Description of document:	National Institutes of Health (NIH) Agendas/Minutes of the most recent three meetings of the Vaccine Research Center Board of Scientific Counselors at the National Institute of Allergy and Infectious Diseases (NIAID), 2016-2018
Requested date:	24-May-2020
Release date:	02-July-2020
Posted date:	20-July-2020
Source of document:	FOIA Request FOIA Officer for NIH Building 31 Room 5B35 9000 Rockville Pike Bethesda, MD 20892 Fax: 301-402-4541 email: nihfoia@mail.nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email

July 2, 2020

Re: NIH FOIA Case No. 54472

This is the final response to your Freedom of Information Act (FOIA) request addressed to the National Institute of Allergy and Infectious Diseases (NIAID) FOIA Office, dated May 24, 2020 and received on May 26, 2020. Your request was referred to this office because of our responsibilities under the FOIA. You requested a copy of the agenda and minutes for the most recent three meetings of the Vaccine Research Center Board of Scientific Counselors at NIAID.

We conducted a search for records and located 51 pages responsive to your request, all of which are enclosed. I have determined to withhold portions of the released pages pursuant to exemption 5 of the FOIA, 5 U.S.C. § 552 (b)(5); and section 5.31 (e) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations) to:

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal".

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison	OGIS
Stephanie Clipper	National Archives and Records Admin.
Public Affairs Specialist	8601 Adelphi Rd – OGIS
Office of Communications and Public Liaison	College Park, MD 20740-6001
Building 1, Room 131	202-741-5770 (phone)
1 Center Drive	1-877-684-6448 (toll-free)
Bethesda, MD 20814	202-741-5769 (fax)
301-496-2411 (phone)	ogis@nara.gov (email)
nihfoia@mail.nih.gov (email)	

In certain circumstances provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the $25 minimum, there are no charges associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-malene -S

Digitally signed by Gorka Garcia-malene -S
Date: 2020.07.02 13:36:53 -04'00'

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosure: one pdf file (51 pages total)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Freedom of Information Office
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Sincerely,

Gorka Garcia-malene -S

Digitally signed by Gorka Garcia-malene -S
Date: 2020.07.02 13:36:53 -04'00'

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosure: one pdf file (51 pages total)

Vaccine Research Center
Board of Scientific Counselors

AGENDA

Vaccine Research Center, NIAID, NIH
40 Convent Drive, Bethesda, MD
December 12-13, 2018

The Entire Proceedings Are Closed

Wednesday, December 12

8:00 – 8:30	Coffee and Light Breakfast
8:30 – 9:00	**Welcome and Introductory Remarks** *Dr. Anthony S. Fauci, Director, NIAID*
9:00 – 9:30	**VRC Overview** *Dr. John R. Mascola, Director, VRC*
9:30 – 10:00	**Vaccine Production Program Overview** *Dr. John R. Mascola, Acting Program Chief*
10:00 – 10:15	*BREAK*
10:15 – 10:45	Individual interview with BSC Members *Dr. Mascola/Dr. Arnold*
10:45 – 11:15	Program Staff interview with BSC Members
11:15 – 1:00	Executive Session and Working Lunch
1:00 – 1:30	**Translational Research Program Overview** *Dr. Mario Roederer, Chief, ImmunoTechnology Section, Immunology Laboratory, VRC and Chair, ACUC* *Dr. Diana Scorpio, Program Chief*
1:30 – 2:00	Individual interview with BSC Members *Dr. Diana Scorpio*
2:00 – 2:30	Program Staff Interview with BSC Members
2:30 – 3:30	Executive Session
3:30 – 5:00	Discussion and Report Writing
6:00	BSC Committee Dinner

Thursday, December 13

8:30 – 9:00	Coffee and Light Breakfast
9:00 – 9:30	**Clinical Trials Program Overview** *Dr. Julie Ledgerwood, Program Chief*
9:30 – 10:00	Individual interview with BSC Members *Dr. Julie Ledgerwood*
10:00 – 10:30	Program Staff interview with BSC Members
10:30 – 11:30	Executive Session
11:30 – 1:00	Working Lunch and Finalization of Reports
1:00 – 2:00	Oral Reports to:

- Director, NIAID
- Principal Deputy Director, NIAID
- Deputy Director, Science Management, NIAID
- Director, VRC
- Deputy Director, Intramural Research, NIH

Adjourn

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Vaccine Research Center
Minutes of the 2018 Meeting of the VRC Subcommittee of the NIAID Board of Scientific Counselors

December 12-13, 2018

The 2018 meeting of the Vaccine Research Center (VRC) Subcommittee of the NIAID Board of Scientific Counselors (BSC) was convened at 8:30 a.m. in Conference Room 1201/1203 of Building 40 at the National Institutes of Health, Bethesda, Maryland. Dr. Eric Hunter presided as Chairman in the absence of Dr. Raphael (Ray) Dolin.

The VRC Board of Scientific Counselors subcommittee consists of members with expertise in virology, immunology, vaccine development, pathogenesis, molecular biology, vaccine licensure, infectious diseases, and antibody neutralization.

BSC Participants:

Eric Hunter, Ph.D., Acting Chair
Thomas Braciale, M.D., Ph.D.
Phillip Gomez, Ph.D.
Nancy Haigwood, Ph.D.
James Hoxie, M.D.
Eric Hunter, Ph.D.
Myron Levine, M.D. D.T.P.H.
Julie McElrath, M.D., Ph.D.
David Montfori, Ph.D.
Connie Schmaljohn, Ph.D.

