-opening of BSL-3 facility. CASE CLOSED.
202	04	Philadelphia	A	8/27/2014	RSAW assisted facility with a question regarding requirements for off-site waivers. CASE CLOSED.
203	12	Hines IL (Edward Hines)	H	8/27/2014	Provided technical assistance on management of the IRB meeting, in particular addressed issues with those participating via teleconference; ICD verbiage related to research injuries and subject's participation in a study once they drop put; and their not using the VAs Conflict of Interest form. CASE CLOSED.
204	01	VA Boston HCS	S	8/28/2014	Assisted facility with research safety stand down question. CASE CLOSED.
205	01	VA Connecticut HCS	S	8/28/2014	Assisted facility with question about research safety stand down. CASE CLOSED.
206	02	Albany (Samuel Stratton)	S	8/28/2014	Assisted facility with question about research safety stand down day. CASE CLOSED.
207	05	VA Maryland HCS	S	8/28/2014	Assisted facility with question about research safety stand down. CASE CLOSED.
208	06	Asheville	S	8/28/2014	Assisted facility with question about research safety stand down. CASE CLOSED.
209	07	Charleston (Ralph Johnson)	A	8/28/2014	Assisted facility with question on ACORP closure and forms. CASE CLOSED.
210	10	Cincinnati	A	8/28/2014	Reviewed an animal care and use MOU between Cincinnati VAMC and the University of Cincinnati. CASE CLOSED.
211	15	Columbia MO (Harry Truman)	A	8/28/2014	Assisted facility with question about justification for use of non-pharmaceutical grade pentobarbital. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
212	16	Southeast Louisiana Veterans HCS	E	**8/28/2014**	Technical assistance: RCO support including coaching and educational needs assessment and resources. Corrective auditing plan reviewed with SRO and accepted. All audits completed. CASE CLOSED.
213	20	Portland	S	**8/28/2014**	Assisted facility with question about reporting lapses in annual SRS reviews of safety protocols. CASE CLOSED.
214	22	VA Greater Los Angeles HCS	A	**8/28/2014**	Assisted facility during an AAALAC site visit. CASE CLOSED.
215	12	Hines IL (Edward Hines)	H	**9/4/2014**	The IRB instituted several practices to concerns relating to participation of voting members attending via teleconference or v-tel. They include: 1) members must make every effort to be physically present; 2) affiliated VA members will attend via v-tel; 3) a roll call will be taken of voting actions taken for those attending via teleconference; and 4) voting members will have to physically announce their departure of meetings. Also the IRB will try to locate a more accommodating room. CASE CLOSED.
216	21	VA Palo Alto HCS	S	**9/5/2014**	RSAW assisted facility with a question regarding research training requirements. CASE CLOSED.
217	05	VA Maryland HCS	E	**9/9/2014**	Technical Assistance: RCO support including coaching and educational needs assessment and resources.
218	06	Durham	S	**9/9/2014**	ORO assisted facility with question about BSAT attestation. CASE CLOSED.
219	06	Richmond (HH McGuire)	E	**9/9/2014**	MOU consultation and review CASE CLOSED.
220	12	Jesse Brown	S	**9/9/2014**	Assisted facility with BSAT attestation question. CASE CLOSED.
221	20	Portland	S	**9/9/2014**	Assisted facility with question on exempt quantities of staph enterotoxin, CASE CLOSED.
222	12	Hines IL (Edward Hines)	S	**9/11/2014**	Assisted facility with question about exempt quantities of ricin toxin. CASE CLOSED.
223	22	VA Loma Linda HCS	A	**9/11/2014**	Assisted facility with question if a WOC employee can serve as the IACUC Chair. CASE CLOSED.
224	12	Jesse Brown	E	**9/15/2014**	MOU in review by Medical Center Director.
225	04	Coatesville	E	**9/16/2014**	FWA modification approved for Acting Director CASE CLOSED.
226	04	Wilkes-Barre	E	**9/16/2014**	MOU consultation and review. CASE CLOSED.
227	12	Hines IL (Edward Hines)	H	**9/16/2014**	Facility will provide documents on 2 studies that received expedited amendment approvals. NERO's concern is that these should probably have gone to full board for review and approval and also have had ISO and PO involvement. A discussion will be held with the facility once documents received and reviewed by NERO. CASE CLOSED.
228	18	Phoenix VA HCS	E	**9/16/2014**	FWA modification approved. CASE CLOSED.
229	04	VA Pittsburgh HCS	E	**9/17/2014**	Completed document review for onsite routine review Pittsburgh. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
230	10	Cincinnati	E	9/17/2014	Document review; MOU consultation and review. CASE CLOSED.
231	18	Phoenix VA HCS	E	9/17/2014	FWA modification approved. CASE CLOSED.
232	22	VA Long Beach HCS	E	9/17/2014	FWA modification approved; Interim signatory official. CASE CLOSED.
233	01	Togus	S	9/18/2014	Answered question about Biologic Select Agents and Toxins Attestation procedures. CASE CLOSED.
234	02	Syracuse	S	9/18/2014	Assisted facility with question about Research Safety Stand Down. CASE CLOSED.
235	04	Philadelphia	S	9/18/2014	Answered question about the need for a safety review if blood samples are collected in the clinical lab by clinical lab staff. CASE CLOSED.
236	06	Durham	S	9/18/2014	Answered question about Research Safety Stand Down. CASE CLOSED.
237	10	Cleveland (Louis Stokes)	A	9/18/2014	Provided AAALAC contact information to facility. CASE CLOSED.
238	08	Tampa (James Haley)	S	9/19/2014	Provided information on Occupational Health and Safety Programs. CASE CLOSED.
239	16	Houston (Michael DeBakey)	S	9/19/2014	Provided information on microbiological agent disposal and reporting. CASE CLOSED.
240	19	VA Eastern Colorado HCS	S	9/19/2014	Reviewed an incident involving a laboratory chemical that had recently expired. Facility working on a program to identify all chemicals with the potential to become hazardous as they expire and take appropriate action. CASE CLOSED.
241	22	VA San Diego HCS	S	9/19/2014	Assisted facility with a question regarding Biological Select Agent and Toxin (BSAT) survey for Governmentwide Research Safety stand-down. CASE CLOSED.
242	07	Atlanta	S	9/24/2014	Assisted facility with question about non-exempt quantities of Biologic Select Agent and Toxins. CASE CLOSED.
243	07	Columbia SC (Wm. Jennings Bryan Dorn)	S	9/24/2014	Assisted facility with question about composition of multidisciplinary vulnerability assessment team. CASE CLOSED.
244	08	North Florida/South Georgia	S	9/24/2014	Assisted facility with question about which researchers must complete the Financial Conflict of Interest form. CASE CLOSED.
245	12	Jesse Brown	H	9/24/2014	Monitor dissolution of affiliate IRB#4 and formation of JBVAMC IRB.
246	20	Portland	S	9/24/2014	Assisted facility with question about non-exempt quantities of biological select agents and toxins. CASE CLOSED.
247	03	Bronx (James J. Peters)	M	9/25/2014	Technical assistance on conducting a research misconduct inquiry in accordance with VHA Handbook 1058.02 ('Research Misconduct') was provided to the research misconduct Inquiry Committee. CASE CLOSED.
248	03	Northport	S	9/25/2014	Provided BSAT Attestation Form to unit per their request. CASE CLOSED.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
249	03	VA Hudson Valley HCS	S	9/25/2014	Assisted facility with Biologic Select Agent and Toxin Attestation. CASE CLOSED.
250	11	VA Ann Arbor HCS	S	9/25/2014	ORO assisted facility with a question regarding reporting requirements for VA research involving exempt quantities of Biological Select Agents and Toxins (BSATs). CASE CLOSED.
251	00	VA Central Office	E	9/26/2014	FWA modification approved. CASE CLOSED.
252	03	VA NY Harbor HCS	E	9/26/2014	FWA modification approved. CASE CLOSED.
253	04	Philadelphia	E	9/26/2014	FWA modification approved. CASE CLOSED.
254	09	Mountain Home (James Quillen)	E	9/26/2014	MOU consultation and review. CASE CLOSED.
255	10	Cincinnati	E	9/26/2014	MOU consultation and review. CASE CLOSED.
256	12	Hines IL (Edward Hines)	H	9/26/2014	Technical Assistance by RCEP for onsite HRPP review.
257	20	Portland	E	9/26/2014	FWA modification approved. CASE CLOSED.
258	22	VA Long Beach HCS	E	9/26/2014	FWA modification approved. CASE CLOSED.
259	10	Cleveland (Stokes)	A	10/1/2014	Assistance with Domestic Assurance requested by Office of Laboratory Animal Welfare (OLAW).
260	11	Detroit (Dingell)	E	10/1/2014	ORO remote technical assistance; MOU consultation and review
261	03	NY Harbor	A	10/1/2014	Assistance with Domestic Assurance requested by the Office of Laboratory Animal Welfare (OLAW).
262	17	South Texas (San Antonio)	A	10/1/2014	Assistance with Domestic Assurance requested by Office of Laboratory Animal Welfare (OLAW).
263	16	Central Arkansas (Little Rock)	E	10/3/2014	Site visit consultation and review.
264	01	Central Western Mass	E	10/3/2014	MOU and document consultation and review.
265	10	Dayton	E	10/3/2014	ORO remote technical assistance; FWA modification.
266	19	Eastern Colorado (Denver)	E	10/3/2014	ORO remote technical assistance; Document review for site visit.
267	07	Atlanta	S	10/8/2014	ORO assisted facility with a question regarding maintenance of electronic Safety Data Sheets (SDSs).
268	08	Caribbean (San Juan)	S	10/8/2014	ORO assisted facility with a question regarding establishment of criteria for determining exempt protocol reviews.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
269	17	Central Texas (Temple)	A	10/8/2014	ORO assisted facility with a question regarding storage of electronic data for animal studies.
270	23	Minneapolis	S	10/8/2014	ORO assisted facility with a question regarding use of unencrypted laboratory research equipment.
271	08	North Florida South Georgia (Gainesville)	S	10/8/2014	ORO assisted the facility with a question regarding SRS composition and union representation.
272	22	Southern Nevada (Las Vegas)	H	10/10/2014	Guiding the transfer of external R&DC and HRPP services; external R&DC and HRPP oversight being moved from a VA facility to another VA facility within the same VISN.
273	01	Connecticut (West Haven)	E	10/15/2014	ORO Remote Technical assistance for RCEP to new RCO (beginning) on 10-14-2014.
274	15	Columbia MO (Truman)	A	10/16/2014	Assisted facility with SOP review and question about use of Form 1358 for veterinary service billing.
275	05	Maryland	S	10/16/2014	Assisted facility with question about research records retention.
276	03	Hudson Valley	E	10/20/2014	Technical assistance: Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED.
277	16	Houston (DeBakey)	E	10/21/2014	Reviewed audit plan, interpersonal communication and dynamics with research program, decision support systems in research program office and RCO office, and progress towards audit goals. CASE CLOSED
278	18	Phoenix	E	10/21/2014	Remote Technical Assistance for HRPP onsite review. CASE CLOSED.
279	07	Charleston (RJohnson)	S	10/27/2014	Assisted facility with draft waiver request.
280	19	Eastern Colorado (Denver)	S	10/27/2014	Assisted facility with submission of Institutional Biosafety Committee (IBC) registration to NIH Office of Biotechnology Activities (OBA).
281	18	New Mexico (Albuquerque)	S	10/27/2014	ORO assisted facility with a question regarding SRS appointment of the Research Safety Coordinator.
282	08	Tampa (Haley)	A	10/27/2014	ORO assisted facility with a question regarding research reporting requirements.
283	16	Central Arkansas (Little Rock)	E	10/28/2014	ORO remote technical assistance; FWA modification for interim director.
284	07	Columbia SC (Dorn)	E	10/28/2014	ORO remote technical assistance; FWA modification for new medical center director
285	03	Hudson Valley	E	10/28/2014	Site visit document review. MOU consultation and document review
286	03	Hudson Valley	E	10/28/2014	FWA modification approved for new medical center director
287	15	Kansas City	E	10/28/2014	Document review and MOU consultation prior to site visit

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
288	16	Muskogee (JMontgomery)	E	10/28/2014	FWA modification for interim director
289	16	Muskogee (JMontgomery)	E	10/28/2014	MOU consultation and review for use of R&D services OK City VAMC
290	18	New Mexico (Albuquerque)	E	10/28/2014	FWA modification approved adding new IRB
291	16	Oklahoma City	R	10/28/2014	FWA modification approved interim director
292	08	Orlando	E	10/28/2014	ORO remote technical assistance for veteran complaint. Contacted veteran for inquiry and referred to VHA patient advocate office.
293	17	Central Texas (Temple)	A	10/30/2014	Assisted facility with question about procurement of controlled substances for a non-VA researcher working in VA owned space.
294	16	Central Arkansas (Little Rock)	S	11/3/2014	Assisted facility with question about use of BSL3 laboratory for patient care.
295	21	Sierra Nevada (Reno)	S	11/3/2014	ORO assisted facility with a question regarding SRS membership composition.
296	08	Orlando	E	11/6/2014	Veteran complaint about unresponsiveness of facility patient advocate repeated failure of facility to update account information. Referred to VHA Deputy Chief Billing Officer and Director of Consolidated Patient Account Centers and followed case until problem successfully resolved. CASE CLOSED.
297	12	Hines	H	11/13/2014	Scheduled consultation postponed.
298	07	Augusta (Norwood)	S	11/17/2014	(1) Assisted facility with question on reporting a potential adverse event to the SRS.
299	01	Central Western Mass	S	11/17/2014	(1) Assisted facility with question on SRS amendment review process.
300	07	Columbia SC (Dorn)	A	11/17/2014	(1) Assisted facility with a question about use of controlled drugs on a VA animal protocol conducted at an affiliate.
301	07	Columbia SC (Dorn)	A	11/17/2014	(1) Assisted facility with question on investigator employment status.
302	21	Pacific Islands (Honolulu)	A	11/17/2014	(1) Technical assistance.
303	21	Palo Alto	S	11/17/2014	(1) Assisted facility with question about WOC status for student on investigator's staff.
304	04	Philadelphia	S	11/17/2014	(1) Assisted facility with question about SRS oversight of exempt research.
305	04	Pittsburgh	A	11/17/2014	(1) Assisted facility with question about records management.
306	06	Richmond (McGuire)	A	11/17/2014	(1) Assisted facility with question about counting animals used in research.
307	15	St Louis	S	11/17/2014	(1) Assisted facility with question on SRS membership.

Case	VISN	Facility	Focus	Date	TABLE 2E. REMOTE TECHNICAL ASSISTANCE REVIEWS
308	08	Tampa (Haley)	A	11/17/2014	(1) Assisted facility with question about use of post mortem animal tissue in research.
309	17	Central Texas (Temple)	S	11/21/2014	(1) NA.
310	08	Miami	S	12/1/2014	(1) Assisted facility with question about how long chemical inventory documentation must be maintained.
311	17	Central Texas (Temple)	E	12/2/2014	(1) RCO in first year of position.
312	07	Birmingham	S	12/3/2014	(1) Assisted facility with question about SRS annual review of safety protocols.
313	11	Detroit (Dingell)	A	12/3/2014	(1) Assisted facility with a question regarding reporting requirements.
314	11	Indianapolis (Roudebush)	A	12/3/2014	(1) Assisted facility with question about full committee review versus designated member review for the IACUC.
315	23	Minneapolis	E	12/3/2014	(1) Remote Technical Assistance in advance of the HRPP/IRB routine review by WRO.
316	09	Mountain Home (Quillen)	S	12/3/2014	(1) Assisted facility with a question regarding safety reporting requirements.
317	17	South Texas (San Antonio)	E	12/3/2014	(1) Remote TA in advance of HRPP/IRB routine review by WRO scheduled for week of January 26-30. (2) RCEP review in support of HRPP/R&DC onsite review.
318	16	Central Arkansas (Little Rock)	E	12/8/2014	ORO Remote Technical assistance for RCEP to new RCO.
319	08	Caribbean (San Juan)	H	12/12/2014	(1) VACHS completed review of the list of pre-2009 protocols still collecting/accessing identifiable private information, including PHI, and found all current study practices consistent with policies.
320	05	Washington DC	H	12/12/2014	(1) Provided assistance to IRB Chair following IRB meeting and directed her to OHRP and FDA guidance for future reference. (2) Advised the Chair that the IRB should have scientific expertise instead of using anonymous reviewers picked by the ACOS/R.
321	06	Ashville	H	12/15/2014	(1) Facility completed review of the list of pre-2009 protocols still collecting/accessing identifiable private information, including PHI, and found all current study practices consistent with policies.
322	04	Wilkes-Barre	E	12/17/2014	(1) Technical assistance to new RCO in first year in role.
323	19	Eastern Colorado (Denver)	A	12/19/2014	(1) Assisted facility with question about annual protocol review mechanism.
324	12	Hines	H	12/23/2014	(1) VA investigator conducting off-site research without appropriate authorization. Research participants included non-veterans. Research related injury text in ICD is noncompliant.
325	06	Durham	E	12/30/2014	(1) RCEP review in support of HRPP/R&DC onsite review.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

VA requires that unanticipated serious adverse events (SAEs) in research be reported to, and rapidly reviewed by, the responsible the Institutional Review Board (IRB). Reporting to ORO is required for unanticipated deaths and other unanticipated SAEs that the IRB judges to be caused by, or probably caused by, the research. ORO uses these reports to review local SAE management and assist facilities in improving their research programs.