Federal NIH Employees:

Anthony, Fauci, M.D. Director, NIAID
Hugh Auchincloss, M.D., Deputy Director, NIAID
Richard G. Wyatt, M.D., Executive Director, Office of Intramural Research, Office of the Director, NIH
John Mascola, M.D., Director, VRC, Chief, Virology Laboratory, Chief Humoral Immunology Section, Acting Director, Vaccine Production Program
Barney Graham, M.D., Ph.D, Deputy Director, Chief, Viral Pathogenesis Laboratory
Richard A. Koup, M.D., Deputy Director, VRC, Chief, Immunology Laboratory, Chief, Human Immunology Section

Mario Roederer, Ph.D. Chief, ImmunoTechnology Section, Immunology Laboratory, Chair, VRC ACUC
Frank Arnold, Ph.D., Contractor Lead for Vaccine Production Program
Diana Scorpio, D.V.M., M.P.H., DACLAM, Section Chief, Translational Research Program
Julie Ledgerwood, D.O.,Program Chief, Clinical Trials Program
Marybeth Daucher, Ph.D., Associate Director for Management and Operations, VRC

Closed Session:

Dr. Hunter called the meeting to order at 8:30 a.m. This portion of the meeting was closed to the public in accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). The Board of Scientific Counselors moved to Closed Session to review tenured scientists.

Report of the VRC Subcommittee of the NIAID Board of Scientific Counselors

The VRC Subcommittee of the NIAID Board of Scientific Counselors met on December 12–13, 2018 to conduct progress reviews of the following programs of the VRC: Dr. John Mascola/Dr. Frank Arnold, Ph.D., Vaccine Production Program, Dr. Diana Scorpio, D.V.M., Translational Research Program, and Dr. Julie Ledgerwood, D.O., Clinical Trials Program.

In attendance were: Drs. Eric Hunter, Thomas Braciale, Phillip Gomez, Nancy Haigwood, James Hoxie, Myron Levine, Julie McElrath, David Montefiori, and Connie Schmaljohn.

The following is an executive summary of the report of the Subcommittee.

Executive Summary

Dr. Anthony Fauci, Director, NIAID welcomed the BSC members and thanked them for their efforts on behalf of the Institute. He provided an overview of some recent changes to the Department of Health and Human Services (DHHS) noting that Alex M. Azar II, J.D. now serves as the Secretary. Mr. Azar is well known in the DHHS where he previously served as the Secretary from 2005 2007 and is knowledgeable about NIH. The Center for Disease Control and Prevention (CDC) is now led by Dr. Robert R. Redfield, M.D. who is also familiar with NIH, and who has recently visited the NIH and met with leadership at the VRC.

Dr. Fauci provided an update on the budget. The NIH was approved to receive a $2 billion increase in funding for the final FY2019 spending bill. This has been the 4th consecutive year that the NIH has received an increase, after more than a decade of flat budgets. Within the NIH, NIAID is the second in terms of institute size and funding. NIAID has operated on a $5.2 billion budget for FY2018 and received approval for a 4.7% increase for a total of $5.5 billion for FY2019.

Dr. Fauci provided a brief legislative update. The Republicans have retained the Senate majority, with Senator Mitch McConnell serving as the Majority Leader and Senator Charles Schumer serving as the Minority Leader. Dr. Fauci indicated the current leadership of the Senate

and House Committees and Subcommittees that have oversight and budgetary duties related to NIH and NIAID and noted that the recent elections will likely result in changes in the leadership when the next Congress convenes in January 2019.

Dr. Fauci outlined recent/ongoing disease outbreaks in 2018, highlighting two Ebola virus disease outbreaks in 2018 in the Democratic Republic of Congo. This area is currently experiencing political turmoil resulting in an upsurge of violence in various regions of the country making access challenging. Nevertheless, a clinical trial for Ebola treatments was initiated in the Democratic Republic of Congo to evaluate the VRC's mAb114 against other products including Remdesivir (Gilead)/GS-5734 REGN3470-3471-3479, and a control group of patients receiving ZMapp™.

Dr. Fauci concluded his remarks indicating this year's BSC focus on the Vaccine Production Program, Translational Research Program, and the Clinical Trials Program and their roles in the VRC.

Following Dr. Fauci's remarks, Dr. John Mascola, Director, VRC, NIAID welcomed and thanked the members of the BSC for their important contributions to improving the programs at the VRC and for providing helpful feedback to the Principal Investigators (PIs) who lead these programs. The purpose of the BSC Review of PIs is to evaluate their scientific programs on a roughly 4-year cycle, while also making recommendations regarding tenure (when appropriate) and resource allocation.

Dr. Mascola outlined the programs that are to be evaluated by the BSC while also briefly covering the overall organization of the VRC. He emphasized that the criteria for the BSC's review of research programs at the VRC include: 1) leadership skill of the Program Chief and the overall scientific quality of the Program, 2) success of each Program's integration and contribution to the overall VRC mission, and 3) success in advancing VRC scientific contributions to the field, including significance and impact. It was noted that these evaluation criteria for Program Chiefs address different roles for the VRC/NIAID compared to that of tenured or tenure-track Investigators within research laboratories. Guidance on the ratings and assessments by the BSC were also provided.

Major research and development programs were covered by Dr. Mascola including a description of the VRC's current product development portfolio. Dr. Mascola mentioned the increased funding of the VRC and noted the growing number of staff since 2010. Expansion plans for the VRC's physical space were also briefly discussed and outlined. Key aspects of the Vaccine Production Program, Translational Research Program, and Clinical Trials Program were highlighted.

Report of the BSC

General Comments:

From the written and oral presentations to the BSC it is very clear that each of the translational programs has made unique contributions to the goal of the VRC to discover, develop, and test novel approaches to the prevention and treatment of HIV and emerging infectious diseases that include influenza, filoviruses, and other pathogens. The Vaccine Production Program (VPP) and the Clinical Trials Program (CTP) have seen significant growth in the past 4 years, with the goal of being able to increase the throughput for clinical assessment of candidate vaccines or antibodies developed through the discovery programs of the VRC from 2-3 per year to 5-6 per year. It is very clear that this goal has been achieved while retaining an exceptionally high level of quality and while increasing efficiency at all levels to optimize opportunities.

As delineated below in the evaluation of the individual Programs, the VPP, TRP, and CTP bring critical capabilities to the VRC. These are coordinated through a central leadership group that ensures prioritization and integration of activities. What is most impressive is the manner in which the expansion of each Program has been executed to ensure outstanding leadership at all levels, and to respond to a constantly changing regulatory environment. The integrated workflow at the VRC of basic research, product generation, and preclinical/clinical assessment facilitated by these translational programs, is unique in its ability to accelerate the development of novel approaches for vaccines and treatment of important human pathogens.

Dr. John Mascola, Acting Program Chief, and Dr. Frank Arnold
General Comments

The VPP has become an (b)(5) component in serving the translational mission of the VRC to advance products developed through the basic science discovery at VRC to clinical studies. Its goal has been to translate candidate research vaccines and therapeutic molecules into FDA-approved materials for proof-of-concept clinical trials and to advance development into licensure with partners. During the last 4 years, there has been a major effort to enhance the VPP capacity with investment in infrastructure and an expansion of personnel from 49 to 126 individuals, thereby increasing the capacity for product development from 2 products per year to 5-6 products per year. The components of this program have been (b)(5)

(b)(5)

(b)(5)

Leadership Skill of the Program Chief and Overall Scientific Quality of the Program:

(b)(5)

Success of the Program's Integration and Contribution to the Overall VRC Mission:

(b)(5)

Success in Advancing the VRC Scientific Contributions to the Field, Including Significance and Impact:

(b)(5)

Additional Comments on Interviews with VPP Senior Scientists:

(b)(5)

Overall Comments and Recommendations:

(b)(5)

Rating: The BSC rated this Program (b)(5)

(b)(5)

The rating of the VPP by the BSC was (b)(5)

(b)(5)

Dr. Diana Scorpio, Translational Research Program

Leadership Skill of the Program Chief and Overall Scientific Quality of the Program:

(b)(5)

(b)(5)

Success of the Program's Integration and Contribution to the Overall VRC Mission:

(b)(5)

Success in Advancing the VRC Scientific Contributions to the Field, Including Significance and Impact:

(b)(5)

Overall Comments and Recommendations:

(b)(5)

(b)(5)

Rating: The BSC rated this Program as (b)(5)

(b)(5)

Dr. Julie Ledgerwood, Clinical Trials Program

General Comments:

The primary mission of the VRC CTP is to perform "high quality clinical research through the intramural conduct of clinical trials at the NIH Clinical Center and through external trials conducted by the VRC or by collaborators and partners." It is also charged with conducting translational immunology research and pursuing advanced clinical development including strategic planning, facilitation, support and oversight of external clinical trials. To pursue these missions, the CTP has collaborative protocols with researchers at the VRC and with external scientists to explore vaccine-induced B-cell maturation, innate immune responses following vaccination, and naturally occurring influenza, filovirus and HIV immune responses.

Leadership Skill of the Program Chief and Overall Scientific Quality of the Program:

In 2018 Julie Ledgerwood, D.O., was designated as the Chief Medical Officer, with the responsibility for Clinical Research Operations, Advanced Clinical Development, and Regulatory Activities of the Vaccine Research Center, NIAID, NIH. (b)(5)

(b)(5)

(b)(5)

Success of the Program's Integration and Contribution to the Overall VRC Mission; and Success in Advancing the VRC Scientific Contributions to the Field, Including Significance and Impact

(b)(5)

The CTP supports and conducts clinical trials of VRC investigational products through three mechanisms. The first is Internal Trials conducted at the NIH Clinical Center. (b)(5)

(b)(5)

(b)(5) The second mechanism is Phase 1 and 2 trials conducted externally utilizing CTP contract mechanisms. For this, the CTP utilizes Contract Research Organizations (CRO) to subcontract qualified and experienced clinical sites within the USA or in

other countries, including developing countries. The CTP nevertheless is fully responsible for writing the protocols for the clinical trials, overseeing regulatory processes, arranging data management and supervising overall clinical operations. (b)(5)

(b)(5)

The third mechanism is clinical trials of VRC products performed via collaboration with established networks of clinical investigators managed by government and non-governmental programs. These include clinical trials of VRC products tested by the NIAID/DAIDS funded HVTN, ACTG, IMPAACT networks, the US Military HIV Research Program, and the International AIDS Vaccine Initiative clinical trials program. Under this mechanism the CTP is responsible for representing the VRC as the product expert. Based on VRC's familiarity with the product, CTP personnel often assist investigators within these networks with protocol design, data management, clinical operations planning and training, and adverse event evaluation. (b)(5)

(b)(5)

(b)(5)

Overall Comments and Recommendations:

(b)(5)

Rating: The BSC's overall rating of the CTP (b)(5)

(b)(5)

Adjournment

The Board adjourned at 2:00 p.m. on December 13, 2018. I certify that, to the best of my knowledge, the foregoing minutes of the NIAID Board of Scientific Counselors meeting are accurate and correct.

The Board has formally submitted its report to NIAID/NIH. It is our understanding that Dr. Mascola has accepted the recommendations of the Board.

Date

Eric Hunter, Ph.D.
Acting Chairman, VRC Subcommittee of the Board of Scientific Counselors
NIAID

These minutes will be formally considered by the Board of Scientific Counselors at its next meeting: corrections and notations will be incorporated into the minutes of that meeting.