Summary

- 4 = Cases Continuing from Previous Calendar Year
- **1 = New Cases – January 1 through March 31**
- **4 = New Cases – April 1 through June 30**
- **12 = New Cases – July 1 through September 30**
- **8 = New Cases – October 1 through December 31**
- 25 = Total New Cases in Calendar Year
- 29 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
1	16	Central Arkansas (Little Rock)	10/25/2013	Facility reported a **subject death** in a Phase IIIb study on peripheral artery disease. Cause of death was unknown at the time of the report.	Upon review of additional information, including the subject's death certificate, **the IRB determined that the death was not unanticipated** as it could be attributed to the characteristics of the study population. The IRB further determined that the risk of the research to participating subjects remained unchanged. CASE CLOSED.
2	15	Kansas City	11/24/2013	Subject admitted with hypotension after beginning study treatment on the lowest dose of treatment in this diabetes and acute coronary syndrome event study.	Upon receipt and review of additional information the IRB determined that the event was not related to the research. CASE CLOSED.
3	22	VA Loma Linda HS	12/06/2013	**Subject death** in an industry sponsored diabetes study. Cause of death was ischemic cardiomyopathy and atherosclerotic heart disease. IRB determined event was serious, possibly anticipated, and possibly related.	Upon review of additional information, **the IRB determined that the death was not unanticipated** relative to the study population and that the event was **unlikely to have been related** to the research. CASE CLOSED.
4	15	Kansas City	12/20/2013	Subject on study drug developed hemolytic anemia requiring hospitalization. The SAE reviewer assessed as possibly related to the study treatment.	Subject on study drug developed hemolytic anemia requiring hospitalization but was ultimately able to return home. The IRB determined that the event was most likely not related to the research. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
5	15	Kansas City	**02/03/2014**	**Unexplained death** of a subject in a hepatocellular carcinoma study with a history of angina, arteriosclerosis and hypertension was not initially reported to ORO as required.	ORO instructed facility regarding reporting requirements. Following review of the death certificate, **the IRB determined that the death was not relate**d to the research. CASE CLOSED.
6	16	Central Arkansas (Little Rock)	**04/01/2014**	A subject in study of Liraglutide Effect and Action in Diabetes with a history of coronary artery disease, type 2 diabetes, congestive heart failure, and chronic obstructive pulmonary disease presented to VA emergency department complaining of chest pain.	IRB determined that the incident was not caused by the research and did not require remedial actions. CASE CLOSED.
7	15	Kansas City	**05/28/2014**	**Unanticipated death** of a Veteran participating in CSP Study # 576, "VA Augmentation and Switching Treatments for Improving Depression Outcomes (VAST-D)." The initial report from the family is that the Veteran died at a non-VA community hospital after suffering a "massive heart attack." **See Case #8, below.**	**See Case #8, below.** The subject (who had serious risk factors for cardiovascular disease to include smoking, hyperlipidemia, obesity, and diabetes) had been randomized to receive aripiprazole (5mg/day). There is no firm evidence that aripiprazole is associated with cardiac death of any sort, but there are reports of atypical antipsychotics increasing the risk of such events. Thus, the possibility that the death could have been related to the study drug could not be ruled out with absolute certainty, but **the IRB determined that it was unlikely that the death was related to the research** and required no additional action. CASE CLOSED.
8	00	VA Central Office	**05/30/2014**	**Unanticipated death** in VHA CSP Study # 576, "VA Augmentation and Switching Treatments for Improving Depression Outcomes (VAST-D)." **See Case #7, above.**	**See Case #7, above.** The VA Central IRB Reviewer determined that the **death was possibly, but not probably, related to the research** because the subject had serious underlying risk factors for cardiovascular disease and atypical antipsychotic medications have been reported to be associated with cardiac arrythmias and sudden cardiac arrest. The VA Central IRB concurred and determined that no further action was required. CASE CLOSED.
9	15	Kansas City	**06/22/2014**	Subject in a Phase 2 study of the efficacy and safety of a chemokine receptor antagonist in adults with Type 2 diabetes and overt nephropathy presented to the emergency department with fever, sore throat, and diffuse rash and was hospitalized due to elevated creatinine and possible kidney injury.	Following hospitalization, the patient recovered significantly with the standard of care, and was discharged for home in stable condition. Per PI's clinical note, the patient's kidney function is improved over baseline and patient continues on prednisone. The IRB determined that this SAE was possibly related to the study and that PI has taken appropriate and timely actions to minimize the risk. CASE CLOSED.
10	10	Cincinnati	**7/17/2014**	Facility reported that an industry sponsored coronary artery disease trial was put on a 'formal clinical hold' due to SAEs that occurred at another site. N/A	Trial was put on hold while sponsor DSMB conducted a risk/benefit analysis and reported to FDA. Sponsor subsequently notified sites that enrollment is permanently stopped based on serious allergic events associated with the study drug. No VA research subjects were enrolled at this facility. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
11	09	Tennessee Valley HCS	**8/7/2014**	A venipuncture procedure of the subject hit a brachial (arm) nerve. Subject experienced initial pain which resolved, but similar pain re-occurred several days later.	IRB reviewer determined it was serious, related, and unexpected. Subject referred to VA neurology department for a consult. IRB determined the event to be serious, unanticipated, and related. Electromyography revealed no neuron/axon damage. Subject has history of diabetic neuropathy. Subject declined further treatment. CASE CLOSED.
12	15	Columbia MO (Harry Truman)	**8/11/2014**	Following maintenance chemotherapy a subject developed a fever and rash and reported to the local Emergency Room. Subject was hospitalized, treated with antibiotics, discharged home on antibiotics for a diagnosis of a cellulitis infection (e.g. skin infection).	IRB determined the SAE was serious, related, and unanticipated. The work up for other serious infections came back negative, and subject is improving on therapy at home and going through routine clinical follow up. CASE CLOSED.
13	20	VA Central California (Fresno)	**8/12/2014**	The facility was notified of an **unanticipated death (suicide)** of a participant in VA Cooperative Study Program (CSP) Protocol #577: Colonoscopy vs Fecal Immunochemical Test (FIT). Following initial contact with the research coordinator, consent, and receipt of the FIT kit, there was no further contact between the facility research staff and the subject. **See Case #22, below.**	**See Case #22, below.** Although the incident was serious and unanticipated, the **IRB determined that the death was not related to the research.** CASE CLOSED.
14	20	VA Puget Sound HCS	**8/26/2014**	A subject came for scheduled chemotherapy/radiation therapy and experienced chest pain/pressure, nausea, shortness of breath, and diaphoresis. The subject was transferred to the ER, admitted to the hospital for monitoring and discharged the following day.	Chemotherapy and radiation therapy doses were skipped the day of the events, but resumed after hospital discharge. PI determined the event was possibly related to the study. The subject subsequently withdrew from the research three days later. CASE CLOSED.
15	16	Central Arkansas (Little Rock)	**8/27/2014**	Facility VA Police Officer informed the PI that two Veterans had registered complaints that they were asked for their credit card information when they called the number listed on the recruitment flyer for this study.	All involved were contacted and OIG was notified. The PI requested a copy of the police report as well as a copy of the altered flyer. The IRB Chairmen determined that that the event met the definition of a UPR. There was no evidence of non-compliance by the study team, and no further corrective actions were required. Information for potential subjects is currently available at the Help Desk. CASE CLOSED.
16	08	North Florida / South Georgia	**8/27/2014**	An unanticipated human death occurred at a **non-VA site** within a clinical trial of a drug to prevent thrombosis (blood clots) and ischemia (restricted blood flow) during coronary intervention procedures.	The DSMB placed the study on clinical hold because anaphylactic reaction with an outcome of death is not listed in the drug's Investigator's Brochure/package insert. At the time of the clinical hold, **five VA subjects had completed the trial with no adverse events.** CASE CLOSED.
17	12	Madison (William Middleton)	**9/4/2014**	A subject required hospitalization for treatment after an apparent suicide attempt during a CSP study involving augmenting and switching treatments for depression.	The IRB determined that this incident was serious and unanticipated, but not related to the research. The subject has been withdrawn from the study, and has received clinical followup. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
18	10	Cincinnati	**9/8/2014**	Due to a medication dispensing error for 3 days one subject took four tablets instead of one tablet. Subject reported having very vivid dreams, described to resemble 'night terrors' for 3 nights of the days that he took 4 pills. Medical monitor instructed the subject to continue to take one pill per day.	The IRB determined the event to be serious, unanticipated, and related to the research. CASE CLOSED.
19	08	Orlando	**9/16/2014**	**Unanticipated death** of a VA research subject participating in "A Phase III Blinded Randomized Study of Peginterferon Lambda-1a and Ribavirin Compared to Peginterferon Alfa-2a and Ribavirin, each Administered with Telaprevir in Subjects with Genotype-1 Chronic Hepatitis C who are Treatment-naive or Relapsed on Treatment with Peg interferon Alfa and Ribaviri."	**The IRB determined the death was probably related to the study** but since enrollment has been closed and **no other subjects were enrolled** locally, no immediate action was required. One additional VA facility is participating in the study. The facility has been notified of the event by the Sponsor, but no unanticipated, serious adverse events have been reported there. CASE CLOSED.
20	15	Kansas City	**9/24/2014**	Subject received 840mg cetuximab when the intended dose was 940mg. PI believes no harm to subject.	IRB Chair determined the event was serious, unanticipated, and related to the research. Study coordinator will no longer calculate dosing. Research pharmacy and clinic staff will each check dosing prior to any order being processed and administered. CASE CLOSED.
21	20	Portland	**9/25/2014**	Facility reported the sponsor of a multi-site implantable cardioverter-defibrillator (ICD) device trial has alerted of a change in risk profile. This change in risk profile has been identified in the new drug packaging insert and will be associated with anticipated changes in the protocol and informed consent. The corresponding new warnings in the prescription information required monitoring patients with decreased kidney function and lowering the dose of Ranolazine in patients taking certain dose levels of Metformin and Atorvastatin.	The coordinating center identified affected participants, the local PI independently reviewed the medical records of locally enrolled subjects, and the study team contacted the eight local subjects. There were no reports of any direct harm to any subjects enrolled at the facility. The IRB reviewed the study amendment, and updated informed consent form (ICF). The IRB determined that the study team must re-consent all affected study participants using the updated ICF. CASE CLOSED.
22	00	VA Central Office	**10/16/2014**	The facility was notified of an **unanticipated death (suicide)** of a participant in VA Cooperative Study Program (CSP) Protocol #577: Colonoscopy vs Fecal Immunochemical Test (FIT). Following initial contact with the research coordinator, consent, and receipt of the FIT kit, there was no further contact between the facility research staff and the subject. **See Case #13, above.**	**See Case #13, above.** Although the incident was serious and unanticipated, the **VA Central IRB determined that the death was not related to the research.** CASE CLOSED. The IRB did not require further action or review. CASE CLOSED.

TABLE 2F. REMOTE REVIEWS OF UNANTICIPATED SERIOUS ADVERSE EVENTS

Case	VISN	Facility	Date	Unanticipated Serious Event	Status / Remedial Actions
23	16	Oklahoma City	**11/13/2014**	(1) Release of Personally Identifiable Information and Protected Health Information. A group text message from a laboratory technician was sent from the lab tech's personal cell phone and included the last name of a VA patient, last four of the VA patient's SSN, and health information regarding the VA Medical Center patient. The message included an individual in the 'group' that was a non-VA employee and not related to the research.	Removed text message from device, sent credit monitoring notification letter to Veteran, education, and message to all VAMC personnel from MCD reminding staff not to use personal devices to text Veterans' PII and PHI. The CIRB determined the incident was an Unanticipated Problem that was serious, and related to the research. CASE CLOSED.
24	00	VA Central Office	**11/24/2014**	(1) A patient participating in a multicenter study of two methods of detecting colorectal cancer developed second degree heart block during a study procedure. He was evaluated and discharged with a heart monitor, which revealed periods of third degree heart block, resulting in referral for pacemaker placement.	(1) This event was determined to be unanticipated, serious, and probably related to the research. The patient underwent placement of a cardiac pacemaker for treatment of heart block. CASE CLOSED.
25	06	Richmond (McGuire)	**11/25/2014**	Delay in local site investigator (LSI) reports to the IRB, Delay in sponsor reports to the LSI.	Notification of all subjects of DSMB findings within 7 days including withdrawal option. Copy of FDA correspondence. Confirmation from sponsor that all future reports will be submitted to the IRB in a timely manner. CASE CLOSED.
26	12	Jesse Brown	**12/5/2014**	(1) Delay in reporting to the VA CIRB a life-threatening SAE that required hospitalization.	(1) VA CIRB determined no further action was required. (2) R&DC concurred with VA CIRB determination. CASE CLOSED.
27	23	Minneapolis	**12/11/2014**	(1) Suicide attempt by Veteran research participant.	(1) IRB assessment and management of reported SAE. CASE CLOSED.
28	15	Kansas City	**12/21/2014**	Study participant presented to a private hospital on the advice of the Investigator after receiving a lab report indicating high potassium levels (hyperkalemia). Investigational product dosage had been reduced after participant reported diarrhea (a known side effect) and dehydration, likely causing acute kidney injury and hyperkalemia. Individual was hospitalized and released 3 days later in stable condition.	Pending.
29	17	South Texas (San Antonio)	**12/29/2014**	A study subject received study medication for 3 days and then required hospitalization for low potassium levels.	IRB require development of an amendment addressing this new risk, specific parameters for monitoring and providing treatment to subjects experiencing cramps; and ensuring modifications are made to the study plan and the informed consent document.

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

ORO monitors all reported cases of alleged research misconduct (i.e., fabrication, falsification, or plagiarism) that involve VA research. ORO ensures that correct procedures are used by each facility's Inquiry and Investigation Committees and provides guidance as needed. ORO determines when notification of various VA offices and federal agencies must be given and facilitates coordination. In certain cases, ORO may perform onsite technical visits to provide assistance.

* NOTE: Because of the need to follow strict federal Inquiry, Investigation, and Adjudication procedures for research misconduct, and because of the range of consequences for research misconduct and debarment, such cases may take months or years to resolve. In addition, the resolution of some cases is delayed because they are also under the jurisdiction of the VA Office of Inspector General (OIG), the Department of Health and Human Services (HHS) Office of Research Integrity, the Food and Drug Administration (FDA), and/or a university affiliate.

Summary

- 7 = Cases Continuing from Previous Calendar Year
- **1 = New Cases – January 1 through March 31**
- **2 = New Cases – April 1 through June 30**
- **3 = New Cases – July 1 through September 30**
- **3 = New Cases – October 1 through December 31**
- 9 = Total New Cases in Calendar Year
- 16 = Total Cases (Continuing Plus New) in Calendar Year

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
1	02	Syracuse	04/29/2010	Research misconduct allegation involving fabrication and falsification.	Status: VISN adjudication resulted in findings of research misconduct against two Respondents; one Respondent filed an appeal with the USH, who overturned the findings against that Respondent; the other Respondent did not file an appeal, and the findings against that Respondent stand. CASE CLOSED.
2	11	Detroit (John Dingell)	03/30/2012	Research misconduct allegations involving falsification.	Status: The acting VISN Director adjudicated the case and made findings of research misconduct; the Respondent appealed the findings and corrective actions; the USH denied the Respondent's appeal and upheld all of the findings and corrective actions. CASE CLOSED.
3	07	Birmingham	11/09/2012	Research misconduct allegation involving falsification.	Status: Inquiry completed. Investigation has been convened.

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
4	03	VA New York Harbor HCS	05/31/2013	Research misconduct allegation involving falsification.	(1) A VA determination was made that there was not a preponderance of evidence to make a finding of research misconduct against the Respondent. However, based on the conclusion that the Respondent engaged in poor research practices, the Respondent will be placed on a probationary period for two years during which the Respondent's data must be reviewed by a senior research scientist. CASE CLOSED.
5	16	Oklahoma City	06/11/2013	Research misconduct allegation involving falsification.	Status: An Inquiry Committee determined that there was insufficient evidence to warrant opening a research misconduct Investigation. CASE CLOSED.
6	01	VA Boston Healthcare System	08/01/2013	Research misconduct allegation involving fabrication and/or falsification.	Status: Inquiry completed. Investigation has been convened.
7	11	Detroit (John Dingell)	08/29/2013	Research misconduct allegations involving fabrication and falsification.	Status: An Inquiry determined that there was insufficient evidence to open an Investigation. CASE CLOSED.
8	01	VA Boston Healthcare System	**01/27/2014**	Research misconduct allegation involving plagiarism.	Status: A determination was made that there was not a reasonable basis on which to re-open, or convene a new, research misconduct Investigation. CASE CLOSED.
9	21	San Francisco	**05/22/2014**	Research misconduct allegations involving falsification.	ORO completed its assessment and determined that a research misconduct inquiry was warranted. Inquiry completed. Investigation has been convened.
10	03	Northport	**06/19/2014**	Potential research misconduct allegation involving fabrication and/or falsification.	A determination was made that the allegation did not pertain to research. CASE CLOSED.
11	07	Atlanta	**8/1/2014**	Research misconduct allegation involving falsification.	ORO completed its assessment of the allegations and determined that the allegations did not pertain to research misconduct. CASE CLOSED.
12	10	Cincinnati	**8/18/2014**	Research misconduct allegation involving plagiarism.	ORO completed it assessment of the allegations and determined that the allegations did not meet the requirements for opening a research misconduct inquiry. CASE CLOSED.
13	03	Bronx (James J. Peters)	**9/7/2014**	Research misconduct allegation involving fabrication.	Inquiry completed. Investigation has been convened.
14	07	Augusta (Norwood)	10/6/2014	(1) Research misconduct allegations involving falsification.	(1) A research misconduct inquiry was convened.
15	11	Indianapolis (Roudebush)	11/13/2014	(1) Research misconduct allegation involving fabrication and/or falsification of research reported in a published journal article.	(1) ORO's assessment of the allegation is pending.

TABLE 2G. RESEARCH MISCONDUCT AND DEBARMENT PROCEDURAL REVIEWS

Case	VISN	Facility	Date	Issue of Misconduct	Status
16	12	Madison (Middleton)	12/18/2014	(1) Research misconduct allegations involving plagiarism in a research abstract and a VA grant application.	(1) RIO processing of the allegations is pending.

TABLE 3. ACRONYMS

A = Animal Care and Use Program Focus
AAALAC = Association for Assessment and Accreditation of Laboratory Animal Care International
AAHRPP = Association for Accreditation of Human Research Protection Programs
ACORP = Animal Component of Research Protocol
ACOS/R = Associate Chief of Staff for Research
ACUP = Animal Care and Use Program
AIB = Administrative Investigation Board
ANSI = American National Standards Institute
AO/R = Administrative Officer for Research
ARF = Animal Research Facility
AWA = Animal Welfare Act
AWR = Animal Welfare Regulations

BSC = Biosafety Cabinet
BSL-3 = Biosafety Level 3

CAP = Corrective Action Plan
CC = CASE CLOSED.
CIO = Chief Information Officer
CIRB = Central Institutional Review Board (ORD)
CITI = Collaborative Institutional Training Initiative
CO = ORO Central Office
COI = Conflict of Interest
CoPI = Co-Principal Investigator
COS = Chief of Staff
CPRS = VHA Computerized Patient Record System
CR = Continuing Review
CRADA = Cooperative Research & Development Agreement
CRADO = VHA Chief Research & Development Officer
CRC = Clinical Research Coordinator
CSP = VHA Cooperative Studies Program
CT = Computerized Tomography (Scan)
CVMO = ORD Chief Veterinary Medical Officer

DMC / DSMB = Data Monitoring Committee / Data and Safety Monitoring Board
DMR = Designated Member Review
DoD = Department of Defense
DTA = Data Transfer Agreement
DUA = Data Use Agreement

E = Research Compliance Officer Education Focus
ECOG = Eastern Cooperative Oncology Group
EIL = Equipment Inventory List
EOC – Environment of Care
ESCCB = Enterprise Security Change Control Board

FCD = Facility Center Director
FCR = Full Committee Review
FDA = Food and Drug Administration
FDC = Facility Director Certification
FIPS = Federal Information Processing Standards
FISMA = Federal Information Security Management Act
FOIA = Freedom of Information Act
FTE/FTEE = Full Time Employee/Equivalent

GFE = Government Furnished Equipment
GFI = Ground Fault Interrupter

H = Human Research Protection Focus
HCS = HCS
HHS = Department of Health and Human Services
HIPAA = Health Insurance Portability & Accountability Act
HRPP = Human Research Protection Program
HSR&D = Health Services Research and Development
HVAC = Heating, Ventilation and Air Conditioning

I = Information Security Focus
IACUC = Institutional Animal Care and Use Committee
IBC = Institutional Biosafety Committee
ICD / ICF = Informed Consent Document / Form
IDE = FDA Investigational Device Exemption
III = Individually Identifiable Information
IND = FDA Investigational New Drug
IRB = Institutional Review Board
IRM = Information Resource Management
ISA/SIA = Interconnection Security Agreement
ISO = Information Security Officer
IT = Information Technology
ITOC = VA OI&T Oversight and Compliance Office

LAN = Local Area Network
LAR = Legally Authorized Representative
LSI = Local Site Investigator

M = Research Misconduct Focus
MCD = Medical Center Director
MOU = Memorandum of Understanding
MRI = Magnetic Resonance Imaging
MVP = VA Million Veteran Program Research Study

NARA = National Archives and Records Administration
NIH = National Institutes of Health
NIOSH = National Institute for Occupational Safety & Health

(continued on next page)

TABLE 3. ACRONYMS

(continued from previous page)

NIST = National Institute of Standards and Technology
NOK = Next of Kin
NPC = Nonprofit Research and Education Corporation
NSOC = VA Network & Security Operations Center

OBA = NIH Office of Biotechnology Activities
OE = Other Equipment (Non-GFE)
OEF-OIF = Operation Enduring Freedom / Iraqi Freedom
OGC = Office of General Counsel
OHRP = HHS Office for Human Research Protections
OHSP = Occupational Health and Safety Program
OIG = Office of Inspector General
OI&T / OIT = VA Office of Information and Technology
OLAW = PHS Office of Laboratory Animal Welfare
ORD = VHA Office of Research and Development
OPC = Outpatient Clinic
ORI = HHS Office of Research Integrity
OSHA = Occupational Safety and Health Administration
OSHP = Occupational Safety and Health Program
OTA = On-Site Technical Assistance

P = Multiple Concerns Focus
PBM = VHA Pharmacy Benefits Management
PET = Positron Emission Tomography (Scan)
PHI = Protected Health Information under HIPAA
PHS = Public Health Service
PI = Principal Investigator
PII = Personally Identifiable Information
PKI = Public Infrastructure Key
PO = Privacy Officer
POC = Person Obtaining Consent
PSETS = Privacy Security Event Tracking System (NSOC)
PTSD = Post-Traumatic Stress Disorder

QA = Quality Assurance
QI = Quality Improvement

R = Research & Development Committee Program Focus
R&DC(P) / RDC(P) = Research and Development Committee (Program)
RAP = Remedial Action Plan
RCEP = Research Compliance Officer Education Program
RCO = Research Compliance Officer
RCS = Record Control Schedule
RCT = Randomized Control Clinical Trial
rDNA = Recombinant Deoxyribonucleic Acid
REAP = VHA Research Enhancement Award Program
REDCaP = Research Electronic Data Capture
RIA = Research Integrity Assurance RIO = Research Integrity Officer
RIPP = Research Information Protection Program
RISP = Research Information Security Program
RO = ORO Regional Office
ROI = Release of Information
RPSS = Research Protocol Safety Survey
RSSP = Research Safety and Security Program

S = Research Safety Focus
SAE = Serious Adverse Event
SAT = Select Agent and Toxin
SECVA = Secretary of Veterans Affairs
SIA/ISA = Interconnection Security Agreement
SMART = Site Monitoring Auditing & Review Team
SNC = Serious Noncompliance
SOP = Standard Operating Procedure
SOR = System of Records
SORP = Scope of Research Practice
SRS = R&DC Subcommittee on Research Safety
SSN = Social Security Number
SWOG = Southwest Oncology Group

T = BSL-3 Program Focus
TAV = Technical Assistance Visit (ORO)
TBI = Traumatic Brain Injury

UPR = Unanticipated Problem(s) involving Risk(s)
USDA = United States Department of Agriculture
USH = VA Under Secretary for Health

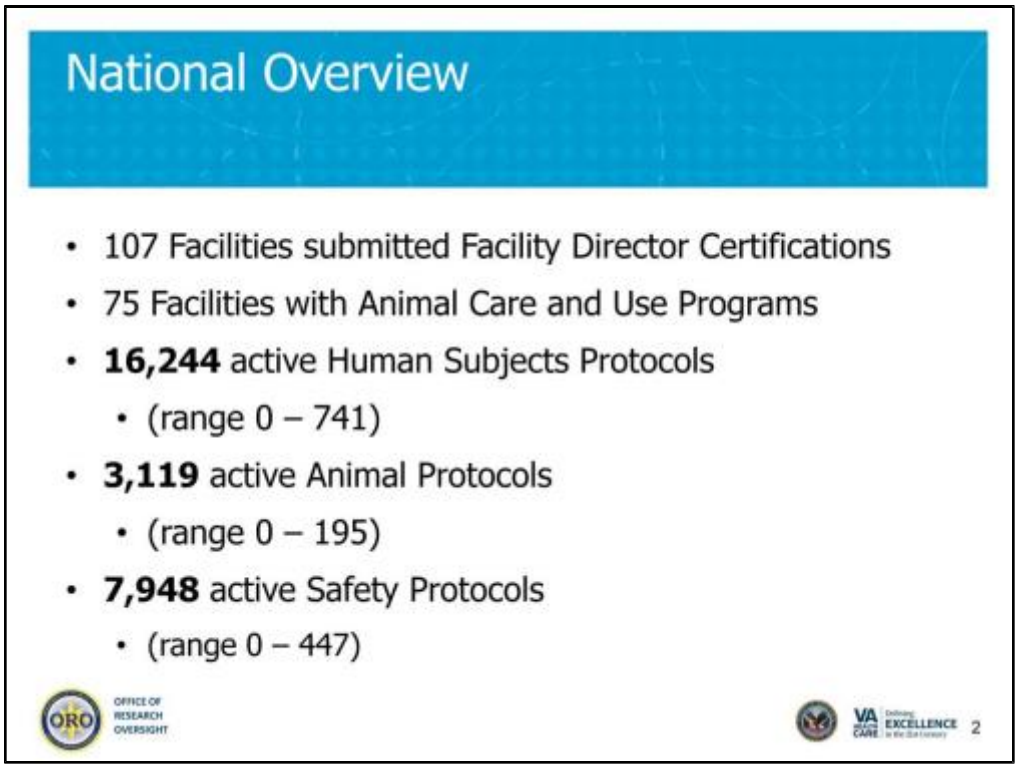
VA = Department of Veterans Affairs
=
VASI = VA Sensitive Information
VHA = Veterans Health Administration
VHACO = VHA Central Office
VINCI = Veterans Informatics Computing Infrastructure
VIREC = VA Information Resource Center
VISN = Veterans Integrated Service Network
VMO = Veterinary Medical Officer
VMU = Veterinary Medical Unit
VPN = Virtual Private Network

WOC = VA Appointment Without Compensation

The Facility Director's Certification of Research Oversight (FDC) has been an annual requirement since 2007. Since 2010, the FDC has consisted of two parts: The first is a review of responsibilities of the Facility Director as well as a checklist of research related requirements meant to serve as a self-review for each research program. The second part is submission of quantitative data related to the Research Program as well as measures obtained from audits completed by the Research Compliance Officer (RCO). The Office of Research Oversight (ORO) monitors this data annually for purposes of 1) reporting back to each research program how their quality metrics compare to other facilities within their Veterans Integrated Service Network (VISN) and nationally, and 2) allowing ORO to assess over time how Veterans Affairs (VA) research programs are performing nationally, and to identify successes in improvement as well as opportunities to do more.