VRC Subcommittee of the National Institute of Allergy and Infectious Diseases Board of Scientific Counselors

AGENDA

Vaccine Research Center, NIAID, NIH
40 Convent Drive, Bethesda, MD
June 7-8 2017

The Entire Proceedings Are Closed

Wednesday, June 7

8:30 – 9:00 a.m.	Introductions
9:00 – 9:15	Greetings and Introductory Comments *Dr. Anthony Fauci, Director, NIAID*
9:15 – 9:30	VRC Overview *Dr. John Mascola, Director, VRC*
9:30 – 10:00	Break
10:00 – 10:30	Structural Biology Section of Virology Laboratory *Dr. Peter Kwong, Section Chief*
10:30 – 11:00	Individual Interview with BSC Members *Dr. Peter Kwong, Section Chief*
11:00 – 11:30	Laboratory Staff Interviews with BSC Members *Staff Members, Structural Biology Section*
11:30 – 12:30	Lunch and Executive Session – Discussion
12:30 – 1:30	Executive Session – Report Writing
1:30 – 1:45	Immunology Laboratory Overview *Dr. Richard Koup, Laboratory Chief*
1:45 – 2:15	Immunology Laboratory *Dr. Richard Koup, Laboratory Chief*
2:15 – 2:30	Break

2:30 – 3:00	Individual Interview with BSC Members *Dr. Richard Koup, Laboratory Chief*
3:00 – 3:30	Laboratory Staff Interviews with BSC Members *Staff Members, Immunology Laboratory*
3:30 – 4:30	Executive Session – Discussion and Report Writing

Thursday, June 8

8:30 – 9:00	Introductions
9:00 – 9:30	Human Immunology Section of Immunology Laboratory *Dr. Daniel Douek, Section Chief*
9:30 – 10:00	ImmunoTechnology Section of Immunology Laboratory *Dr. Mario Roederer, Section Chief*
10:00 – 10:30	Individual Interviews with BSC Members *Dr. Daniel Douek, Section Chief* *Dr. Mario Roederer, Section Chief*
10:30 – 10:45	Break
10:45 – 11:15	Laboratory Staff Interviews *Staff Members, Human Immunology Section* *Staff Members, ImmunoTechnology Section*
11:15 – 12:15	Executive Session – Discussion
12:15 – 1:15	Lunch and Executive Session – Report Writing
1:15 – 2:15	Executive Session – Finalization of Reports
2:15 – 3:30	Oral Reports to: ○ Director, NIAID ○ Deputy Director, NIAID ○ Deputy Director, Science Management, NIAID ○ Director, VRC ○ DDIR
3:30 p.m.	Adjourn

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Vaccine Research Center
Minutes of the 2017 Meeting of the VRC Subcommittee of the NIAID Board of Scientific Counselors

June 7-8, 2017

The 2017 meeting of the Vaccine Research Center (VRC) Subcommittee of the NIAID Board of Scientific Counselors (BSC) was convened at 8:30 a.m. in Conference Room 1201/1203 of Building 40 at the National Institutes of Health, Bethesda, Maryland. Dr. Raphael (Ray) Dolin presided as Chairman.

The VRC Board of Scientific Counselors subcommittee consists of members with expertise in virology, immunology, cellular immunology, cellular biology, antibody neutralization, molecular biology, pathogenesis, vaccines, vaccine licensure, infectious diseases, and clinical research.

BSC Participants:

Raphael (Ray) Dolin, M.D., Chairman
Rafi Ahmed, Ph.D.
Thomas Braciale, M.D., Ph.D.
Nancy Haigwood, Ph.D.
James Hoxie, M.D.
Eric Hunter, Ph.D.
Myron Levine, M.D., D.T.P.H.
Julie McElrath, M.D., Ph.D.
David Montefiori, Ph.D.
Connie Schmaljohn, Ph.D.

Federal NIH Employees:

Anthony, Fauci, M.D. Director, NIAID
John Mascola, M.D., Director, VRC, Chief, Virology Laboratory, Chief Humoral Immunology Section
Hugh Auchincloss, M.D., Deputy Director, NIAID
Richard G. Wyatt, M.D., Executive Director, Office of Intramural Research, Office of the Director, NIH
Richard Koup, M.D., Chief, Immunology Laboratory
Peter Kwong, Ph.D., Chief, Structural Biology Section, Virology Laboratory

Daniel Douek, Chief, Human Immunology Section, Immunology Laboratory
Mario Roederer, Ph.D., Chief, ImmunoTechnology Section, Immunology Laboratory
Marybeth Daucher, Ph.D., Associate Director for Management and Operations, VRC
Carole Hudgings, Office of the Director, NIAID

Closed Session:

Dr. Dolin called the meeting to order at 8:30 a.m. This portion of the meeting was closed to the public in accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). The Board of Scientific Counselors moved to Closed Session to review tenured scientists.

Report of the VRC Subcommittee of the NIAID Board of Scientific Counselors

The VRC Subcommittee of the NIAID Board of Scientific Counselors met on June 7-8, 2017 to conduct progress reviews of the following laboratories of the VRC: Dr. Peter Kwong, Structural Biology Section, Virology Laboratory; Dr. Richard Koup, M.D., Immunology Laboratory; Dr. Daniel Douek, Human Immunology Section, Immunology Laboratory; and Dr. Mario Roederer, ImmunoTechnology Section, Immunology Laboratory.

In attendance were: Drs. Raphael Dolin, Rafi Ahmed, Thomas Braciale, Nancy Haigwood, James Hoxie, Eric Hunter, Myron Levine, Julie McElrath, David Montefiori, and Connie Schmaljohn,

The following is an executive summary of the report of the Subcommittee.

Executive Summary

Dr. Anthony Fauci, Director, NIAID welcomed the BSC members and thanked them for their efforts on behalf of the Institute. He provided an overview of changes at DHHS, NIH and NIAID. Dr. Thomas Price is now Secretary, DHHS, and made his first visit to NIH in that capacity on February 21, 2017. Dr. Scott Gottlieb is now Commissioner at the FDA where he had been a Deputy Commissioner previously. Dr. Anne Schuchat is Acting Director at CDC, and a nominee for the Director position has not yet been submitted. President Trump has asked the NIH Director, Dr. Francis Collins to stay on permanently in his position. Dr. Emily Erbelding has been named as the Director of NIAID's Division of Microbiology and Infectious Diseases; she was previously Deputy Director of the Division of AIDS.