This presentation will review the quantitative data obtained from the FDC covering the reporting period of June 1, 2013, through May 31, 2014. When possible, comparisons will be made with previous years' data. The presentation will highlight those measures where the VA field has documented very good performance. For measures with notable rates of deficiency, possible reasons for the deficiency will be discussed.

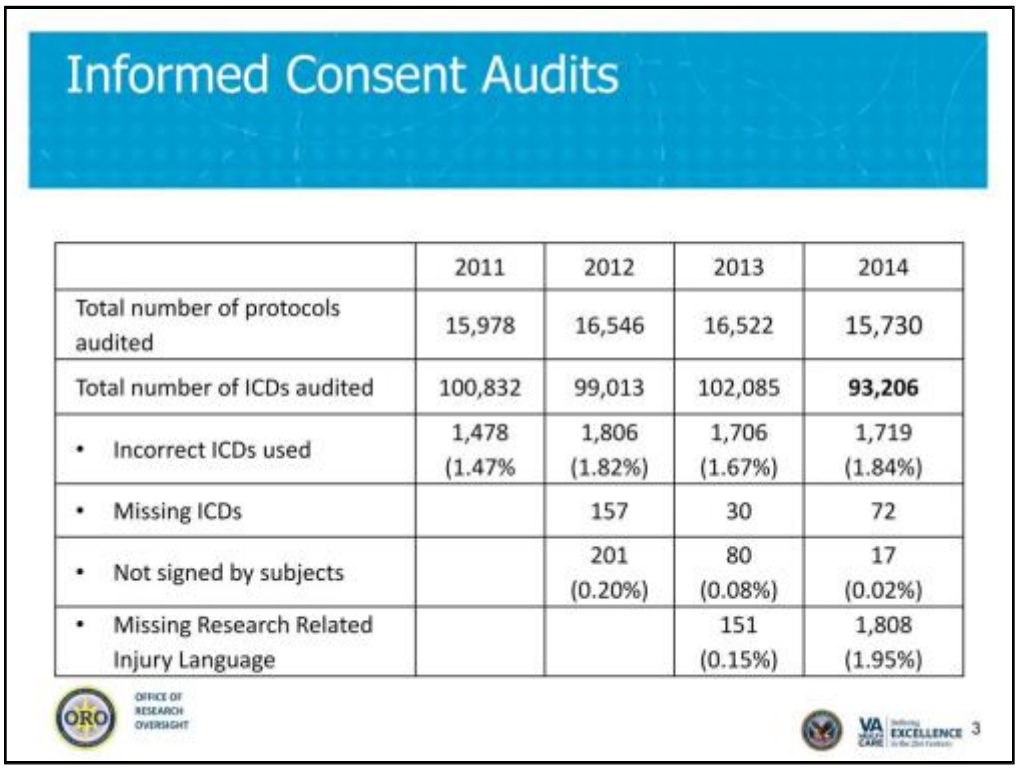
ORO recognizes the tremendous amount of work by the field personnel in the research and compliance efforts that are represented in the data presented here.



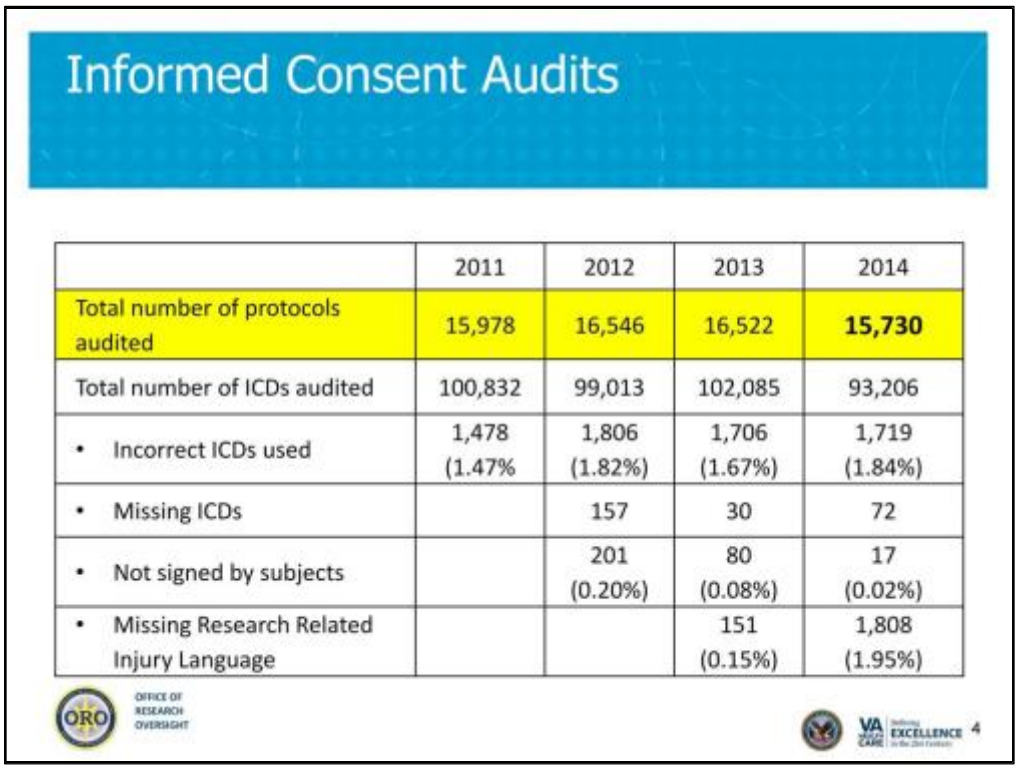
This slide presents a brief overview of the facilities that submitted a Facility Director's Certification and the volume of VA research for this reporting period, 2014. There are currently 107 VA facilities or health care systems that have Federalwide assurances with active human subject research programs submitting an FDC for 2014. This is one facility fewer than last year since one facility elected to close its program in 2013.

There are 75 facilities with active animal programs which is the same as last year. There were 16,244 active human subject protocols reported nationally, as well as 3,119 active animal protocols and 7,945 active safety protocols. ORO uses "safety protocols" here to refer to research overseen by a VA Subcommittee on Research Safety (SRS). These safety studies would typically include basic science research and animal research, as well as certain human studies with safety concerns. The number of open human, animal, and safety studies has remained fairly constant since 2011 with around 16,000 human studies, 3,000 animal studies and 8,000 safety studies.

	2011	2012	2013	2014
Human	16,421	16,602	16,568	16,244
Animal	2,830	3,079	3,203	3,119
Safety	7,097	7,588	8,111	7,948



This slide shows a summary of the data obtained from human subject protocols receiving Informed Consent (IC) audits. Research Compliance Officers (RCOs) are required to audit 100 percent of human subject protocols each reporting period. Deficiencies were identified in fewer than four percent of the Informed Consent Documents (ICDs) audited.

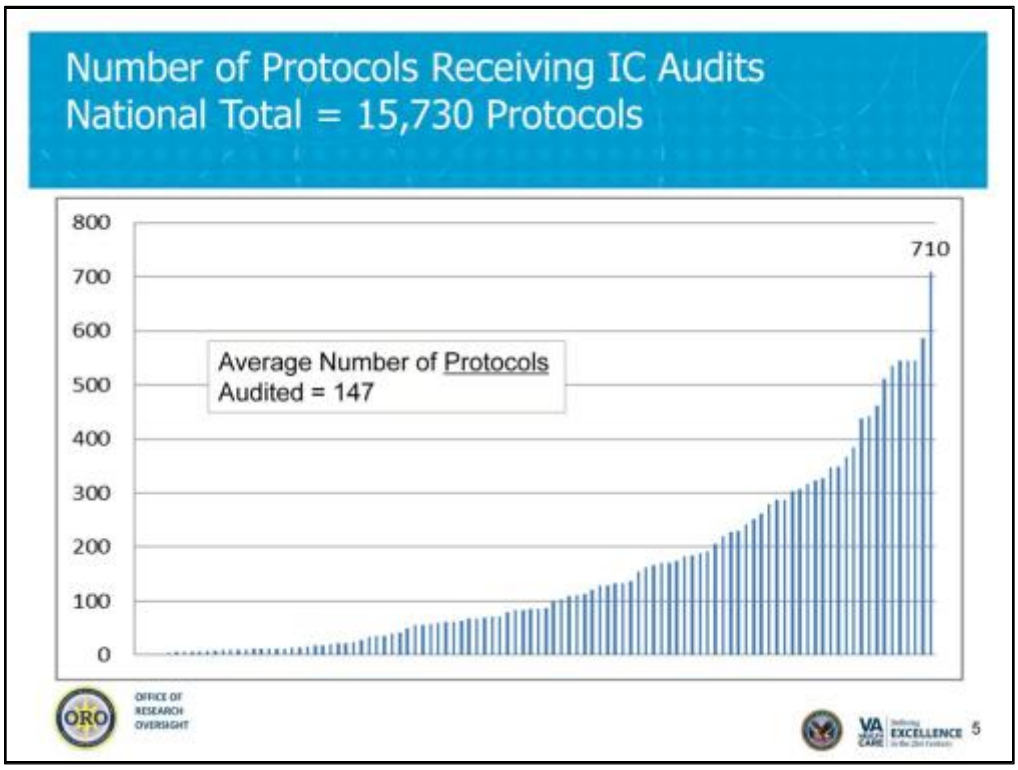


This year, 15,730 protocols were audited, which represents about 97 percent of open human protocols. The number of protocols receiving an IC audit was lower for 2014 than in previous years. However, one facility with almost 400 active protocols was unable to complete any IC audits.

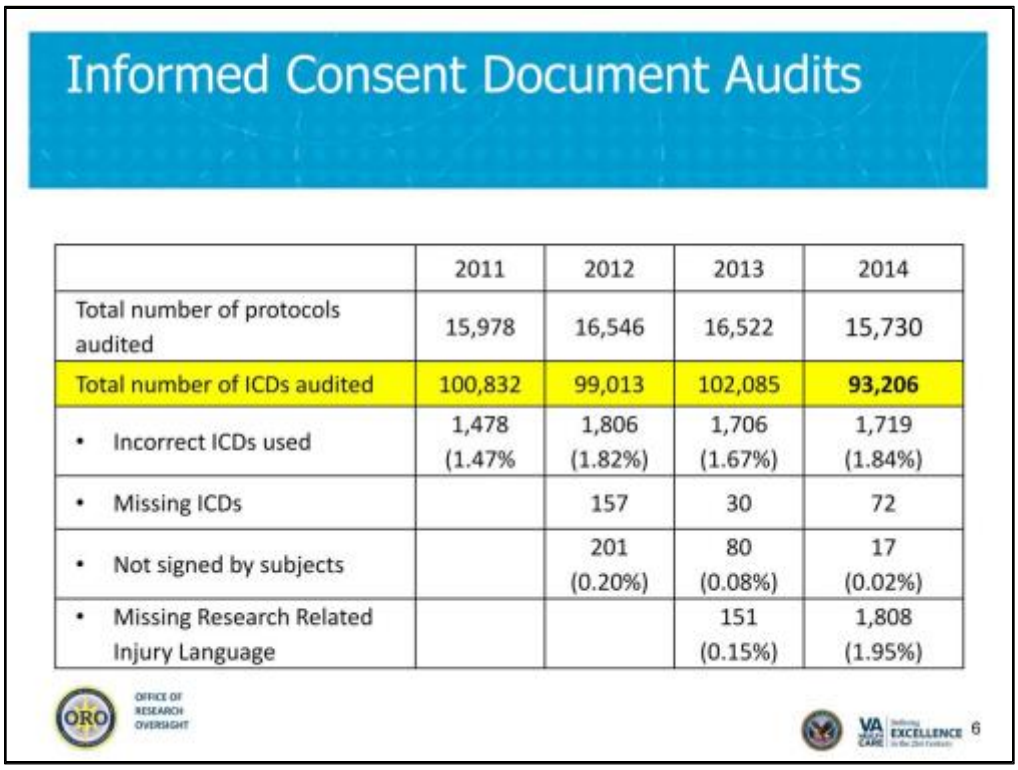
Not shown on this slide is that the number of protocols with actual informed consent documents made up about 25 percent of all protocols audited, which is similar to previous years.

Four years of data has demonstrated fairly consistently that roughly 75 percent of VA human subject research does not involve an actual signed informed consent document. Reasons include that the research may be exempt, the Institutional Review Board (IRB) may have waived informed consent or the documentation of informed consent, or the research did not enroll any new subjects during the reporting period.

RCOs are required to audit all active human subject protocols every year, whether the study has any signed ICDs during the period or not. IC audits for research with no signed documents include an administrative review and assurance that appropriate continuing review (CR) occurred.

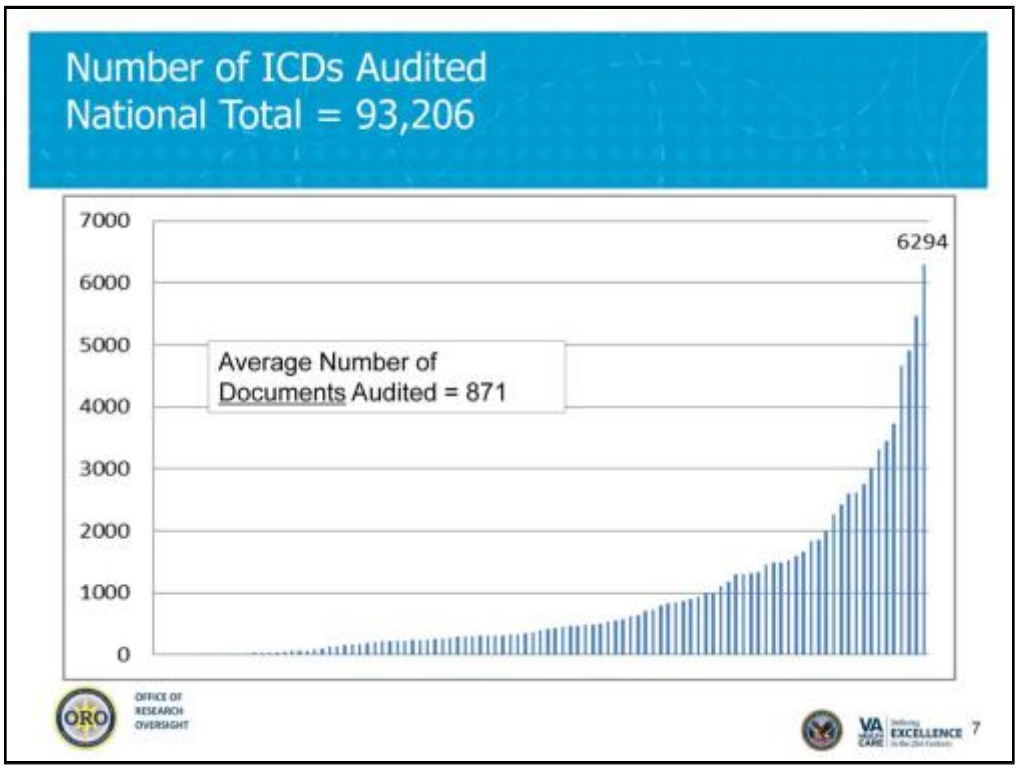


This graph shows the entire population of 107 VA research facilities, with each bar representing one facility. They are in rank order by the number of human research PROTOCOLS audited in 2014 with the largest number to the right. The average number of protocols audited was 147. The largest facility by this measure audited 710 human subject protocols. There were 24 facilities with more than 250 protocols audited. This national profile is not significantly different than last year with about one-half of the facilities auditing 100 or fewer protocols, one-fourth of facilities auditing 101 to 250 protocols, and one-fourth of facilities auditing more than 250 protocols.



The actual number of ICDs audited decreased this year compared to the previous three years, which saw about 100,000 documents audited. In 2014, about 93,000 ICDs were audited. It is important to note that this number does not include the Million Veteran Program (MVP). The presentation will discuss the MVP more in a later slide.

ORO wishes to highlight that whenever RCOs audit an ICD, they also audit for the presence of a required HIPAA authorization. Therefore, in addition to more than 93,000 ICDs audited this period, almost 90,000 HIPAA documents were also audited by RCOs. This will be reviewed again in a later slide.

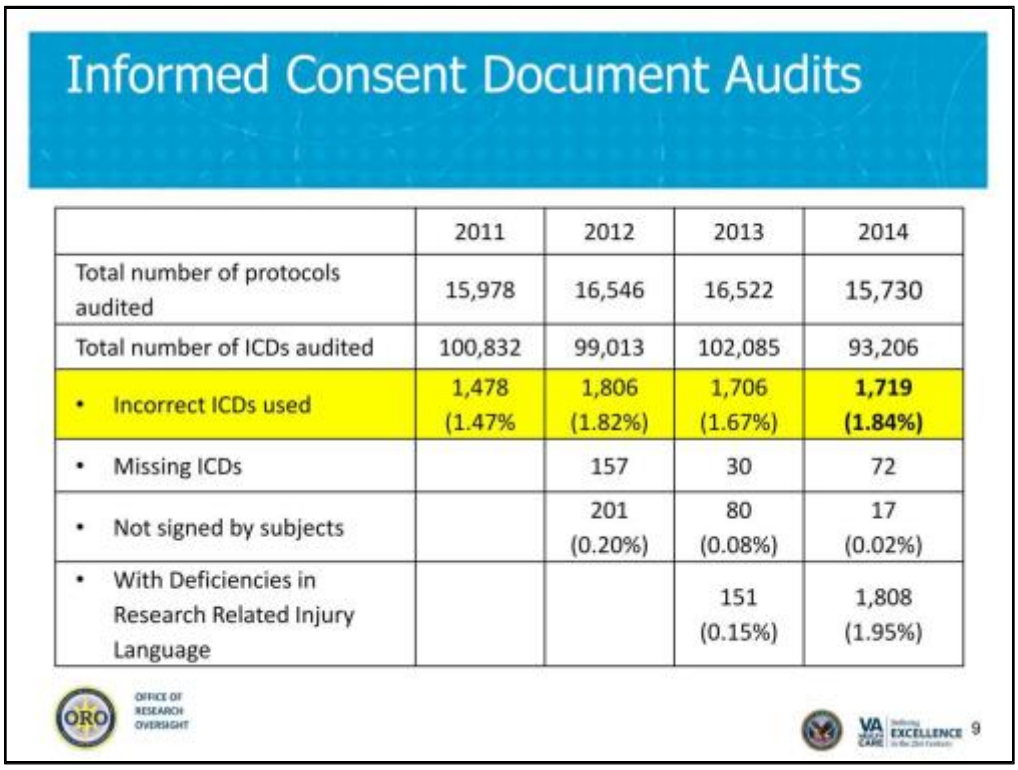


This graph shows the entire population of 107 VA research facilities ranked by the number of ICDs audited during the 2014 reporting period. Again, the largest number of ICDs audited is to the right. The largest number of ICDs audited by one facility was 6,294. Last year, the largest number audited at one facility was 8,060. Eight facilities audited more than 3,000 ICDs. Those eight facilities represented almost 40 percent of all ICDs audited this reporting period. The average number of ICDs audited was 871, with the larger facilities bringing up the average. Ten facilities reported zero documents audited. Again this does not include data for the MVP.