Dr. John Mascola, Director, VRC, thanked the BSC members for their willingness to participate in this important process. He stated the purpose of the BSC review is to assess the scientific programs of the individual investigators and make recommendations on scientific direction and resources, as well as to provide information for tenure decisions and for key staff positions in the VRC. There will not be any tenure recommendations needed for this BSC meeting. Dr. Mascola summarized the NIH and VRC review criteria as well as the rating system, and indicated the laboratories to be reviewed at this meeting and their focus.

He reported on the range of viruses that are studied at the VRC, with major efforts on HIV, Zika, Ebola, Influenza and RSV, and summarized the status of the various studies of vaccines under development.

Dr. Mascola provided an overview of VRC funding for the past six years, the major components for which have been for HIV and for biodefense, with support for emerging diseases as well.

Dr. Mascola summarized the off-campus expansion of VRC efforts which include the immunology core (NVITAL), the vaccine production facility, and aspects of the NHP Core, genome analysis core, tissue analysis core and crystallography.

He delineated the personnel in the VRC Office of Director and noted that several of these positions relate to the increase in the VRC's involvement in vaccine trials, with over 10,000 volunteers having participated in the clinical aspects of vaccine development. Additional staff is therefore needed in terms of regulatory expertise and effort, staffing for project management and vaccine production, as well as for strategic planning and scientific collaborations.

He indicated that Dr. Eli Boritz has been selected as a new tenure track PI for the Virus Persistence and Dynamics Section, in the Immunology Laboratory.

Dr. Mascola provided a brief overview of the status of Zika virus in terms of epidemiology in Polynesia and the Americas and of the Zika vaccine construct. He noted that in August 2016 NIH began testing an investigational Zika vaccine in humans. A phase 2b efficacy trial will begin at 20 sites in the US, Caribbean and South American in July 2017. The initial vaccine was DNA based using technology that the VRC had developed. Using this approach, it was possible to make an immunogen for testing in 3.5 months. The vaccine effort is in collaboration with DMID, NIAID. The VRC is part of an interagency group that includes BARDA, FDA and CDC as well as Walter Reed Army Medical Center, to develop a strategic plan for the Zika vaccine effort.

Report of the BSC

General Comments

The four laboratories that were reviewed were the Structural Biology Section, the Immunology Section, the Human Immunology Section, and the Immunotechnologic Section. (b)(5)

(b)(5)

(b)(5)

Review of Laboratories

Dr. Peter Kwong, Structural Biology Section, Virology Laboratory

Overall Rating: (b)(5)

General Description

Dr. Peter Kwong is chief of the structural biology section of the VRC, a position he has held for 7 years (b)(5)

(b)(5)

Dr. Kwong's research program encompasses three broad aims: 1) To gain a structural understanding at the atomic level of the functional HIV-1 envelope (Env) gp120/gp41 trimer; 2) To define how antibodies recognize this trimer to neutralize viruses, as well as the pathways of B cell development that are required for their induction; and 3) To utilize structural information to design immunogens that are capable of eliciting a broadly neutralizing antibody response. As

(b)(5)

(b)(5)

Summary:

(b)(5)

Dr. Richard Koup, Immunology Laboratory

Overall Assessment and Recommendations: (b)(5)
Adapted from VRC, NIAID website:

The mission of the Immunology Laboratory (IML) is to investigate novel aspects of the cellular immune response to pathogens in support of the rational development of a vaccine against HIV and other lethal human viral pathogens.

There are 3 main areas of research: (1) Immune correlates of protection from virus infection; (2) HIV/SIV replication in vivo; and (3) T follicular helper (Tfh) cells in HIV/SIV pathogenesis and vaccination.

The overall goals of the IML are accomplished through three projects. First and foremost, understanding how the immune response affects virus acquisition and virus replication – whether in HIV, influenza, or Ebola virus infections – will be crucial in determining appropriate vaccination strategies for these pathogens. In addition, recent successes in the development of vaccines for all three of these agents allow for an interrogation of possible immune correlates. Therefore, the IML has a project to evaluate immune correlates of protection from virus infection. Based upon clinical observations, it is hypothesized that not all CD4 T cells are infected equally by HIV or SIV, and these differences can affect the differential depletion of CD4 T cells specific for different pathogens. Therefore, the IML has a project to investigate HIV/SIV replication in vivo in an effort to determine what cells are infected and depleted by HIV/SIV and what cells are actively expressing HIV/SIV. A beneficial outcome of this project is the ability to specifically target HIV-expressing cells for elimination as part of a cure agenda. The final and newest project derives from the observation that most broadly neutralizing antibodies to HIV have undergone extensive somatic hypermutation. Therefore, The IML is investigating T follicular helper cells in HIV/SIV pathogenesis and vaccination with the goal of coming up with better strategies to induce the generation of hypermutated neutralizing antibodies to HIV through vaccination. All of the projects should help inform decision on next-generation vaccines.

Review Criteria:

(b)(5)

(b)(5)

(b)(5)

Dr. Daniel Douek, Human Immunology Section, Immunology Laboratory

Overall Rating; (b)(5)

Dr. Douek serves as the Vaccine Research Center Chief of the Human Immunology Section, a position he has held since 2000. His research seeks to determine the course of human diseases in which the immune system, particularly its T cell arm, plays a central role in their pathogenesis and outcome. The aim is to use the knowledge gained through these studies to initiate clinical studies of new therapeutic and vaccine approaches.

Review Criteria:

(b)(5)

(b)(5)

(b)(5)

Dr. Mario Roederer, ImmunoTechnology Section, Immunology Laboratory

Rating: (b)(5)

(b)(5)

Summary

Dr. Mario Roederer is a tenured investigator and Chief of the ImmunoTechnology section at the VRC (b)(5)

(b)(5)

Significance

Dr. Roederer's laboratory program incorporates three major areas of investigation designed to quantitatively elucidate the regulation of the adaptive immune responses, with a focus on antigen-specific functions elicited by vaccination and infection. (b)(5)

(b)(5)

1. Modeling antibody-based interventions against HIV in the NHP model
2. Genetic and environmental influences on the human immune system
3. Leukocyte trafficking dynamics in NHP

(b)(5)

(b)(5)

(b)(5)

Discussion with Representatives of NIAID and NIH

There was a brief discussion after the BSC members presented their assessments to Drs. Auchincloss and Wyatt, both of whom thanked the BSC members for their time and efforts on behalf of NIAID and NIH.

(b)(5)

Adjournment

The Board adjourned at 2:50 p.m. on June 8, 2017. I certify that, to the best of my knowledge, the foregoing minutes of the NIAID Board of Scientific Counselors meeting are accurate and correct.

The Board has formally submitted its report to NIAID/NIH. It is our understanding that Dr. Mascola has accepted the recommendations of the Board.

7/13/17 Raphael Dolin
Date

Raphael (Ray) Dolin, M.D.
Chairman
VRC Subcommittee of the Board of Scientific Counselors
NIAID

These minutes will be formally considered by the Board of Scientific Counselors at its next meeting: corrections and notations will be incorporated into the minutes of that meeting.

VRC Subcommittee of the National Institute of Allergy and Infectious Diseases Board of Scientific Counselors

Vaccine Research Center, NIAID, NIH
40 Convent Drive
Bethesda, MD 20892

September 8-9, 2016

The Entire Proceedings Are Closed

Thursday, September 8

8:00 – 8:30 a.m.	Coffee and Introductions
8:30 – 8:45	Greetings and Introductory Comments Dr. Anthony S. Fauci, Director, NIAID
8:45 – 9:15	Overview of the VRC Dr. John Mascola, Director, VRC, NIAID
9:15 – 9:45	Overview of the Humoral Immunology Section, Virology Laboratory Dr. John Mascola
9:45 – 10:15	Laboratory Staff Interviews
10:15 – 10:45	Individual Interview with BSC Members Dr. John Mascola
10:45 – 11:00	Break
11:00 – 11:30	Overview of the Viral Pathogenesis Section, Viral Pathogenesis Laboratory Dr. Barney Graham
11:30 – 12:00 p.m.	Laboratory Staff Interviews
12:00 – 12:30	Individual Interview with BSC Members Dr. Barney Graham
12:30 – 1:30	Lunch
1:30 – 1:45	Overview of the Immunology Laboratory Dr. Richard Koup
1:45 – 2:15	Overview of the Cellular Immunology Section, Immunology Laboratory Dr. Robert Seder
2:15 – 2:45	Laboratory Staff Interviews
2:45 – 3:15	Individual Interview with BSC Members Dr. Robert Seder

3:15 – 3:30	Break
3:30 – 5:30	Executive Session - Discussion and Report Writing

Friday, September 9

8:00 – 8:30 a.m.	Coffee and Introductions
8:30 – 9:00	Overview of the Biodefense Research Section, Immunology Laboratory Dr. Nancy Sullivan
9:00 – 9:30	Laboratory Staff Interviews
9:30 – 10:00	Individual Interview with BSC Members Dr. Nancy Sullivan
10:00 – 10:30	Break
10:30 – 11:30	Executive Session – Discussion
11:30 – 12:30 p.m.	Lunch – Executive Session and Report Writing
12:30 – 1:30	Executive Session – Finalization of Reports
1:30 – 2:30	Oral Reports to: ○ Director, NIAID ○ Deputy Director, NIAID ○ Deputy Director, Science Management, NIAID ○ Director, VRC, NIAID ○ DDIR, NIH
2:30	Adjourn

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Vaccine Research Center
Minutes of the 2016 Meeting of the VRC Subcommittee of the NIAID Board of Scientific Counselors

September 8-9, 2016

The 2016 meeting of the Vaccine Research Center (VRC) Subcommittee of the NIAID Board of Scientific Counselors (BSC) was convened at 8:30 a.m. in Conference Room 1201/1203 of Building 40 at the National Institutes of Health, Bethesda, Maryland. Dr. Eric Hunter presided as Acting Chairman.

The VRC Board of Scientific Counselors subcommittee consists of members with expertise in virology, immunology, cellular immunology, cellular biology, antibody neutralization, molecular biology, pathogenesis, vaccines, vaccine licensure, infectious diseases, and clinical research.

BSC Participants:

*Raphael (Ray) Dolin, M.D., Chairman
Rafi Ahmed, Ph.D.
Nina Bhardwaj, M.D., Ph.D.
Thomas Braciale, M.D., Ph.D.
Nancy Haigwood, Ph.D.
James Hoxie, M.D.
Eric Hunter, Ph.D., Acting Chairman
Myron Levine, M.D. D.T.P.H.
Julie McElrath, M.D., Ph.D
David Montefiori, Ph.D.
Connie Schmaljohn, Ph.D.
*Did not attend

Federal NIH Employees:

Anthony, Fauci, M.D. Director, NIAID
John Mascola, M.D., Director, VRC, Chief, Virology Laboratory, Chief Humoral Immunology Section
Carole Hudgings, Ph.D., Senior Advisor to the Deputy Director, NIAID
Jill Harper, Ph.D., Associate Director for Science Management, NIAID
Richard G. Wyatt, M.D., Executive Director, Office of Intramural Research, Office of the Director, NIH
Richard Koup, M.D., Deputy Director, VRC, Chief, Immunology Laboratory
Robert Seder, M.D., Chief, Cellular Immunology Section, Immunology Laboratory

Barney Graham, M.D., Ph.D. Deputy Director, VRC, Chief, Viral Pathogenesis Laboratory
Nancy Sullivan, Ph.D., Chief, Biodefense Research Section, Immunology Laboratory
Marybeth Daucher, Ph.D., Associate Director for Management and Operations, VRC

Closed Session:

Dr. Hunter called the meeting to order at 8:30 a.m. This portion of the meeting was closed to the public in accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). The Board of Scientific Counselors moved to a Closed Session to review tenured scientists.