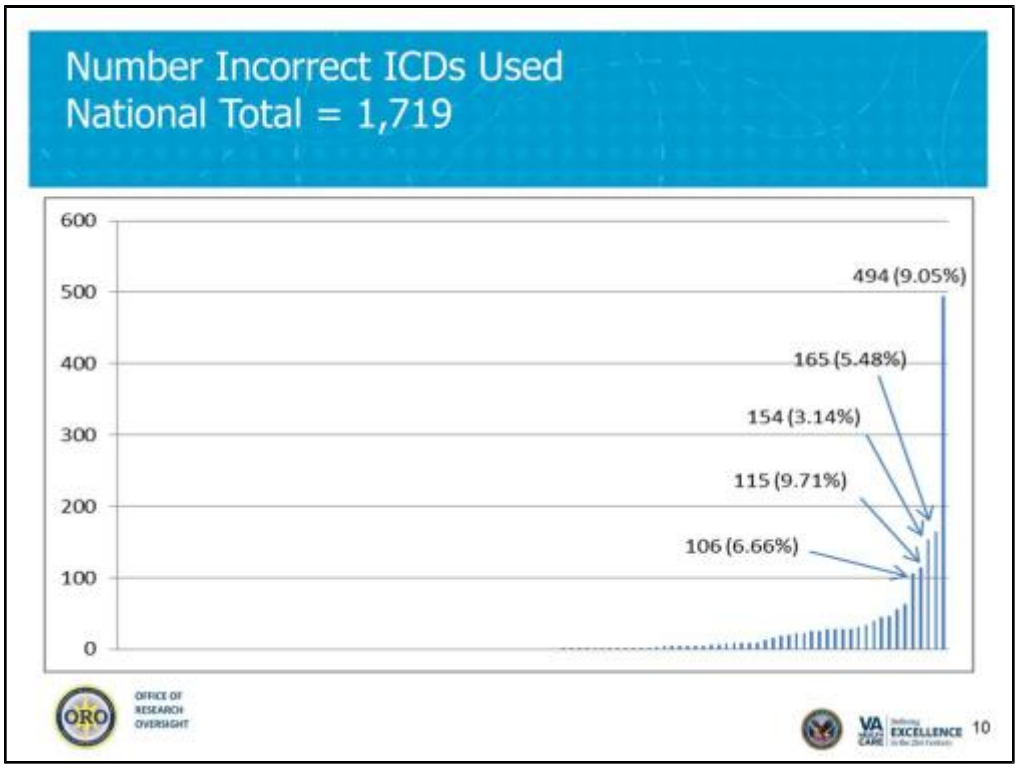
As mentioned previously, the MVP IC audits were not included on the FDC. Currently, 50 of the 107 VA research facilities are participating in the MVP. ORO requires RCOs to audit 10 percent of ICDs in the MVP on a monthly basis and report to ORO on a quarterly basis. The reason for this alternative reporting process is due to the extremely high volume of ICDs generated by the MVP and the fact that the MVP has a process in place to detect and correct deficiencies quickly. Because of this, ORO asks that the RCOs report the number of audited ICDs found to have any deficiency and of those, the number of deficiencies that were NOT corrected before a repeat audit is completed two weeks later.

For this reporting period, 109,604 veterans enrolled in the MVP. To put the volume of ICDs from the MVP into perspective, consider that the number of ICDs signed for the MVP (109,604) is greater than the total number of ICDs audited from all other studies combined (93,206) for this reporting period. Of those roughly 110,000 ICDs, RCOs audited 14,881 ICDs (or 13.58 percent of ICDs) and found a 0.13 percent rate of any deficiency for MVP. This represented only 20 deficient IC documents out of more than 14,000 audited. Furthermore, of those 20 deficient IC documents, only 5 were not corrected by the MVP's internal quality control processes within two weeks.

Nationally, the rate of any deficiency reported on this year's FDC for informed consent was 5.46 percent. While not a direct comparison, it appears that the MVP has a rate of deficiency that is much lower (0.13 percent) that other studies, which may show the benefit of the semi-automated process of the MVP.

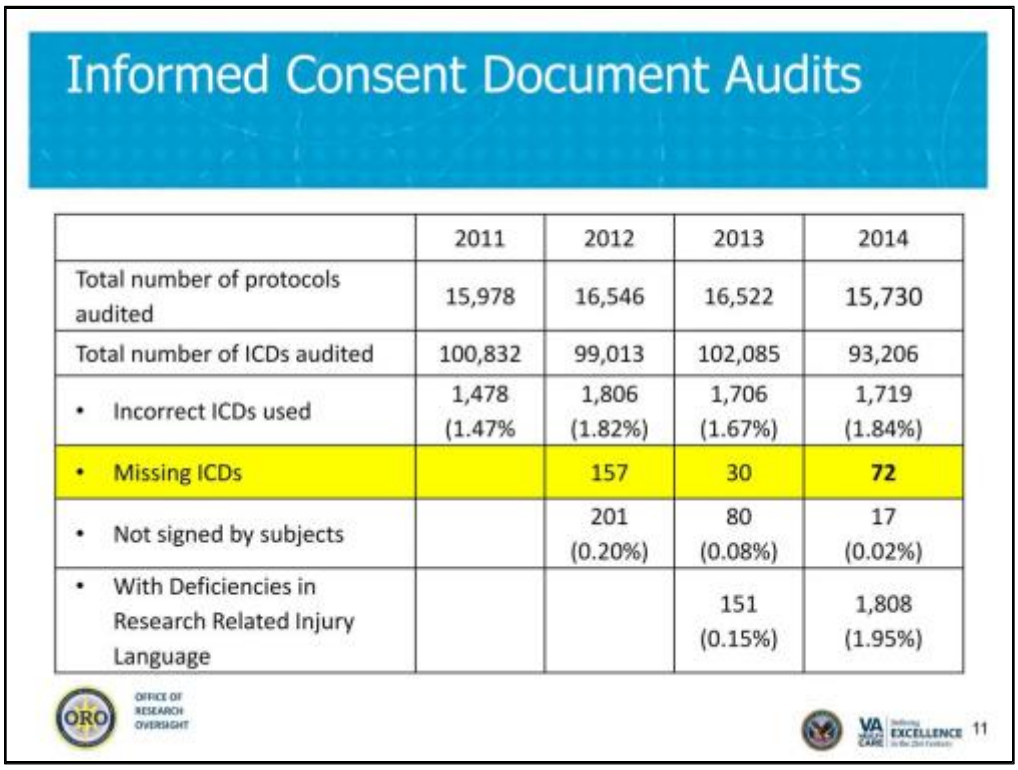


FDC data on the use of incorrect ICDs: Examples of this deficiency would be using the wrong version of the ICD for the study, an ICD from another study, or an unapproved ICD. The number of deficiencies for this measure did not increase or decrease significantly from the past two years. The national rate of this deficiency was around 1.84 percent.



This graph shows each facility in rank order by the number of incorrect informed consent documents used. Zero values lack a bar so the table shows that over half of all facilities reported zero incorrect documents used, although 50 facilities reported at least one incorrect ICD used. The highest number of reported instances of this deficiency (494) was from a facility with a large volume, as might be expected. Four other facilities reported more than 100 incorrect ICDs. The percentages shown represent the rate of deficiency for that facility. For example, these 494 incorrect documents represented nine percent of ICDs audited at that facility. Those five facilities accounted for a majority of all incorrect ICD's used. Four of those five facilities are considered large facilities (greater than 250 active protocols), and the remaining one is considered a mid-sized facility (101 to 250 active protocols). The overall national rate of this deficiency was 1.84 percent.

This display demonstrates that the great majority of VA facilities have no (or extremely few) incorrect ICDs used, while a few larger facilities are struggling with a much higher rate.

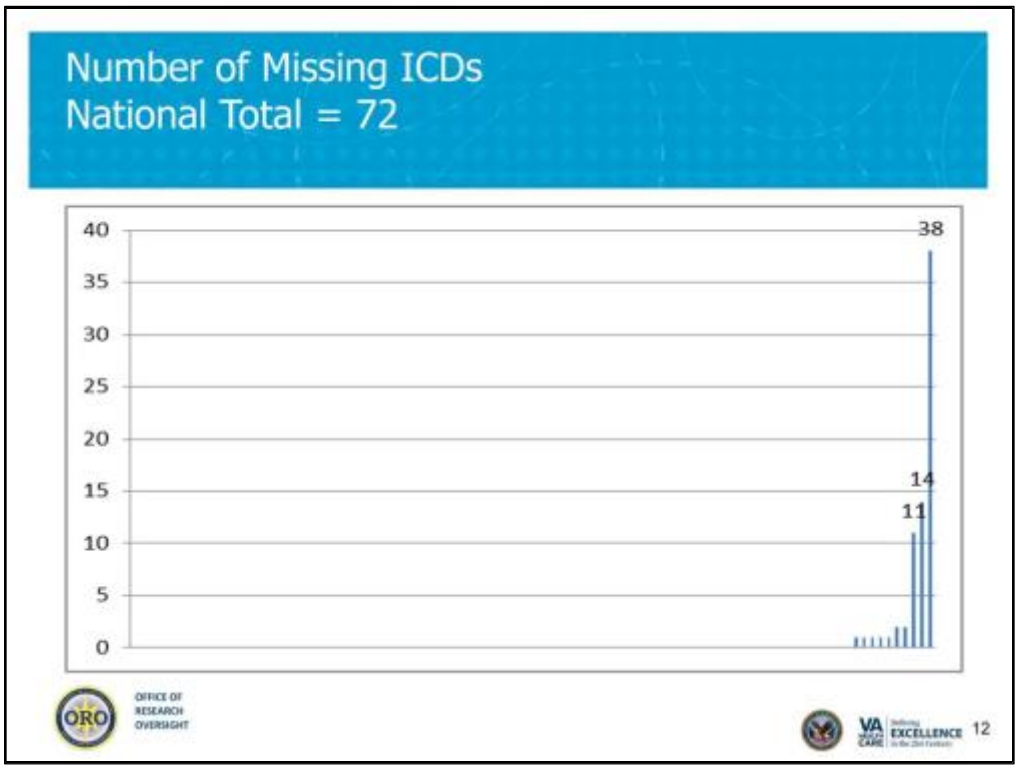


Informed Consent Document Audits

	2011	2012	2013	2014
Total number of protocols audited	15,978	16,546	16,522	15,730
Total number of ICDs audited	100,832	99,013	102,085	93,206
• Incorrect ICDs used	1,478 (1.47%	1,806 (1.82%)	1,706 (1.67%)	1,719 (1.84%)
• Missing ICDs		157	30	**72**
• Not signed by subjects		201 (0.20%)	80 (0.08%)	17 (0.02%)
• With Deficiencies in Research Related Injury Language			151 (0.15%)	1,808 (1.95%)

For the third year, ORO has asked on the FDC to report any missing ICDs. ORO did not specifically separate out the number of missing ICDs in 2011. ORO's guidance was to report an ICD missing if no copy (an original, copy, or scanned version) was able to be located. This year, like last year, ORO also specifically advised RCOs NOT to count these missing ICDs in counts for any other deficiency. This becomes important when examining the other deficiencies.

The number of missing ICDs was more than double last year's numbers but remained a small fraction of the total number of ICDs audited.

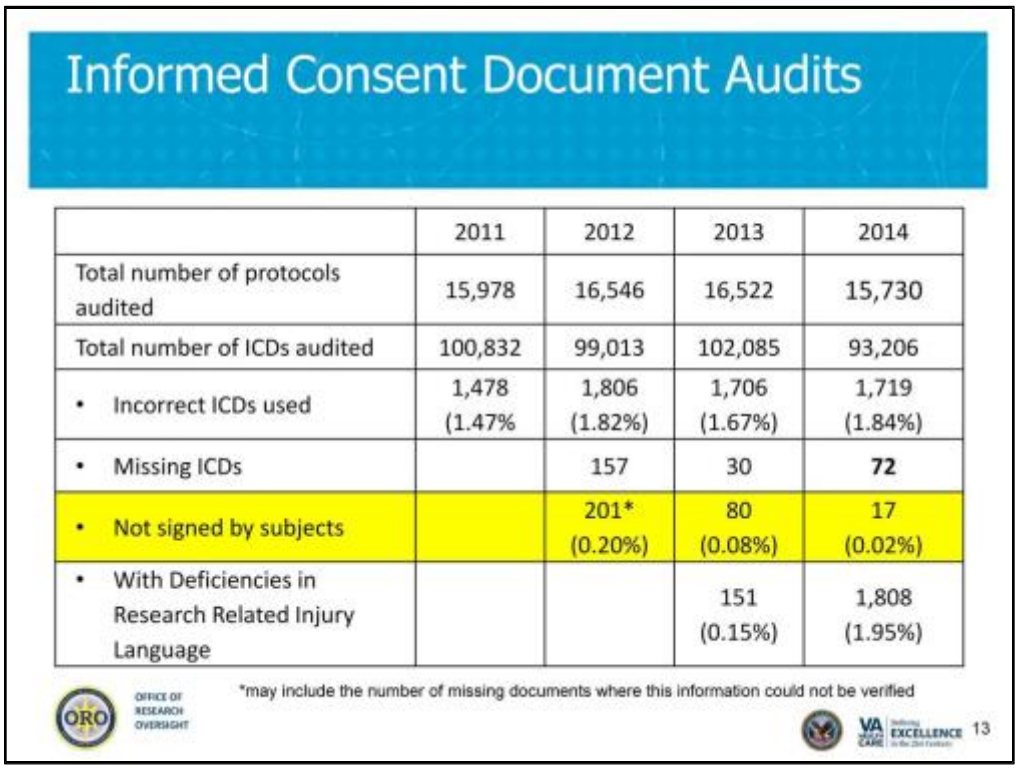


This year, 72 missing ICDs were reported. A total of 10 facilities reported missing ICDs. Eighty-eight percent of the missing documents were reported by three facilities, and over half came from one facility that reported 38 missing documents. All 38 came from one study with ICDs dating back to 2007. The loss of documents was determined to be due to multiple office moves through the years. This same facility reported zero missing ICDs on the 2013 FDC.

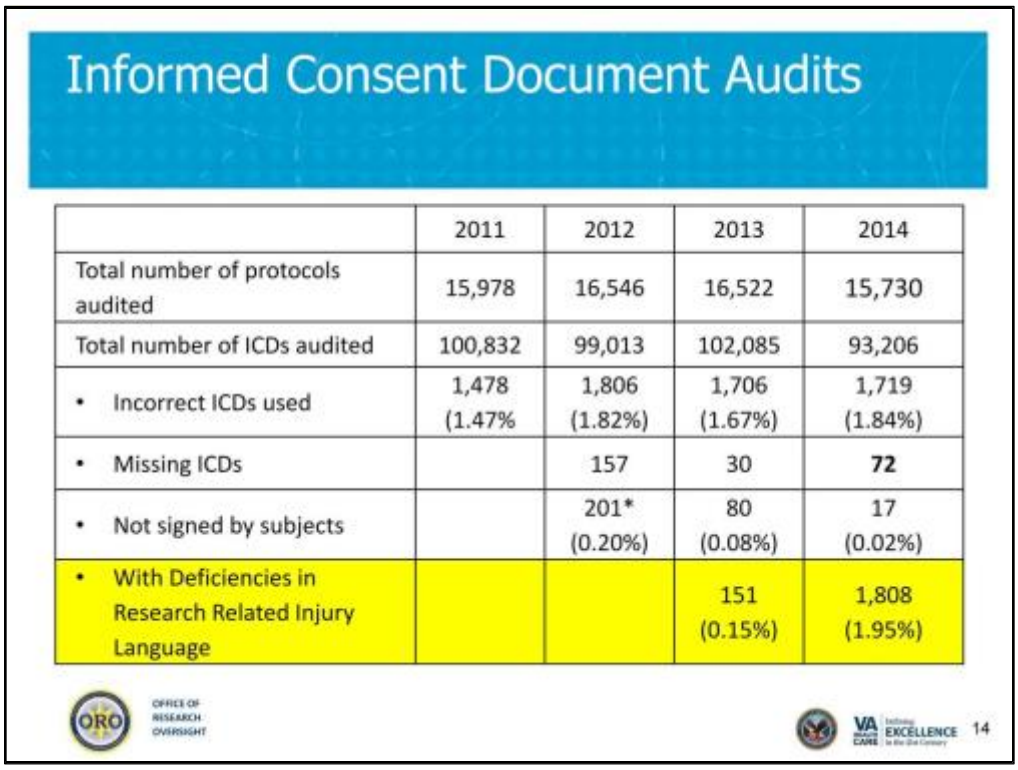
Another facility reported 14 missing documents, all from one minimal risk study. This facility also reported zero missing ICDs on the 2013 FDC.

One other facility reported 11 missing documents that were from multiple studies.

Oftentimes the outliers for many of the deficiencies are not the same facilities from year to year, making it difficult to pinpoint trends at one facility. Obtaining informed consent when required by the IRB is critical for protection of Veterans' rights and to maintain their trust in the VA system. These data demonstrate that VA research programs are performing extremely well in obtaining and documenting informed consent. However auditing of these documents every year is important, because individual instances of deficiency continue to arise and must be identified and corrected.

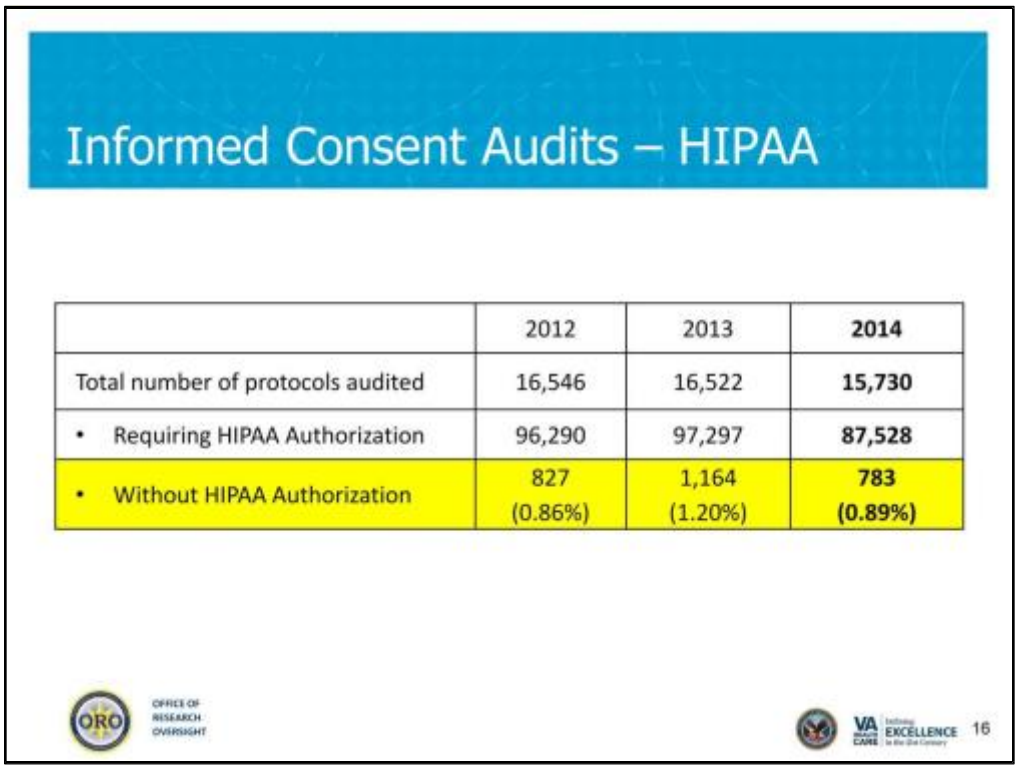


The number of missing subject signatures for 2012 was 201. However ORO believes that this number also includes the number of informed consent documents that were reported to be missing (157). Beginning in 2013 ORO specifically advised the RCOs NOT to include missing ICDs in counts for any other deficiency. The number of missing subject signatures was reported to be 17 for this year from 11 different facilities, all reporting between one and four ICDs. This was a sharp decrease from last year.

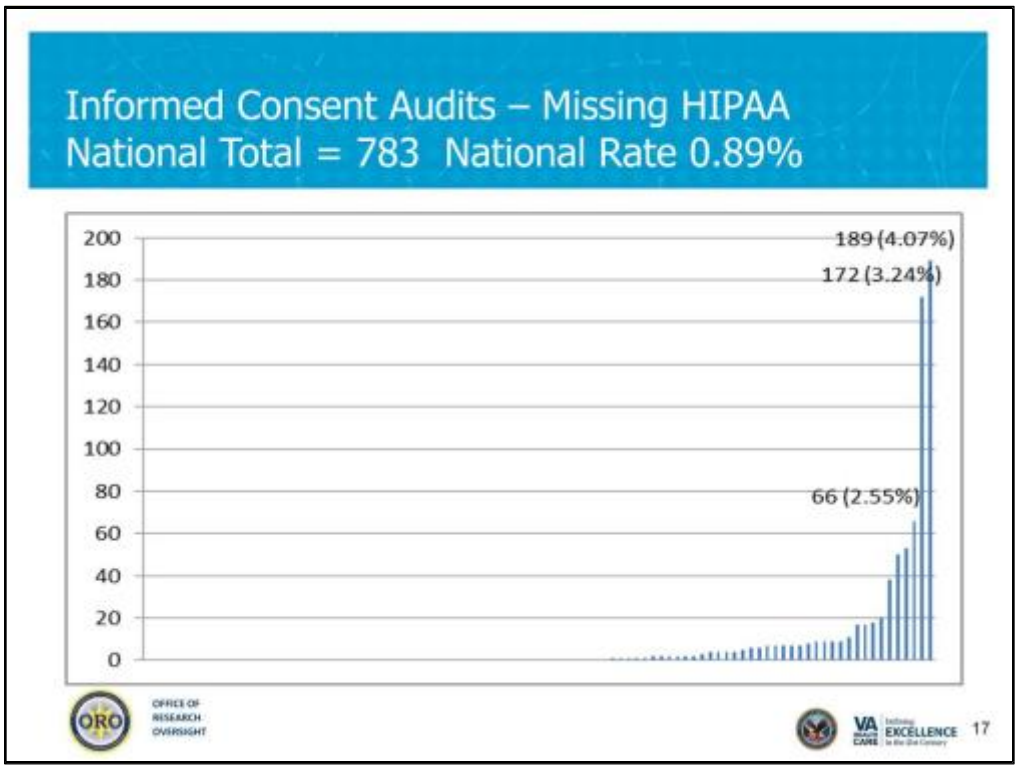


Deficient research related injury language: The RCOs have been capturing deficiencies in research related injury language for only two years now. Last year, 151 of these deficiencies were reported from six different facilities. This year, about 1,800 cases of this deficiency were reported. The deficiency was again reported at only six facilities; however, roughly 95 percent (1,696) of the reported cases came from one facility that was using a deficient template.