Report of the VRC Subcommittee of the NIAID Board of Scientific Counselors

The VRC Subcommittee of the NIAID Board of Scientific Counselors met on September 8-9, 2016 to conduct progress reviews of the following laboratories and cores of the VRC: Dr. John Mascola, Chief, Humoral Immunology Section, Virology Laboratory; Dr. Robert Seder, M.D., Chief, Cellular Immunology Section, Immunology Laboratory; Dr. Barney Graham, Chief, Viral Pathogenesis Laboratory, and Dr. Nancy Sullivan, Chief, Biodefense Research Section, Immunology Laboratory.

In attendance were: Drs. Rafi Ahmed, Nina Bhardwaj, Thomas Braciale, Nancy Haigwood, James Hoxie, Eric Hunter, Myron Levine, Julie McElrath, David Montefiori, and Connie Schmaljohn.

The following is an executive summary of the report of the Subcommittee.

Executive Summary

Dr. Fauci welcomed the BSC members and thanked them for their service. He appreciated the effort made by the BSC board members and how their work makes the VRC outstanding. He mentioned that Dr. Goodenow is now the Director of the NIH Office of AIDS Research and Dr. Holland is the Head of DIR. Dr. Fauci provided an overview of the NIAID budget (2000-2017) and stated that the budget is essentially flat; the proposed increase is all earmarked. The increase in the budget does not go to the larger NIH pool of researchers. The President has asked for 2.6% increase for NIH, however this is earmarked for the NCI moonshot.

Dr. Fauci noted that NIAID has a dual mandate, to maintain and grow a robust research portfolio in microbiology, infectious diseases, immunology and immune mediated diseases as well as to respond rapidly to emerging and re-emerging disease threats. No other NIH institute has the responsibility of responding to a public health emergency. In this regard, Zika Virus in the Americas, yet another arbovirus threat follows on a number of infectious disease outbreaks in 2015-2016 including those ranging from measles, drug-resistant TB, malaria, and avian influenza, etc. Dr. Fauci summarized the number of reported cases of Zika Virus in the U.S., US Territories as well as affected pregnancies and the consequences of these. He summarized the local Zika transmission in Florida. He also mentioned the media coverage of the disease and the government responses. Dr. Fauci talked about Zika and how the number of cases in the US is

underestimated. Florida has been hard hit and the only way to control the epidemic is to control mosquitoes. Phase I testing of the VRC DNA vaccine is starting here at NIH with initial results expected by the end of 2016. There is a plan to start Phase II in Jan/Feb 2017. Florida may be a site for a Phase II trial, as also Singapore, where the number of reported Zika cases is increasing. He indicated the progress towards Zika vaccine development in which there is NIAID involvement, including DNA and mRNA candidates at the VRC, an intramural live-attenuated vaccine, an NISID extramural VSV vectored vaccine, and VRC collaborative efforts with WRAIR and Sanofic Pasteur (inactivated vaccine).

For funding the Phase 1 trial, NIAID moved S47M from malaria, TB . For Phase II, the Secretary exercised a 1% transfer authority and provided $34M of which S33M is to the VRC. The President has requested an emergency supplement to address the ZIKA crisis, with S277,000,000 designed for NIH/NIAID of the total of 1,885,094,000 total. In 2016 NIAID spent a total of $92 million on Zika- related research. This included some funds from the NIAID appropriations, but also a significant amount of repurposed Ebola funds and a transfer from the HHS Secretary.

Overview of the BSC and Virology Laboratory

Dr. John Mascola, Director, VRC, thanked the BSC members for their willingness to participate in this important process. He stated that the BSC has an advisory role to the NIAID Director and the purpose of the BSC review is assessing the scientific programs of the individual investigators and making recommendations on scientific direction and resources. The BSC evaluation is part of many reports and is considered by NIAID, NIH as part of the process of evaluating requests for promotions and salary justifications. There will not be any tenure recommendations needed for this BSC meeting. The criteria for review are provided by the NIH, which tries to harmonize across different institutions. Somewhat unique to the VRC is that while maintaining their scientific programs, BSC should consider and comment on the investigators' contributions to the vaccine mission of the VRC and NIAID.

Dr. Mascola provided a brief background and highlights of VRC accomplishments between 2014 and 2016. He gave an overview of the VRC Clinical Product Portfolio in 2016, which includes HIV, Influenza, Ebola/Marburg, Chikungunya (CHIKV), Venezuelan, Eastern and Western Encephalitis Virus (VEE, EEE, WEE), West Nile, Zika, RSV, Malaria, MERS-CoV and Tuberculosis. Of the VRC products in trials globally, VRC01, CHIKV VLP and cAd3-EBO are in more extensive testing. It is extremely challenging to maintain basic research while continuing advanced development.

The engineering group at Gaithersburg has grown into a large group, with 13 people working there, who manage all the clinical trial assays. A key role is screening neutralizing antibodies and finding new ones. This group will be headed by Dr. Adrian McDermott.

Dr. Mascola provided an overview of VRC funding for the past ten years, the major components of which are for biodefense and HIV, with some resources for emerging diseases. He noted that VRC staff has expanded considerably from 168 in 2005 to 300 in 2015, with about 1/3 of the staff members consisting of FTEs, non-FTEs and contractors. Although the budget has remained relatively constant between 2012 and 2015, an increase is expected in 2016 and 2017. The two

major components of the budget are HIV and Biodefense & Emerging Infectious Diseases. A small component of the budget is used for Infectious and Immunological Diseases such as RSV, Leishmania, Malaria, TB and MERS-CoV.

Dr. Mascola presented a brief overview of the Laboratories and Sections that will be reviewed at this meeting, emphasizing the scientific progress and new knowledge yielded by each of the individual groups and noting the collaborative endeavors among VRC investigators, as well as with other intramural and extramural scientists. He mentioned the rapid pace of Zika vaccine development and that first in human Phase I trials commenced on August 3, 2016. Previously, VRC has developed and conducted a Phase 1 study of a West Nile DNA vaccine, which has been the most immunogenic DNA vaccine; thus they took a similar approach of developing a DNA vaccine for Zika.