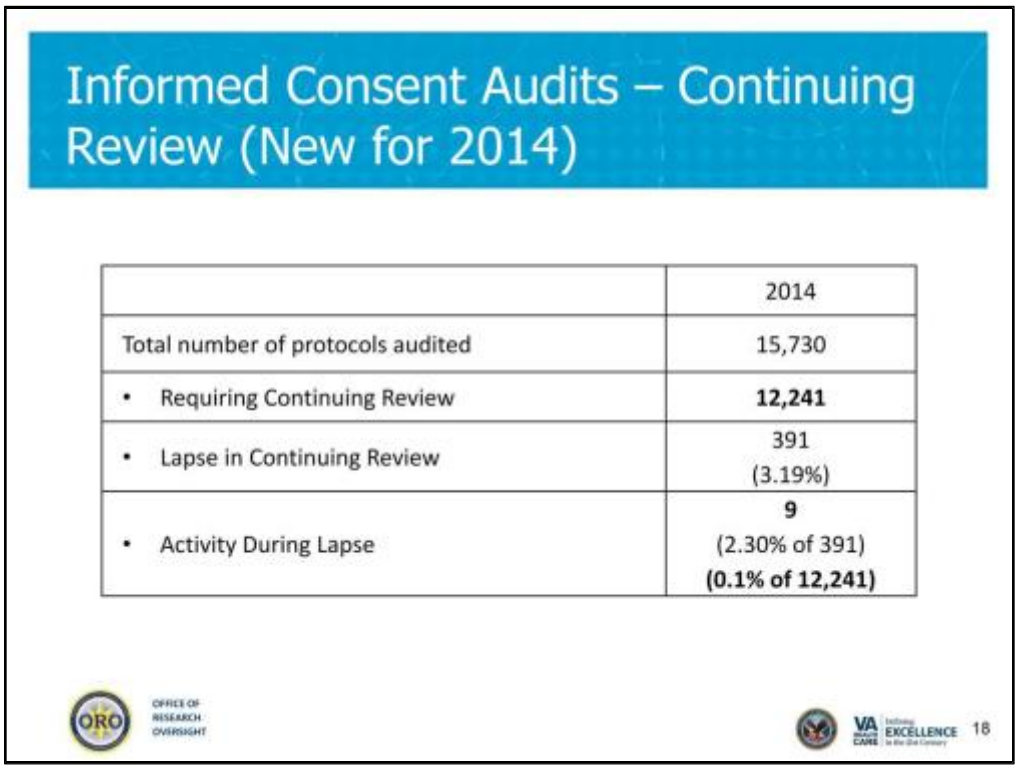
This slide illustrates the deficiencies reported in research related injury language. The great majority of these deficiencies come from the one facility referenced previously. The deficiency was due to noncompliant language in the facility's ICD template. Because it was a template problem, this deficiency was found in about half of all ICDs audited at this facility.



The rate of deficiency for missing HIPAA authorizations was lower than last year and similar to 2012. Over the past three years the percentage of ICDs missing the required HIPPA authorization has remained around one percent.

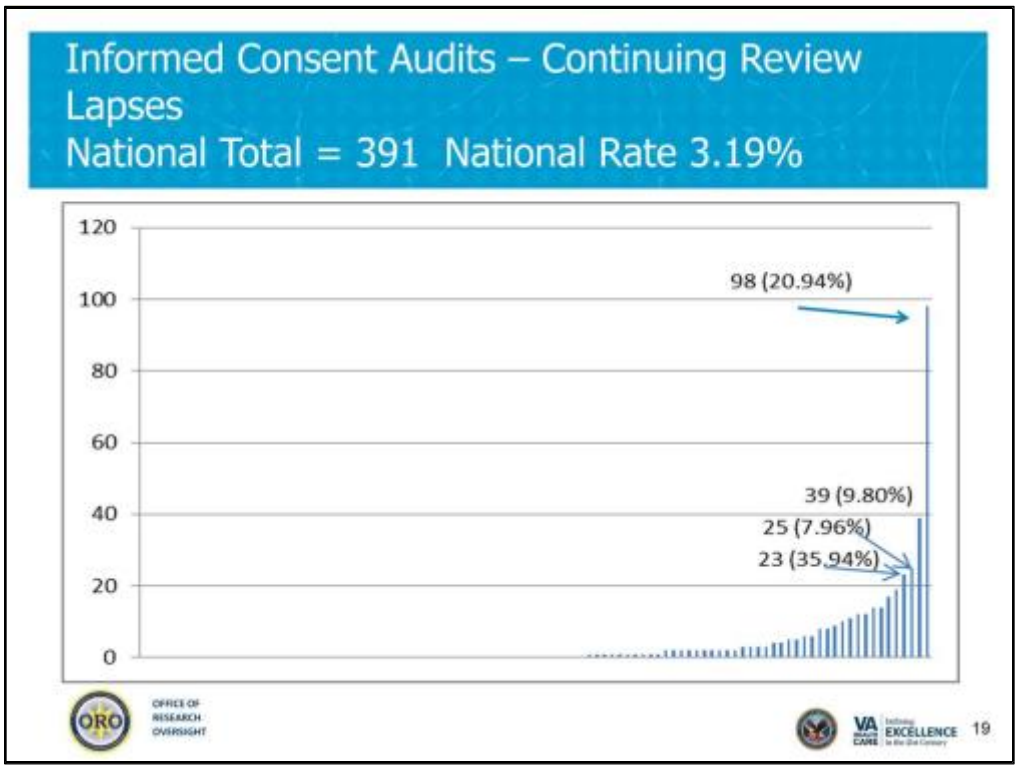


Compared to last year, fewer facilities reported missing HIPAA authorizations. Thirty-nine facilities reported missing HIPAA authorizations this year compared to 45 last year. Additionally, six facilities reported more than 100 missing HIPAA documents last year compared to only two facilities reporting the same this year. This slide illustrates all of the facilities reporting missing HIPAA authorizations. The top three facilities are labeled with the rate of deficiency next to the total number. One hundred and eighty-nine missing authorizations were reported from one facility (mostly from one study) representing four percent of HIPAA authorizations required at that facility. In the case of the 189 missing HIPAA authorizations, the PI incorrectly believed that the IRB had approved a waiver of authorization. One hundred and seventy-two missing HIPAA authorizations from numerous studies were reported from another facility. Those two facilities accounted for about half of all missing HIPAA authorizations. Four of the five facilities reporting the highest numbers of missing HIPAA authorizations were all large facilities (more than 250 protocols).



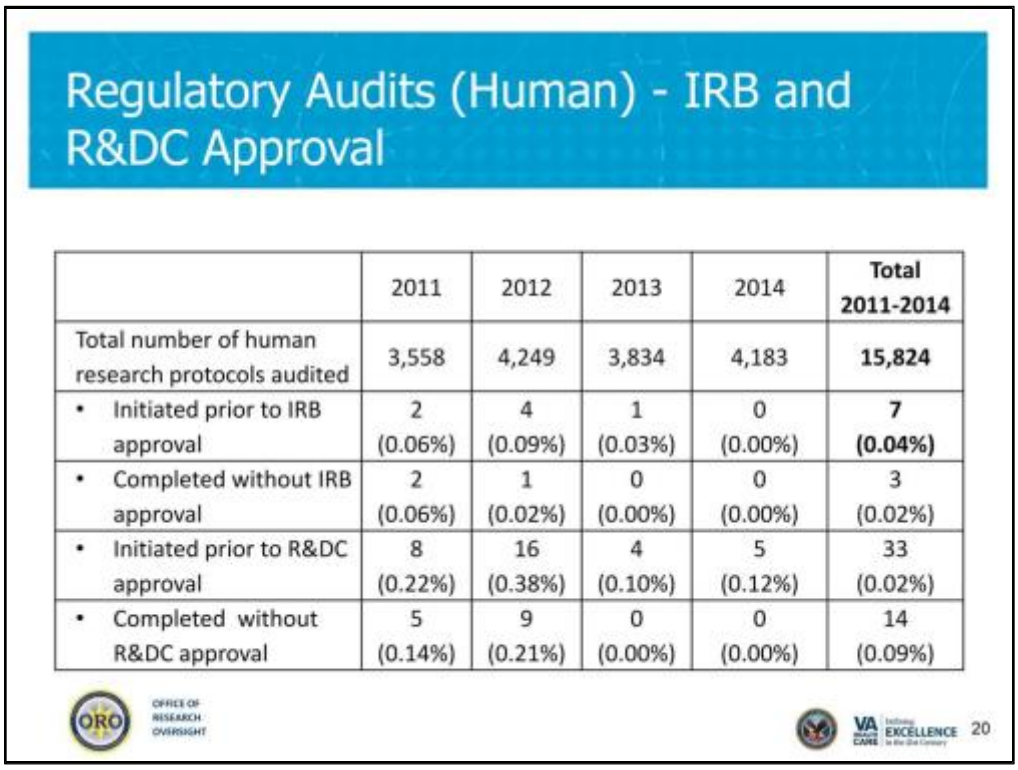
For the first time, ORO asked the RCOs to identify continuing (CR) lapses during the informed consent audits for the 2014 reporting period. Until now, evaluation for CR status was done only on the triennial audits which have a three-year look back. ORO received feedback that the triennial audit results may have been lagging behind actual improvements in the field. In response to this concern, ORO adjusted the audit data collected so that this year a comparison can be made between the CR lapse rate with a three-year look-back and the CR lapse rate in the most recent 12 months at each program.

This slide shows the rate of CR lapses of 3.19 percent with a 12 month look back. The rate of protocols with activity during a CR lapse was 2.3 percent of the 390 protocols that lapsed (only nine protocols nationally) and 0.1 percent of the 12,241 protocols requiring CR. The presentation will review these numbers again when relative to the triennial audits in a later slide.



As previously mentioned, 45 facilities reported at least one CR lapse. One facility reported 98 protocols with a CR lapse, which accounted for 20.94 percent of the protocols requiring a CR at that facility.

While the overall national rate of CR lapse in the last 12 months was 3.19 percent, this display demonstrates that the great majority of VA research programs have zero or very few lapses in CR. This is true for both small and large VA research programs. While lapse in CR alone, without continuing research activity during the lapse, may not violate the rights and welfare of subjects, ORO is concerned that a few VA facilities continue to struggle with high percentages of CR lapses, and that this may be a symptom of significant administrative oversight issues. ORO is continuing to work with each VA facility with a high rate of CR lapse to analyze and correct these issues.



Regulatory Audits (Human) - IRB and R&DC Approval

	2011	2012	2013	2014	**Total 2011-2014**
Total number of human research protocols audited	3,558	4,249	3,834	4,183	**15,824**
• Initiated prior to IRB approval	2 (0.06%)	4 (0.09%)	1 (0.03%)	0 (0.00%)	**7 (0.04%)**
• Completed without IRB approval	2 (0.06%)	1 (0.02%)	0 (0.00%)	0 (0.00%)	3 (0.02%)
• Initiated prior to R&DC approval	8 (0.22%)	16 (0.38%)	4 (0.10%)	5 (0.12%)	33 (0.02%)
• Completed without R&DC approval	5 (0.14%)	9 (0.21%)	0 (0.00%)	0 (0.00%)	14 (0.09%)

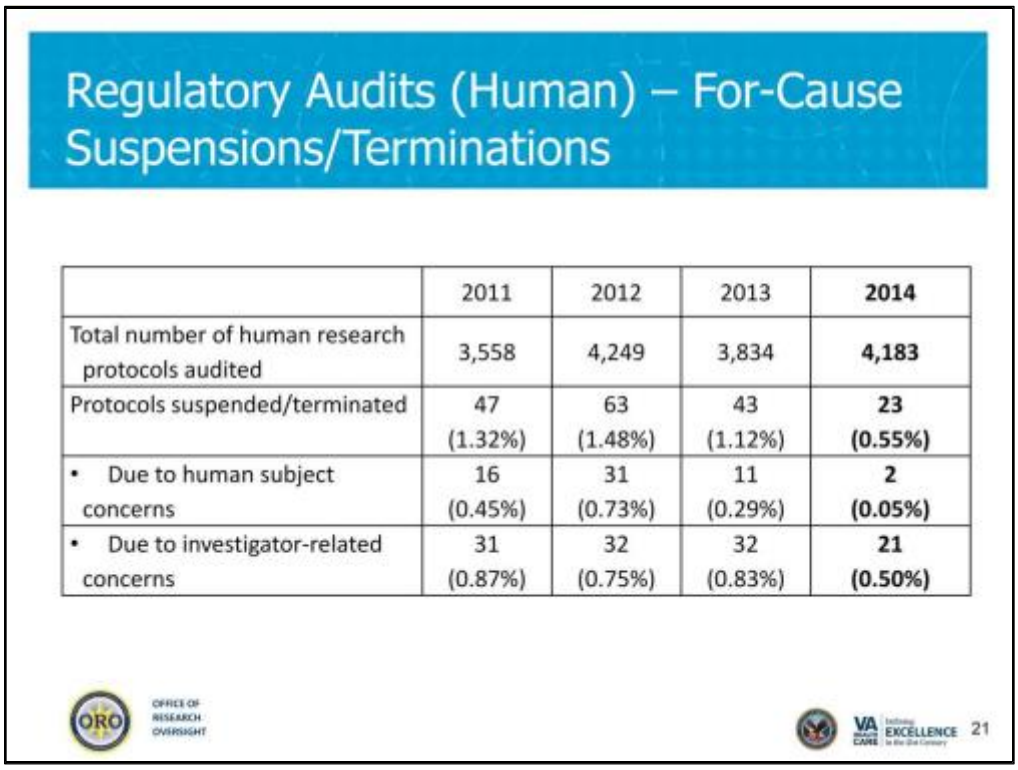
ORO OFFICE OF RESEARCH OVERSIGHT

VA HEALTH CARE EXCELLENCE 20

Regulatory audits of human subject research: ORO requires all active research initiated after 2008, and research initiated prior to 2008 that still involves interaction/intervention with subjects, to be audited at least once every three years. In interpreting the regulatory audit data, it is important to remember that the individual protocols audited during the 2014 period will be different from those audited during the 2013 period. Unlike the informed consent audits, which occur for 100 percent of active human research protocols every year, roughly one-third of all VA research receive a regulatory audit annually. Regulatory audits occur on a three-year cycle, and include a three-year look-back period for each protocol. Therefore, as improved processes are implemented, reports of regulatory audits may continue to reflect issues that occurred up to three years previously. For this reason, improvements reflected in audit results may lag actual improvements in the field.

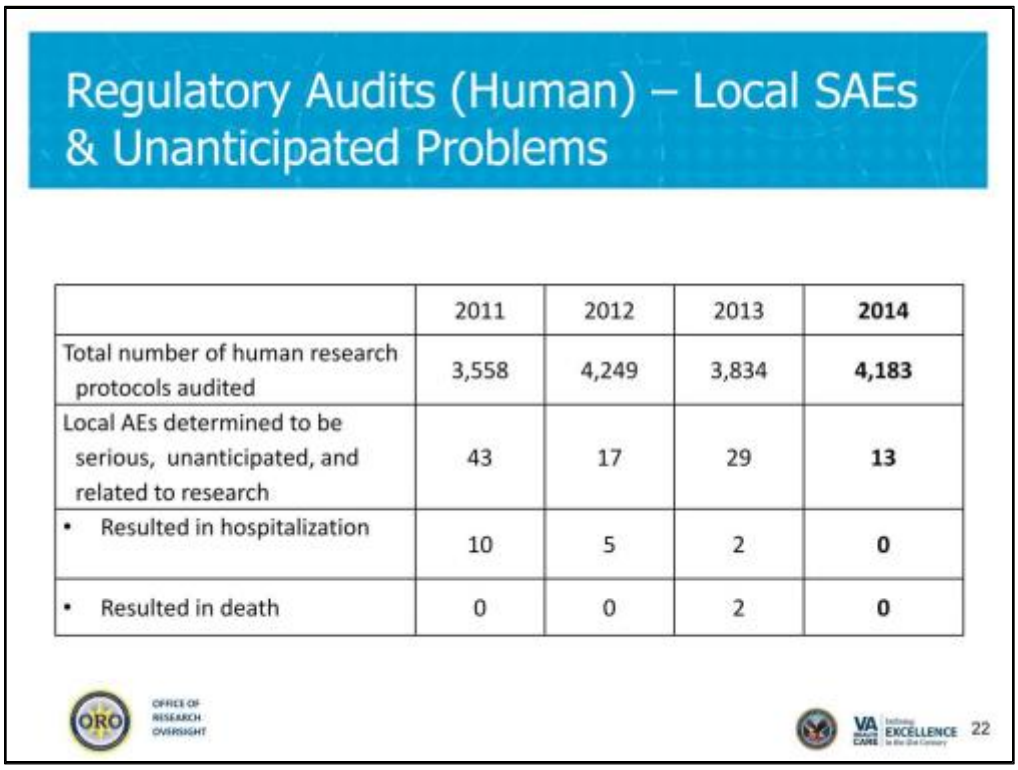
This slide shows data for the past four years for committee approvals before initiation of research and completion of research. For 2014, there were zero protocols audited nationally that were initiated prior to or completed without IRB approval and zero protocols that were completed without Research and Development Committee (R&DC) approval. There were five protocols audited that were initiated prior to R&DC approval. These five protocols came from three facilities, all of them utilizing affiliate IRBs.

ORO can state with confidence that the rate of human subject research occurring without proper oversight and approvals is extremely low in VA.

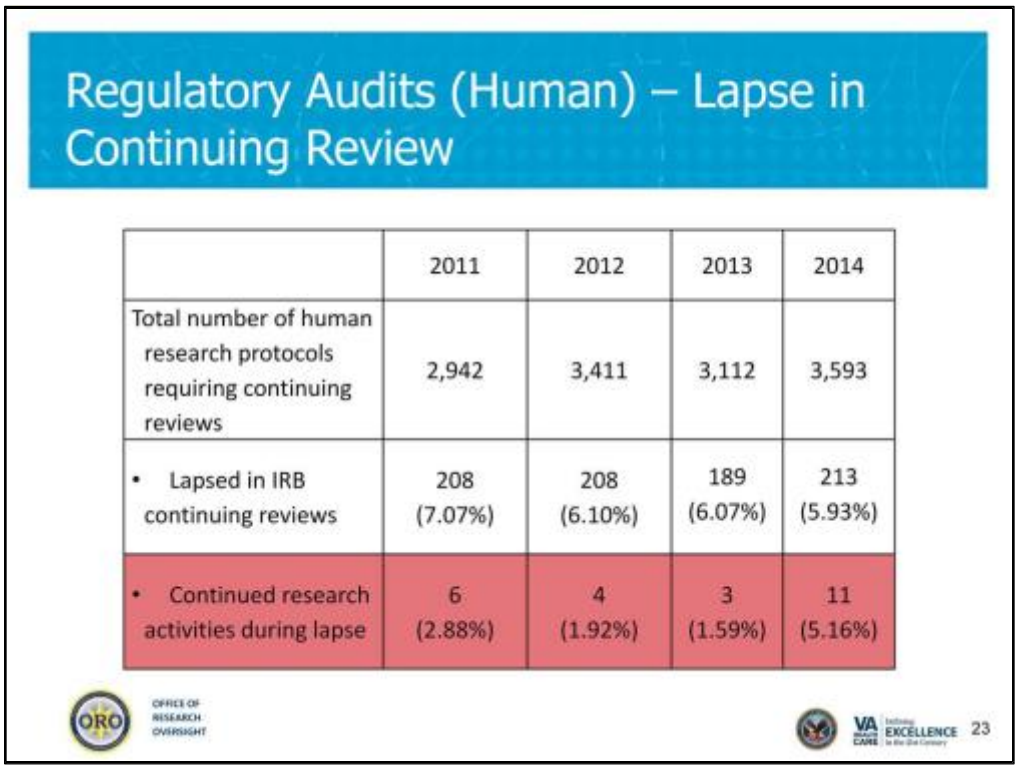


The number of for-cause suspensions/terminations went down this reporting period. From 2012 to 2014, there is a continued downward trend. The significance of this measure as a quality metric is questionable, however. It is not clear whether fewer suspensions/terminations indicate a stronger program. It is possible that the stronger programs are monitoring more closely and suspending more quickly. In any case, 13 facilities reported suspensions on the FDC this year, all reporting between one and five, so no one facility had a majority of cases. Keep in mind that these only reflect those protocols that were audited this year, each with a three-year look back. (For animal and safety studies, ORO asked the information on suspensions and terminations of all open protocols, not just the audited protocols. ORO may consider moving to the same procedure in the future for human studies.)

ORO will continue to collect this information as a way to monitor nationally the activities of VA research oversight committees. Suspensions or terminations of research should not be viewed as a concern in performance, however. ORO strongly supports the responsible oversight work of VA research oversight committees, as well as their duty to take any actions necessary to protect the rights and welfare of research subjects and employees.



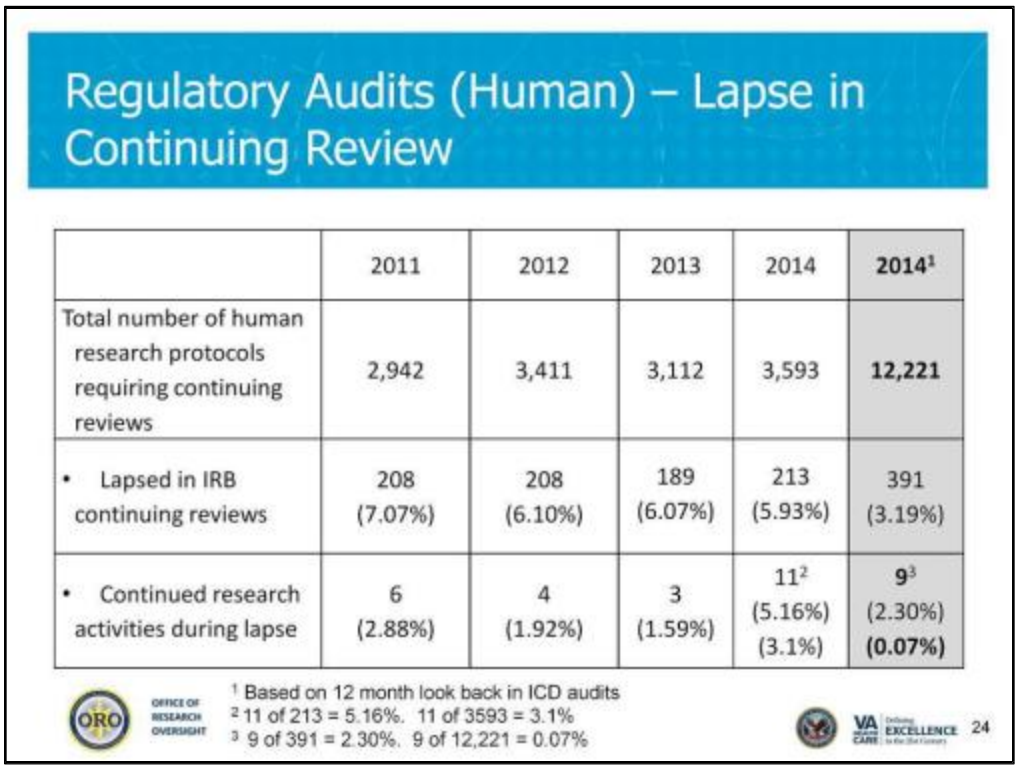
Local Serious Adverse Events: There were 13 Adverse Events determined by IRBs to be serious, unanticipated, and related to research reported this period.



The presentation previously reviewed the data on CR lapses that were evaluated on the RCO IC audits with a 12 month look back. Here are the data on CR lapses found during the triennial regulatory audits.

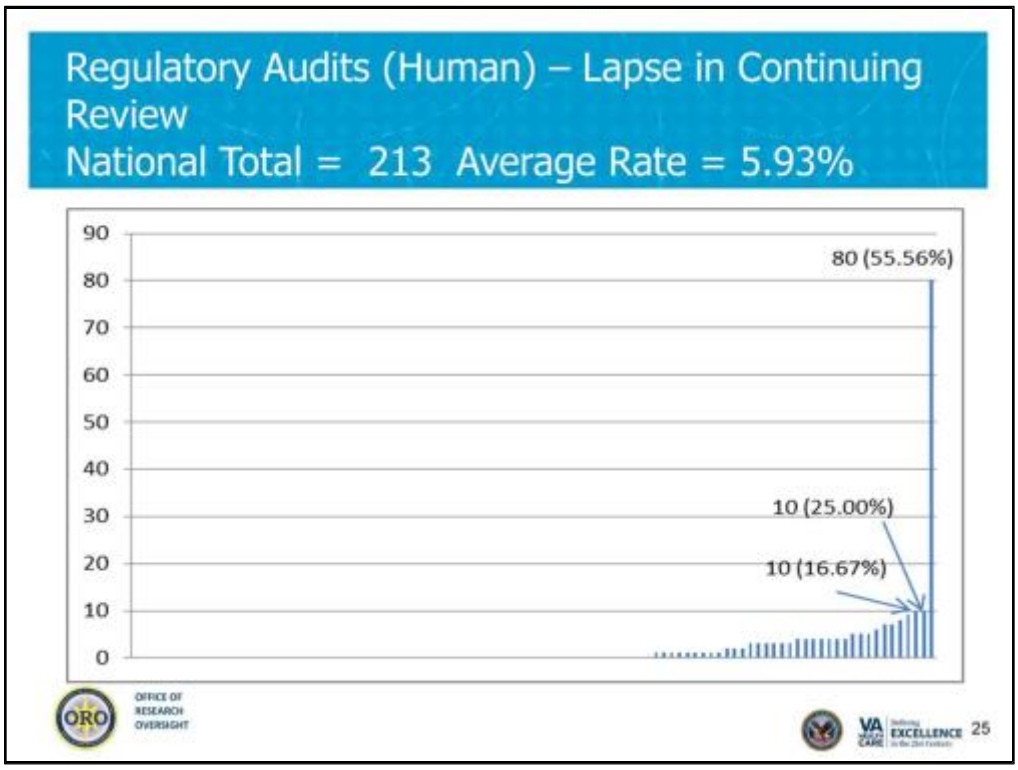
There were actually more facilities reporting at least one CR lapse for the most recent 12 months than there were in the data with a three-year look back. 45 facilities reported lapses in CR with a one-year look back; 36 facilities reported CR lapse with three-year look back. 32 facilities reported lapses on both on year and three-year look backs.

By contrast, more than 60 VA research programs reported no lapses in CR at all.



This table directly compares the CR data from the IC audits versus the regulatory audits. The gray, shaded column to the right contains data based on audits of the most recent 12 months (IC audits), while the column to the left of that shows data based on audits with a 3-year look back (regulatory audits).

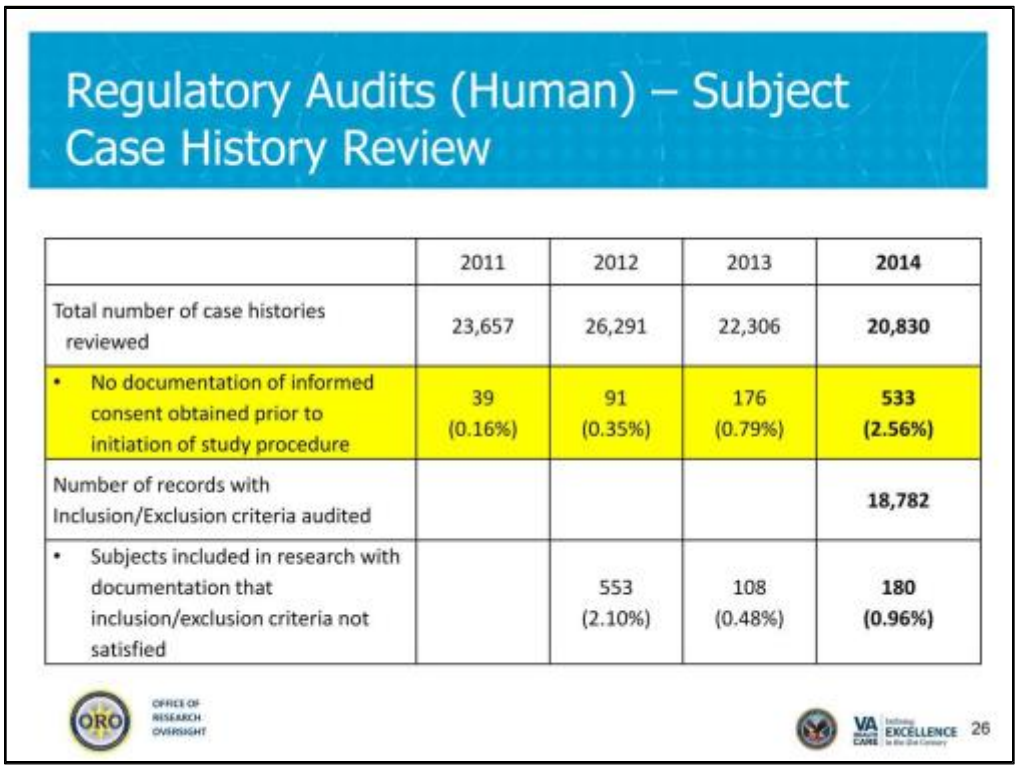
While more facilities reported CR lapses on the IC audits, rates were lower than on the regulatory audits (3.19 percent versus 5.93 percent).



About two-thirds of all facilities did not report any deficiencies at all in CR lapses on regulatory audits of human studies. One facility reported 80 protocols with lapses accounting for 55 percent of their audited protocols requiring a CR.

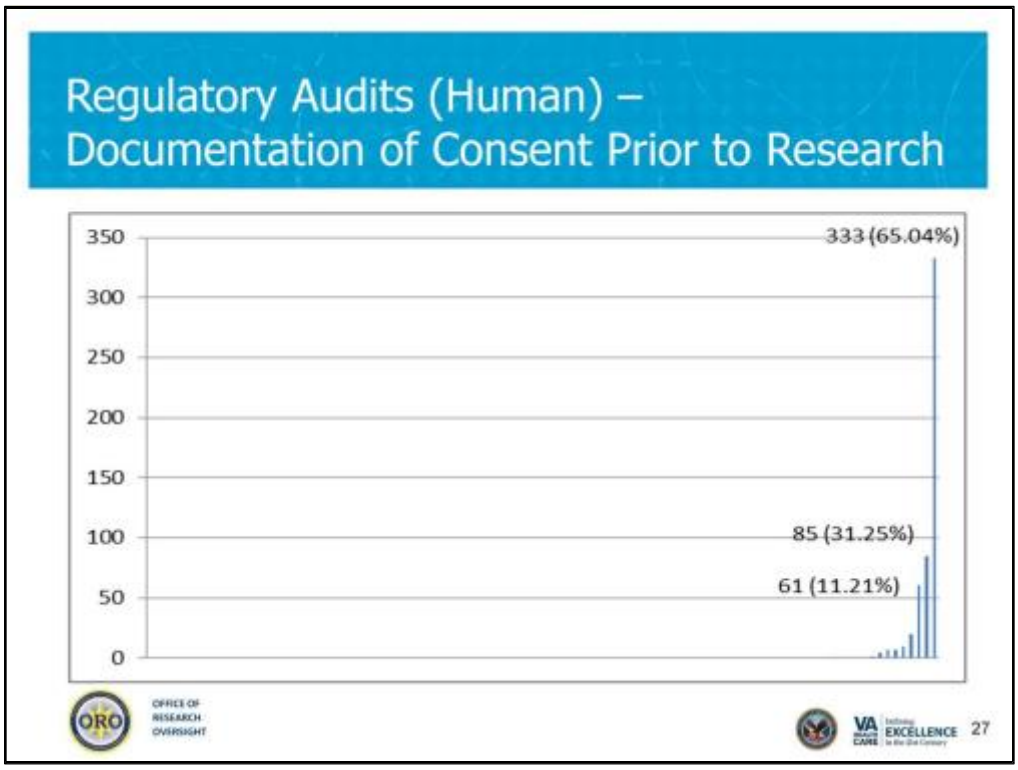
Every year, ORO sends each VA research facility a report comparing its performance on selected quality metrics with the performance of other programs within their VISN and nationally. Last year, ORO focused some attention on high rates of CR lapses in these reports. Facilities with a rate of lapse greater than 10 percent for three consecutive years received a memo that highlighted this deficiency. These memos went to 10 facilities. Out of 10 facilities, seven have improved markedly. Two facilities dropped to 0 percent for both the three-year look-back and one-year look-back periods. One facility has shown improvement but still has a high rate of lapse. Two facilities had higher rates this year than last year. However, the one-year look-back revealed a lower rate than the three-year look-back, possibly indicating a positive change. ORO is continuing to work closely with specific facilities in this matter.

Overall, ORO wishes to recognize the extremely good performance on this measure of all but a few VA research programs.



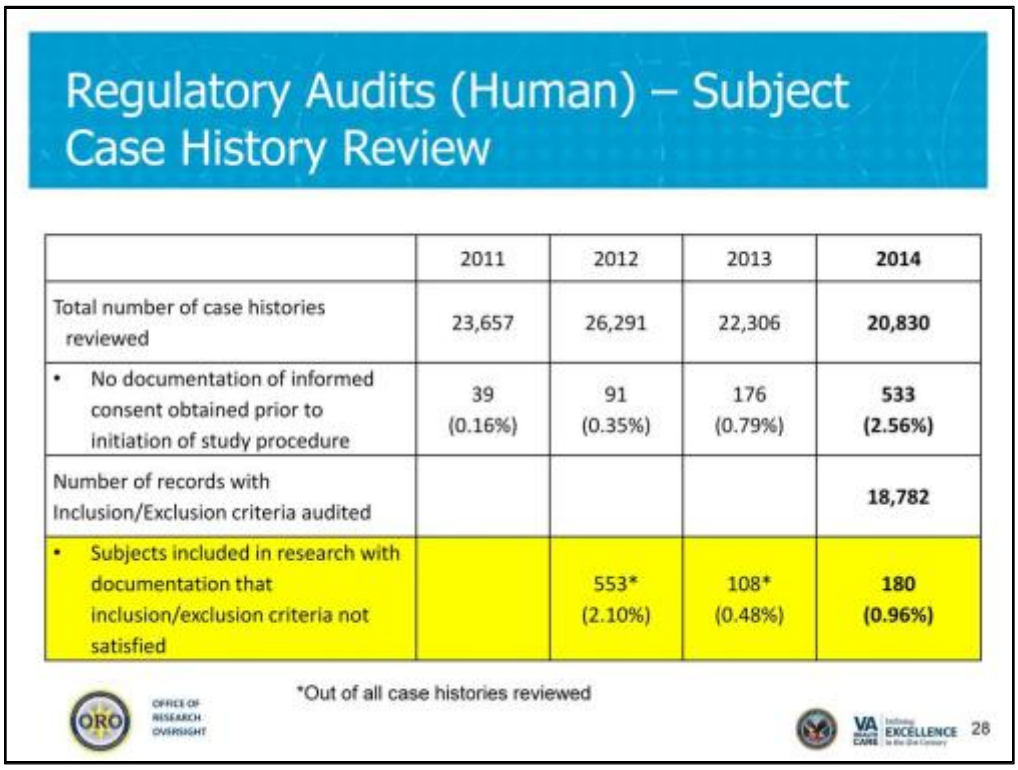
The RCO regulatory audits involve examining a percentage of subject case histories for required documentation of certain elements. This includes documentation that informed consent was obtained prior to any study procedures, and evaluation of inclusion and exclusion criteria.

Data for failure to document informed consent being prior to initiating any study procedure demonstrate an increasing trend in the rate of deficiency.

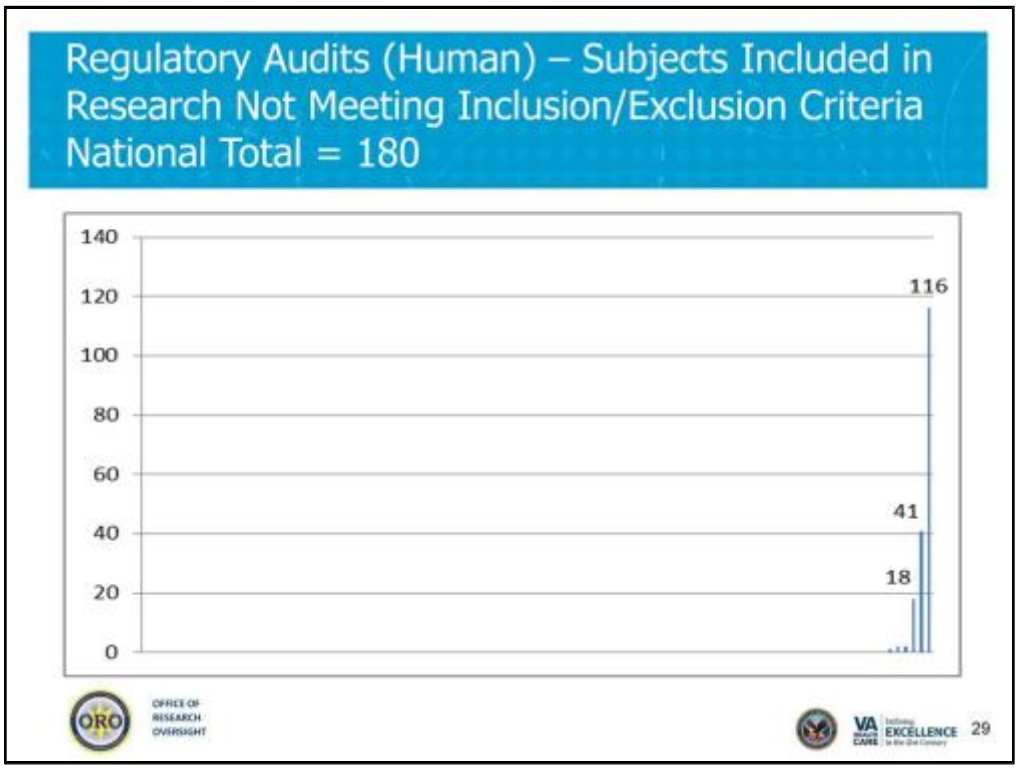


This graph shows the distribution of this finding ranked by incidence. The top three are labeled with the rate of deficiency for that facility next to the total number.

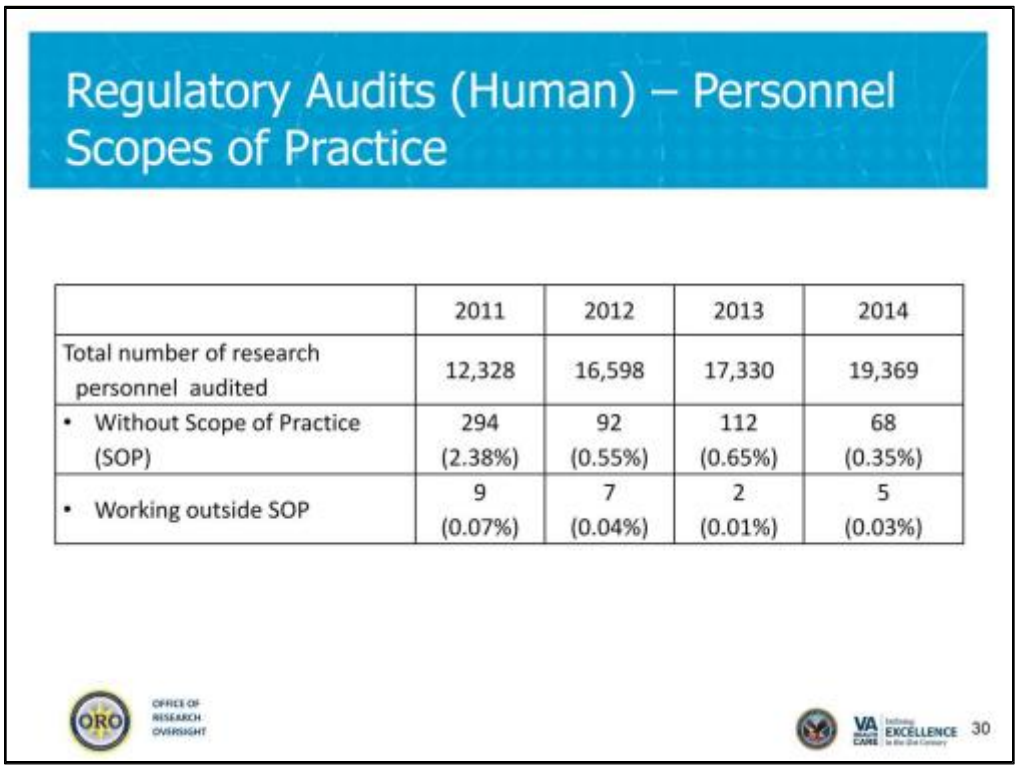
Fourteen facilities reported this deficiency with a majority of cases coming from one facility, mostly from one protocol. At that facility, there is a requirement to document the date and time of consent as well as the date and time of the first research activity. Informed consent and the first research activity for each subject occurred on the same day for this particular protocol, but the PI was unable provide evidence that consent occurred prior to the activity. Most cases of this deficiency appear to be related to documentation for protocols with consent and first activity occurring on the same day. In one case, screening tools were administered to subjects prior to consent. In another case, medical histories were accessed without informed consent or a waiver.



Inclusion and exclusion criteria: For the 2014 reporting period, ORO only required auditing of inclusion and exclusion criteria for subjects in studies of more than minimal risk so it was also necessary to record the number of records with inclusion/exclusion criteria that were audited. RCOs audited for subjects who were included in research with evidence that they did not qualify for the study. A total of 180 subjects were reported nationally this year to have been included in research despite evidence that they did not meet inclusion/exclusion criteria.

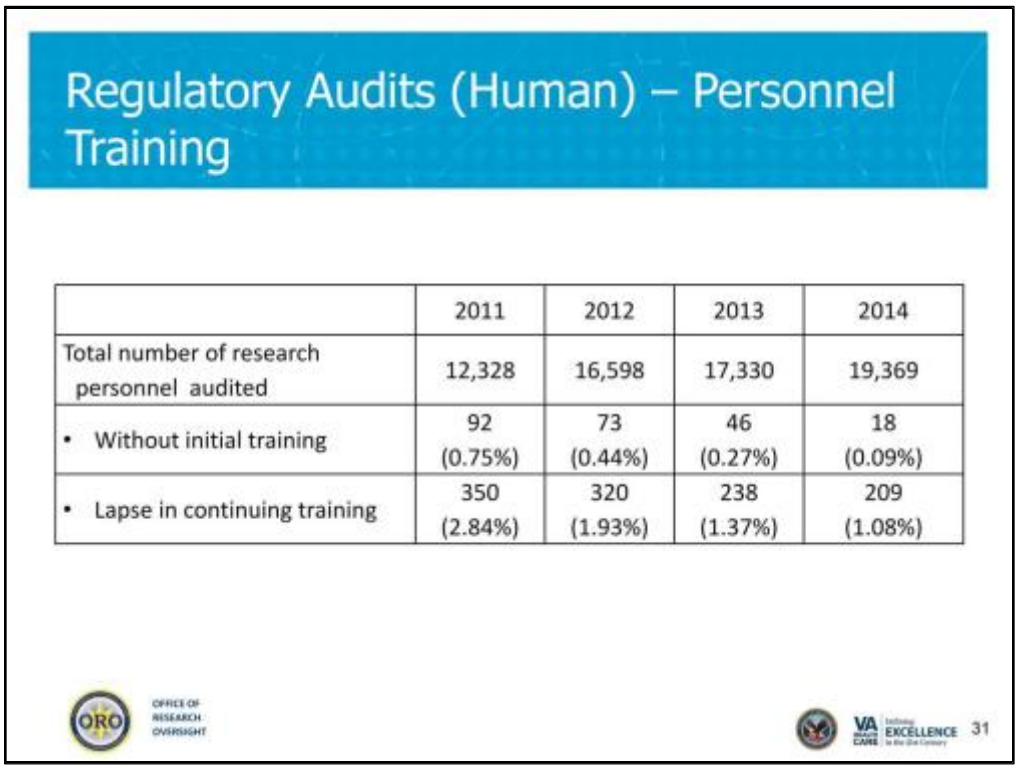


Only six facilities reported evidence of involving subjects in research who did not meet inclusion/exclusion criteria. One facility reported 116 cases, including 112 subjects from one protocol where subjects fell outside the age range permitted in the protocol.

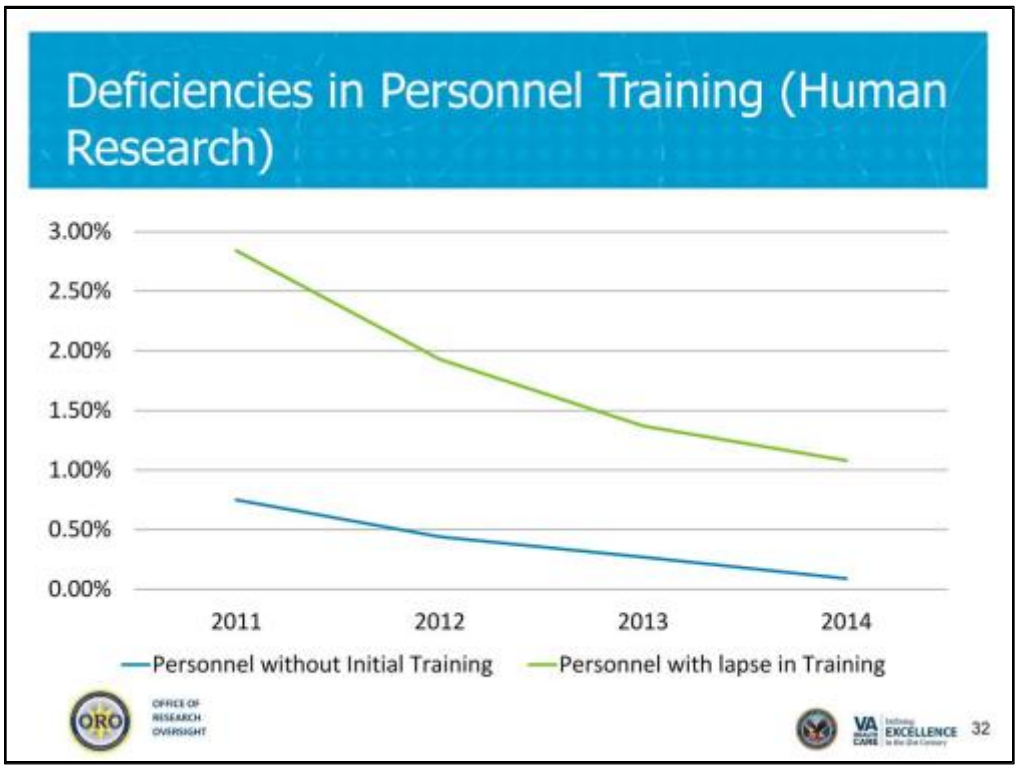


Research scopes of practice for personnel in human studies: There were 68 reported cases of personnel without required research scopes of practice. This deficiency was reported by 16 facilities. Rates of personnel working outside their scopes of practice remained very low, approaching zero.

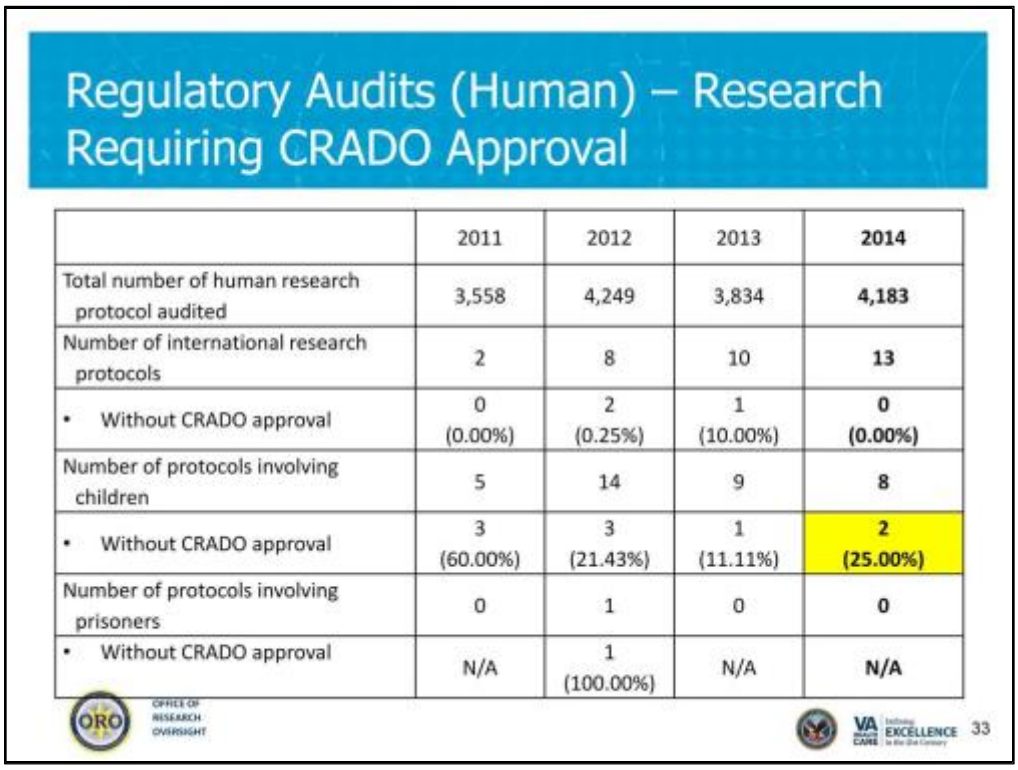
ORO recognizes that VA research programs have put great effort into assuring appropriate research scopes of practice in recent years, and this table documents steady improvement by almost ten-fold since 2011.



Personnel training for human subject protocols: There is a continued, positive trend from 2011 to the present both in initial training and continuing training. Deficiencies were reported by 39 facilities without any outliers that accounted for most of the deficiencies.



This graph demonstrates the downward trend in training deficiencies since 2011.



Regulatory Audits (Human) – Research Requiring CRADO Approval

	2011	2012	2013	**2014**
Total number of human research protocol audited	3,558	4,249	3,834	**4,183**
Number of international research protocols	2	8	10	**13**
• Without CRADO approval	0 (0.00%)	2 (0.25%)	1 (10.00%)	**0 (0.00%)**
Number of protocols involving children	5	14	9	**8**
• Without CRADO approval	3 (60.00%)	3 (21.43%)	1 (11.11%)	**2 (25.00%)**
Number of protocols involving prisoners	0	1	0	**0**
• Without CRADO approval	N/A	1 (100.00%)	N/A	**N/A**

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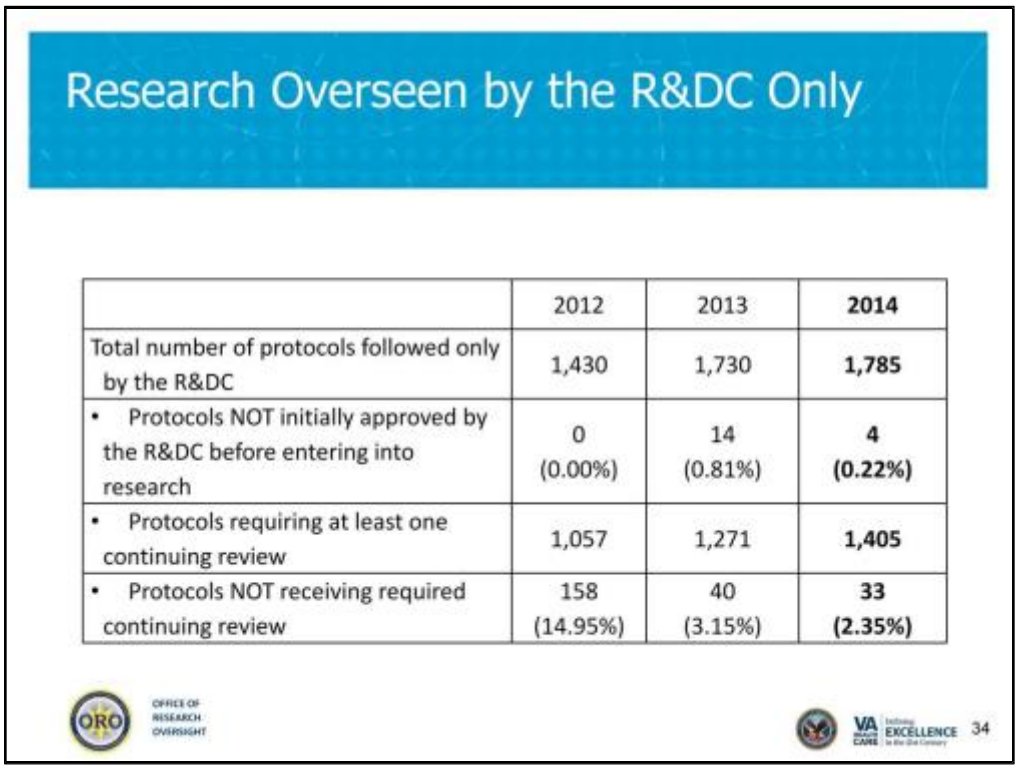
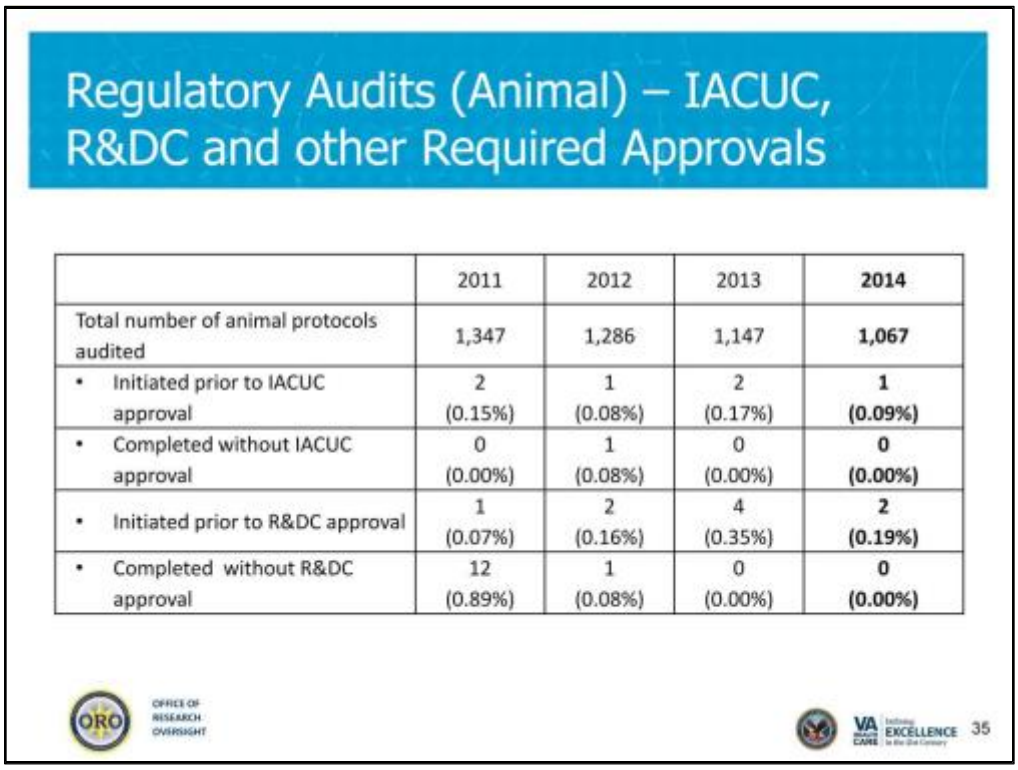
Research requiring a Chief Research and Development Officer (CRADO) waiver: International research, research involving children, and research involving prisoners are not allowed in VA without a waiver from the VHA CRADO. The numbers are very low for this type of research. One trend to point out is that the number of international research protocols appears to be increasing slightly from year to year. This year, two protocols did not receive the required CRADO waiver, both were studies involving children. One study involved data analysis related to children, and the other study involved actual interaction with children.



Research overseen only by the R&DC: ORO obtained the data in this table from the Research Program (i.e., these data were not obtained from the RCO audits). The data reflect only the current one-year reporting period.

The four protocols that were initiated prior to R&DC approval were reported from just one facility.

The rate of not receiving required R&DC CR continues to fall and has fallen markedly since ORO first started collecting this information is 2012.

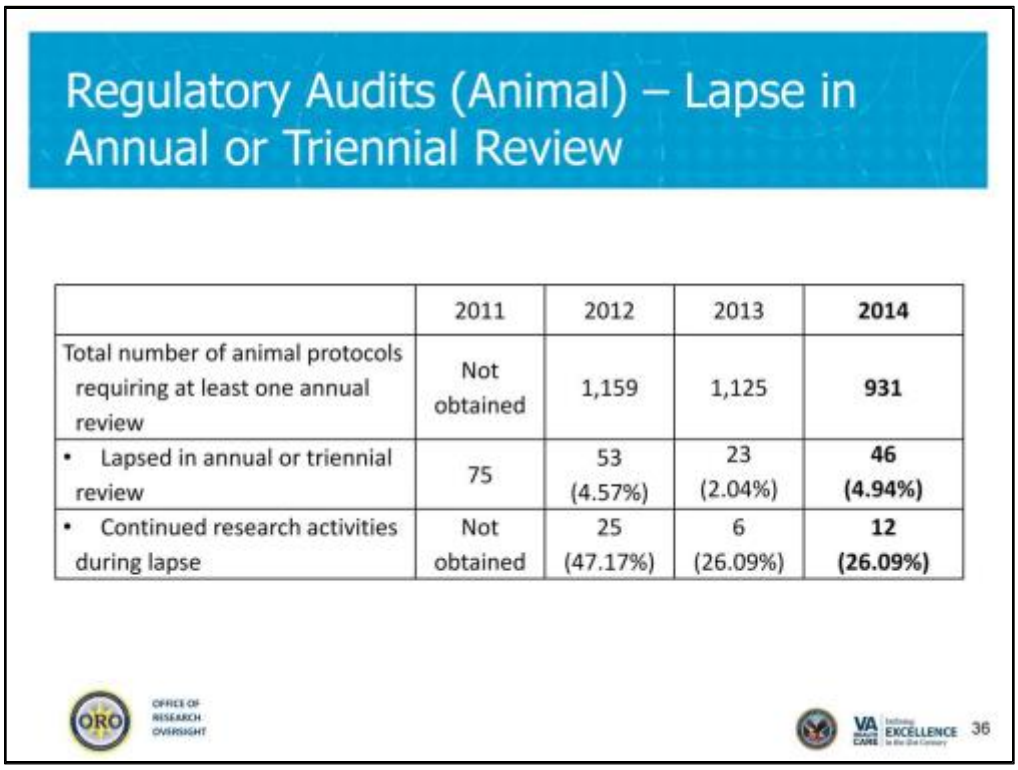


Regulatory Audits (Animal) – IACUC, R&DC and other Required Approvals

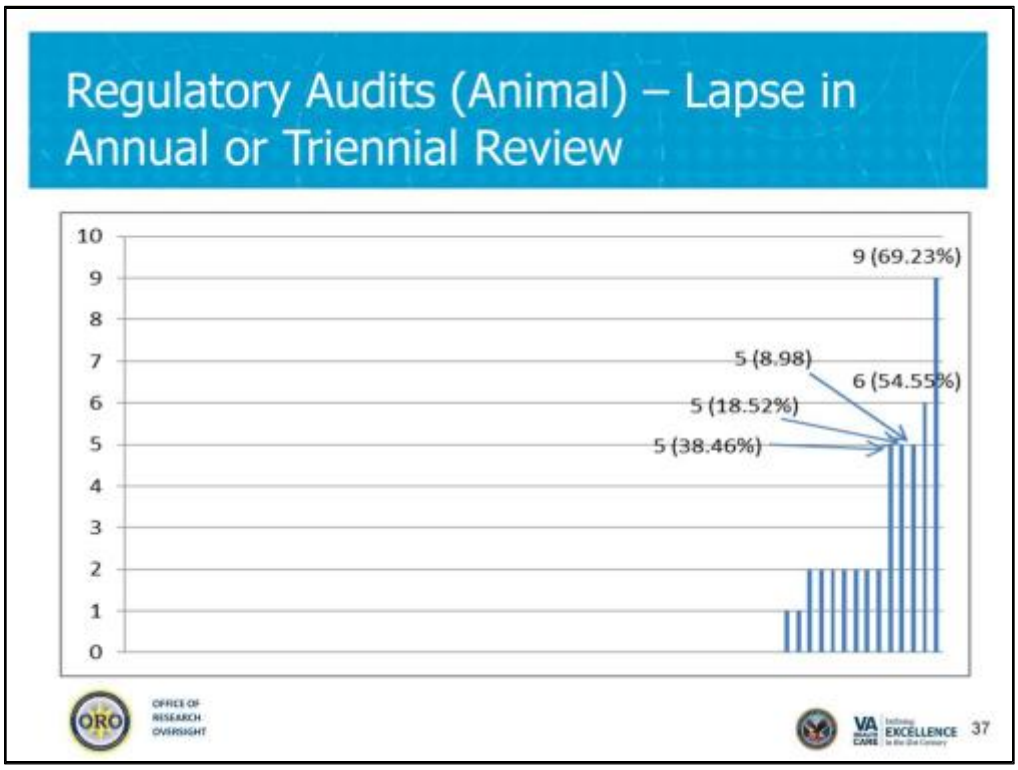
	2011	2012	2013	**2014**
Total number of animal protocols audited	1,347	1,286	1,147	**1,067**
• Initiated prior to IACUC approval	2 (0.15%)	1 (0.08%)	2 (0.17%)	**1 (0.09%)**
• Completed without IACUC approval	0 (0.00%)	1 (0.08%)	0 (0.00%)	**0 (0.00%)**
• Initiated prior to R&DC approval	1 (0.07%)	2 (0.16%)	4 (0.35%)	**2 (0.19%)**
• Completed without R&DC approval	12 (0.89%)	1 (0.08%)	0 (0.00%)	**0 (0.00%)**

RCO regulatory audits of animal protocols: This table shows the data for deficiencies found with respect to Institutional Animal Care and Use Committee (IACUC) and R&DC approvals. Out of 1,067 animal protocols audited, there was one protocol found to have been initiated prior to IACUC approval and two protocols found to have been initiated prior to R&DC approval.

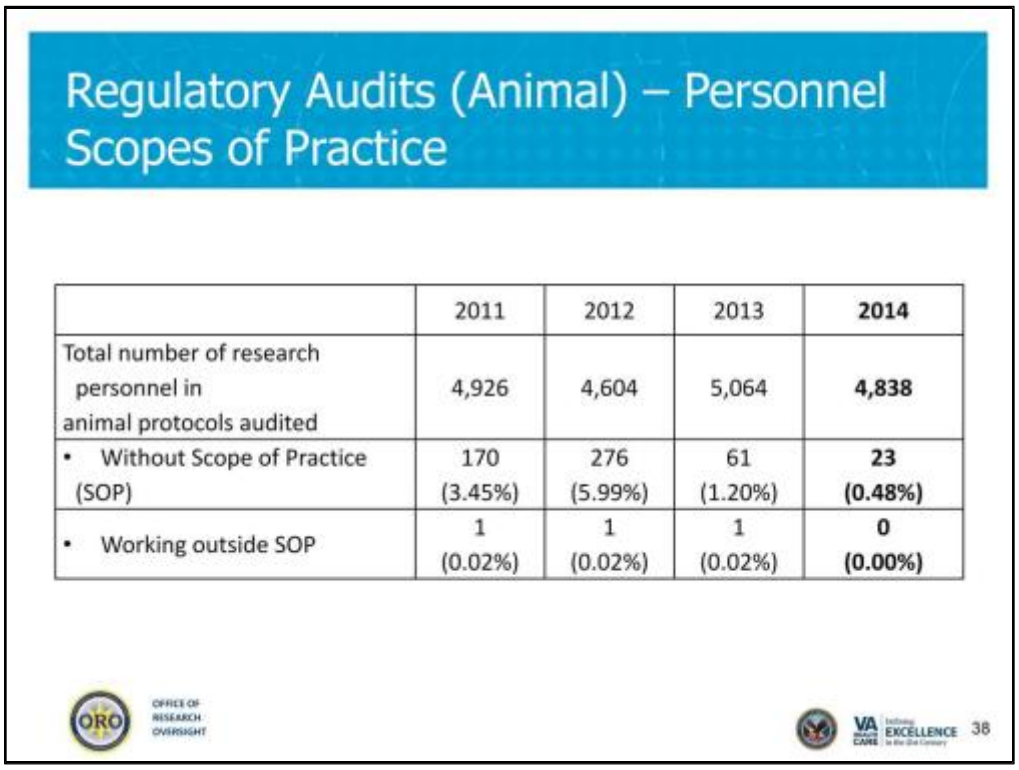
Similar to the human subject protocols, there were no protocols found to have been completed without IACUC or R&DC Approval.



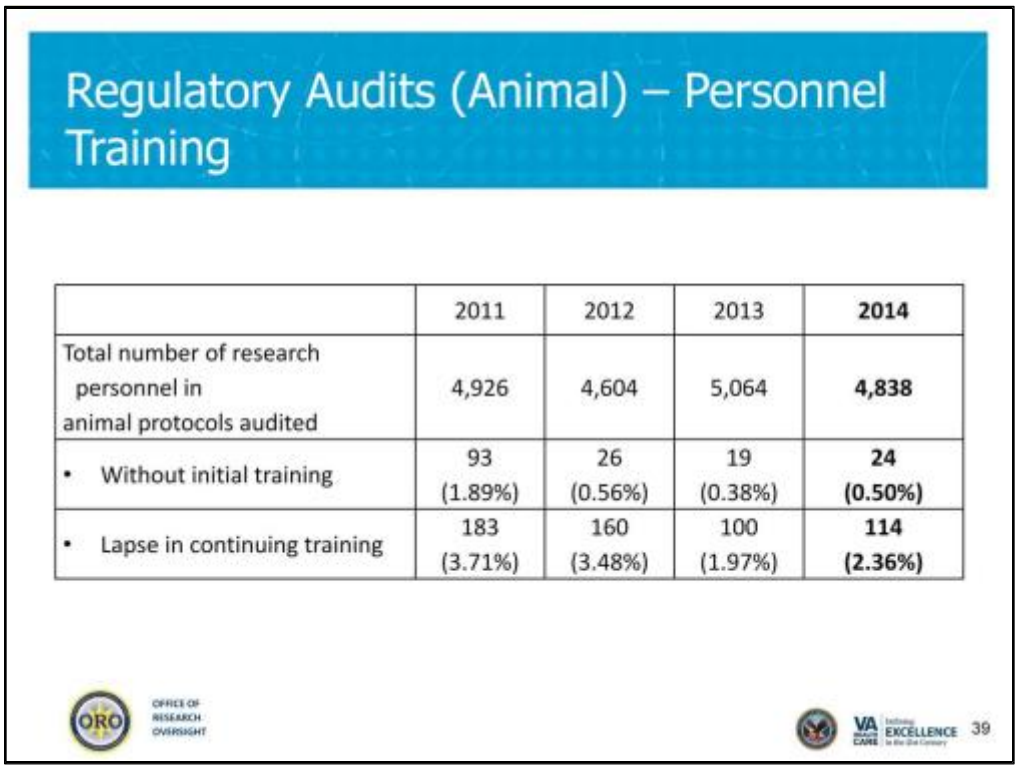
Looking at lapses in annual or triennial review of animal studies, there was an increase in the rate of annual or triennial review lapses this year compared to last. More concerning is the rate of protocols with activity during the lapse is very high at 26 percent. By comparison, the rate of human studies with research activities that continued during a lapse of CR was 2.3 percent.



Fourteen facilities reporting lapses in annual or triennial review, most reporting only one or two. One facility reported nine. While the reported numbers are low, for some of the facilities, the protocols identified represent a high percentage of all protocols audited requiring CR. Of the 14 facilities reporting lapses, five facilities reported activity during the lapse.



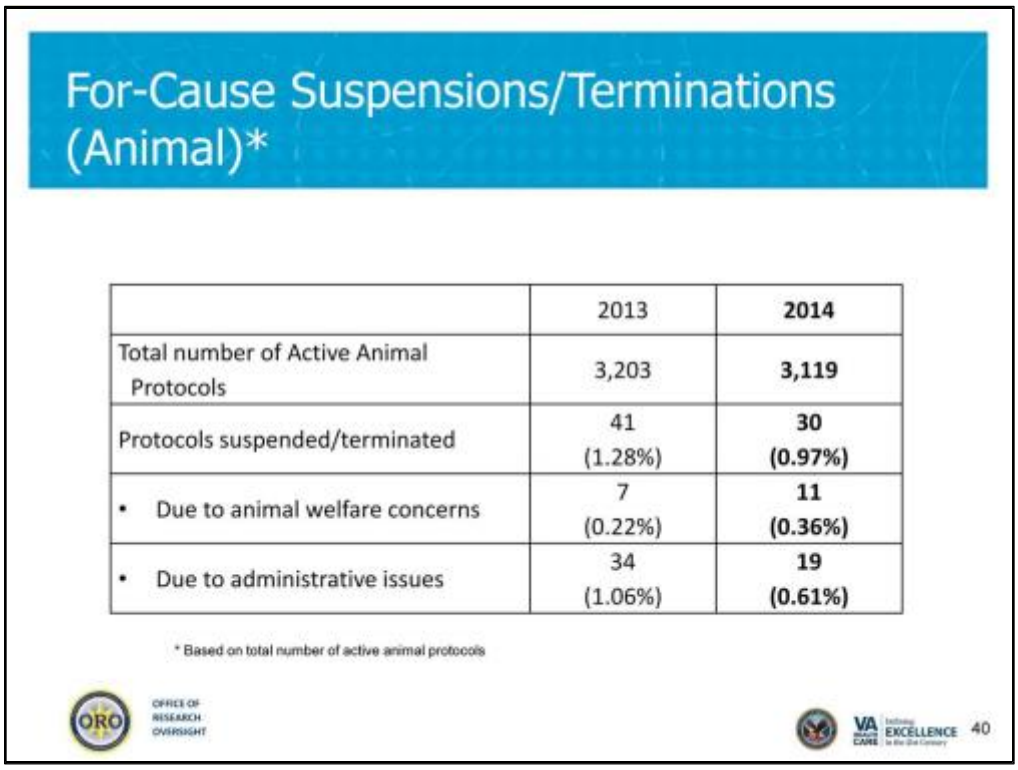
Scopes of Practice for personnel in animal studies: There was continued improvement from 2012 to 2014 in the rate of personnel without scopes of practice. No personnel were found to be working outside their scope of practice this year.



Regulatory Audits (Animal) – Personnel Training

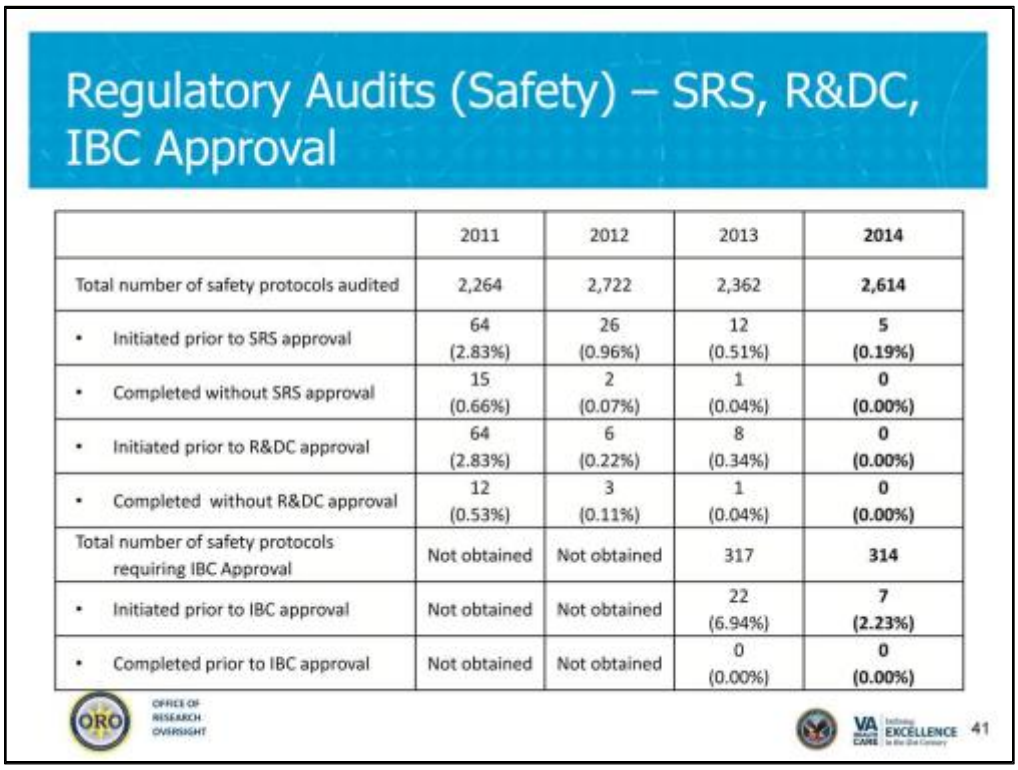
	2011	2012	2013	**2014**
Total number of research personnel in animal protocols audited	4,926	4,604	5,064	**4,838**
• Without initial training	93 (1.89%)	26 (0.56%)	19 (0.38%)	**24 (0.50%)**
• Lapse in continuing training	183 (3.71%)	160 (3.48%)	100 (1.97%)	**114 (2.36%)**

Personnel training for animal protocols: There was just a slight increase this year in reported training deficiencies for personnel in animal protocols.



For-cause suspensions/terminations: This is second year that ORO has obtained this information from the Research Program as opposed to the RCO audits. Therefore, these data are based on the number of active animal studies for this reporting period (most recent 12 months).

There were 30 animal protocols suspended or terminated, most related to administrative issues.



Regulatory Audits (Safety) – SRS, R&DC, IBC Approval

	2011	2012	2013	**2014**
Total number of safety protocols audited	2,264	2,722	2,362	**2,614**
• Initiated prior to SRS approval	64 (2.83%)	26 (0.96%)	12 (0.51%)	**5 (0.19%)**
• Completed without SRS approval	15 (0.66%)	2 (0.07%)	1 (0.04%)	**0 (0.00%)**
• Initiated prior to R&DC approval	64 (2.83%)	6 (0.22%)	8 (0.34%)	**0 (0.00%)**
• Completed without R&DC approval	12 (0.53%)	3 (0.11%)	1 (0.04%)	**0 (0.00%)**
Total number of safety protocols requiring IBC Approval	Not obtained	Not obtained	317	**314**
• Initiated prior to IBC approval	Not obtained	Not obtained	22 (6.94%)	**7 (2.23%)**
• Completed prior to IBC approval	Not obtained	Not obtained	0 (0.00%)	**0 (0.00%)**

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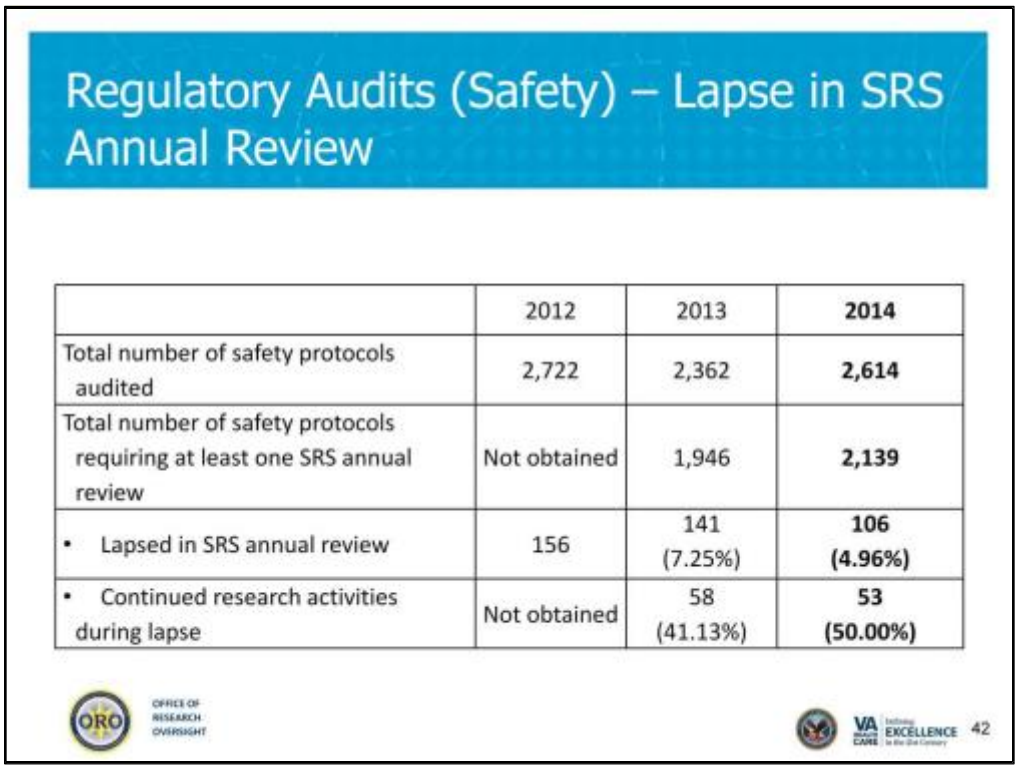
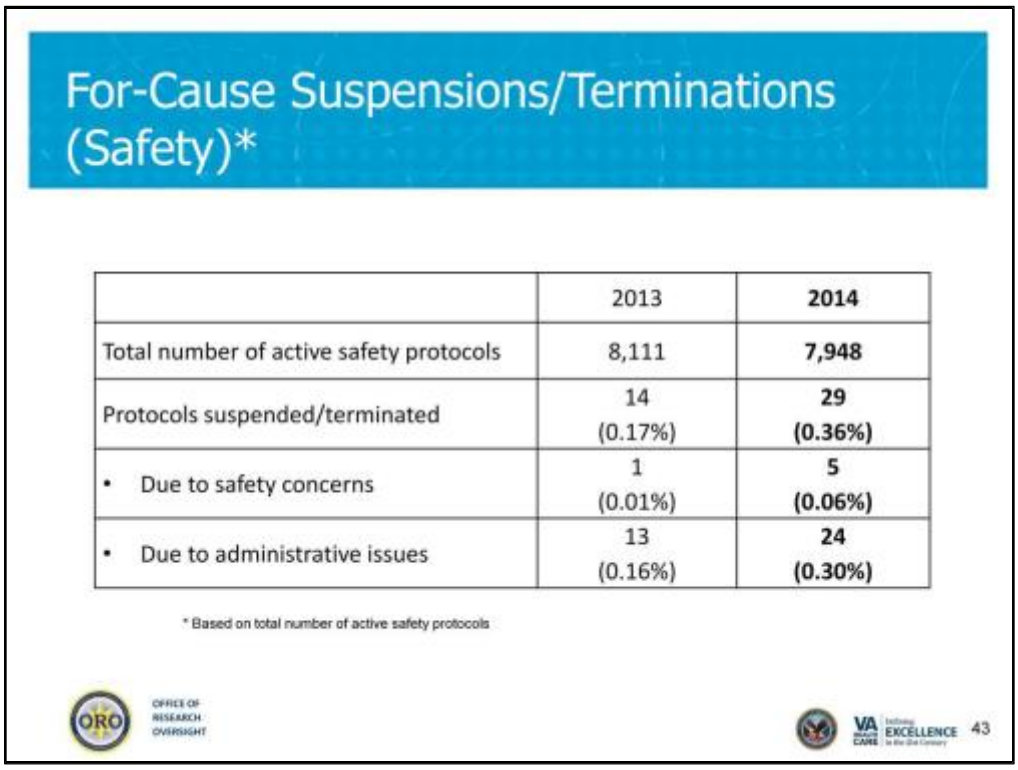
This slide reviews findings related to safety studies. RCOs are required to do safety audits of all protocols followed by the SRS including protocols that may also be followed by other subcommittees. In other words, these protocols include not just bench or basic science studies but any studies that have a safety component that the SRS is following. These studies include animal research and some human research with safety concerns.

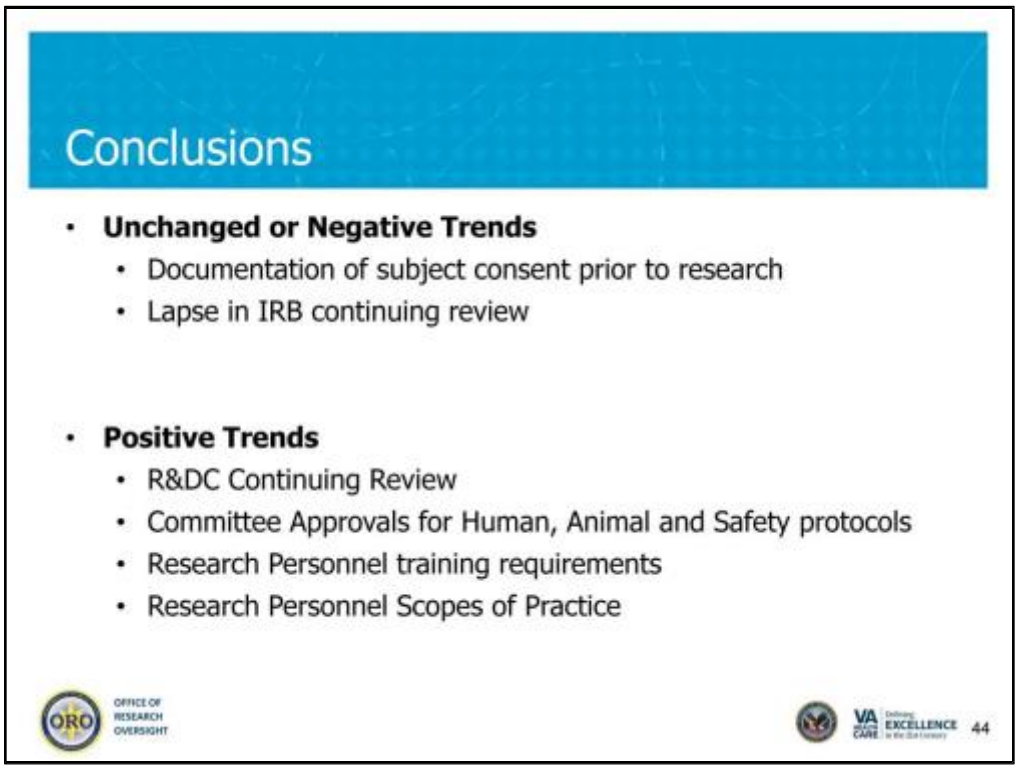
This table shows the data for deficiencies found with respect to SRS, R&DC, and Institutional Biosafety Committee (IBC) approvals. Note the overall positive trend from 2011 when ORO began collecting these data. Rates of protocols initiated prior to SRS review has trended downward each year, starting at 2.83 percent in 2011 to 0.19 percent in 2014. There is a similar trend in each measure, with zero protocols reported to have been initiated without SRS approval or completed without SRS, R&DC or IBC approval during the 2014 reporting period. Rates of protocols initiated without IBC approval has dropped markedly from 2013 (first year of measurement) to this year.



This table presents the data for lapses in SRS annual review. There was a marked improvement in lapses in SRS approvals from 2013 to 2014, although the rate of continued activities during the lapse was high. Lapses were reported by 27 facilities, while continued activity during the lapse was reported by 11 facilities



Data regarding For-Cause Suspensions of safety protocols were also provided by the Research Program and based on the total number of active safety protocols, not based on RCO audits, for the one-year reporting period. There were 29 protocols suspended by Safety Committees this reporting period, the great majority due to administrative issues.



For the past five years, ORO has been able to collect an expanded set of data regarding VA research programs and the findings of audits performed by Research Compliance Officers (RCOs). This report summarizes data for the past four years. While comparisons are difficult for some measures, some possible trends can be identified.

For most measures, small fluctuations up or down from year to year occurred but no definite trends emerged and deficiency rates remained fairly low overall. For some measures, one or two facilities accounted for the majority of deficiencies, which makes identifying trends more challenging.

ORO has identified two measures that may require some focused attention. One of these measures is assuring subject consent prior to research. Rates of this deficiency trended higher again for the 4th year consecutively. Although rates are generally low, it is an important measure with respect to human subject protections, the principle of respect for persons, and maintaining the trust of Veterans and other subjects in VA research. However, this deficiency appears to result from incidents at only a few VA facilities, and the involved facilities appear to change year-to-year.

The other measure is the rate of IRB CR lapses, which has remained persistently high since 2010. This year, the RCOs started collecting data on CR lapses with a 12 month look back. These data suggest recent improvement on this measure. ORO will continue to look at these data in future years.

On the positive side, there are several measures that demonstrate an improvement from last year to this year and a number of measures that have improved for four years consecutively.

Rates of deficiencies in R&DC CR went down for the third year in a row. Training and Scope of Practice deficiencies have gone down over the past four years as well.

Any type of research occurring without proper oversight committee approval is very rare in VA.

ORO will continue to collect these data and provide reports for quality improvement purposes to each facility. Each facility will receive a report with its own data in addition to VISN and National data.

ORO will continue working with the field in evaluating and refining the questions asked on the FDC in order to find questions that will provide valuable information for quality improvement.