There was a question regarding the continued importance and funding of HIV at the VRC since HIV is not currently getting a lot of national attention. Dr. Mascola said HIV would continue to be very important especially since the VRC is starting to make trimers and antigens at the GMP facility. Regarding a question on backlog at the processing plant and the VRC's strategy of working with commercial manufacturing to get the vaccines out to the public, Dr. Mascola said that there was ongoing strategic planning for making decisions. HIV is #1 priority and flu is #2. At the same time, the VRC has adapted to challenges e.g. Zika has taken huge amount of time.

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Dr. Mascola reiterated that the VRC PIs maintain their strong interest in basic research while balancing the translational aspects of the programs.

Regarding a question on funding for Zika, Dr. Mascola mentioned that there is a certain amount of flexibility since Zika is a flavivirus; moneys allocated to the study of other flaviviruses can be used for Zika. There was a discussion on flexibility in funding and that there is a possibility that there will be a budget authorized for public health emergencies.

The VRC is reaching out to other groups at NIH and beyond in order to manage the extensive clinical portfolio. The Universities of MD and Emory have been very helpful in setting up Ebola trials in the US and Uganda, VRC01 in Thailand; Dr. Levine helped to set up Ebola trials in Mali. Dr. Mascola pointed out to the BSC board members that when they reviewed the CTP in 2014, they had said that the CTP should get more resources, and this is happening albeit slowly.

Immune assays for all the Zika Phase I trials involve Ted Pearson, within NIH, and it will be moved into NVITAL. Dr. Fauci has allowed the VRC to work with extramural divisions even though funding lines are different.

Immunology Laboratory Overview

Dr. Rick Koup, Deputy Director, VRC and Chief, Immunology Laboratory provided an overview of the various organizational changes recently occurring at the VRC with a focus on promoting the careers of young investigators. This includes (b)(5) for Staff Scientists to head new cores e.g. Costas Petrovas for the Tissue Analysis Core (TAC), establishment of a new unit, Precision Medicine Incubator with Pratip Chattopadhyay as Head. A new program, Vaccine Immunogenicity Program has been established with Adrian McDermott, Senior Scientist as Chief. The VRC has also created new tenure track positions for young investigators.

Dr. Koup went on to provide research highlights of the Biodefense Research Section (BRS) and the Cellular Immunology Section (CIS), whose Chiefs, Dr. Nancy Sullivan and Dr. Robert Seder are being reviewed by the BSC this year. (b)(5)

(b)(5)

Report of the BSC

Based on the presentations of the four laboratories under review, the BSC concluded that the

(b)(5)

(b)(5)

Dr. John Mascola, Humoral Immunology Section, Virology Laboratory

Overview

Dr. Mascola provided an overview of the Humoral Immunology Section, the Humoral Immunology Core, and the Virology Core, all under the Virology Laboratory. The Virology Laboratory (b)(5)

(b)(5)

(b)(5)

(b)(5)

Dr. Barney Graham, Viral Pathogenesis Laboratory

Mission: The mission of the VPL is to define immunologic mechanisms by which vaccines can be used to prevent or modify disease; and to design vaccine antigens and develop assays that support the advancement of new candidate vaccines into manufacture and clinical evaluation.

Description of Program and Presentation to the BSC on September 8, 2016

Dr. Barney Graham leads the Viral Pathogenesis Laboratory (VPL), which includes the Translational Science Core. The VPL has 3 projects: Project 1, Respiratory syncytial virus (RSV) vaccine development and pathogenesis; Project 2, Development of universal influenza vaccines; Project 3: Vaccine development for MERS CoV and other emerging virus infections. Dr. Graham addressed 5 areas of progress that related to different aspects of the 3 projects: 1) Structure of prefusion form of RSV F; 2) Development of a candidate RSV vaccine based on the prefusion form of RSV F; 3) Defining the pattern of RSV-induced antibody responses, specifically the fraction of RSV -induced antibody to the pre-fusion and post fusion form of the protein; 4) Structure-based design paradigm informed by the findings with the RSV F protein and other viral membrane glycoproteins; and 5) Rapid development of a Zika virus vaccine.

Review Criteria:

(b)(5)

(b)(5)

(b)(5)

Dr. Robert Seder, Cellular Immunology Section, Immunology Laboratory

Dr. Robert Seder serves as the Vaccine Research Center Chief of the Cellular Immunology Section, a position held since 2000. His research seeks to understand innate and adaptive immune mechanisms by which vaccines mediate protection against infections and tumors in preclinical animal models. Findings from these studies are then translated into human disease, specifically in the development of vaccines against malaria, tuberculosis, HIV and therapeutic vaccines against cancer. (b)(5)

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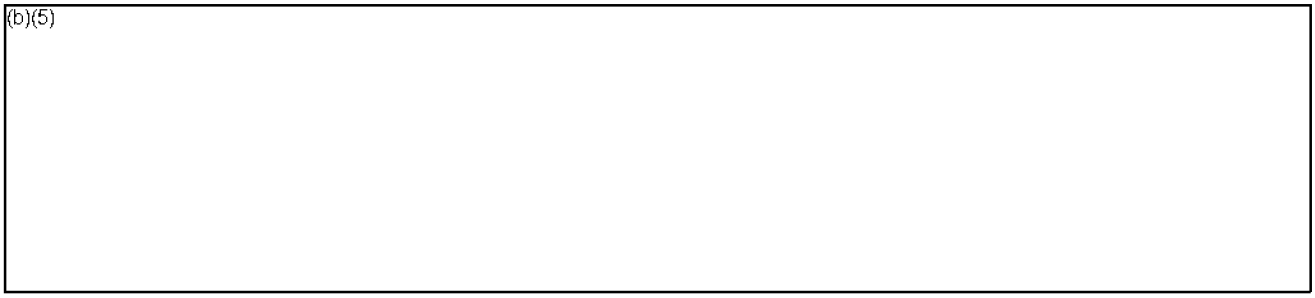
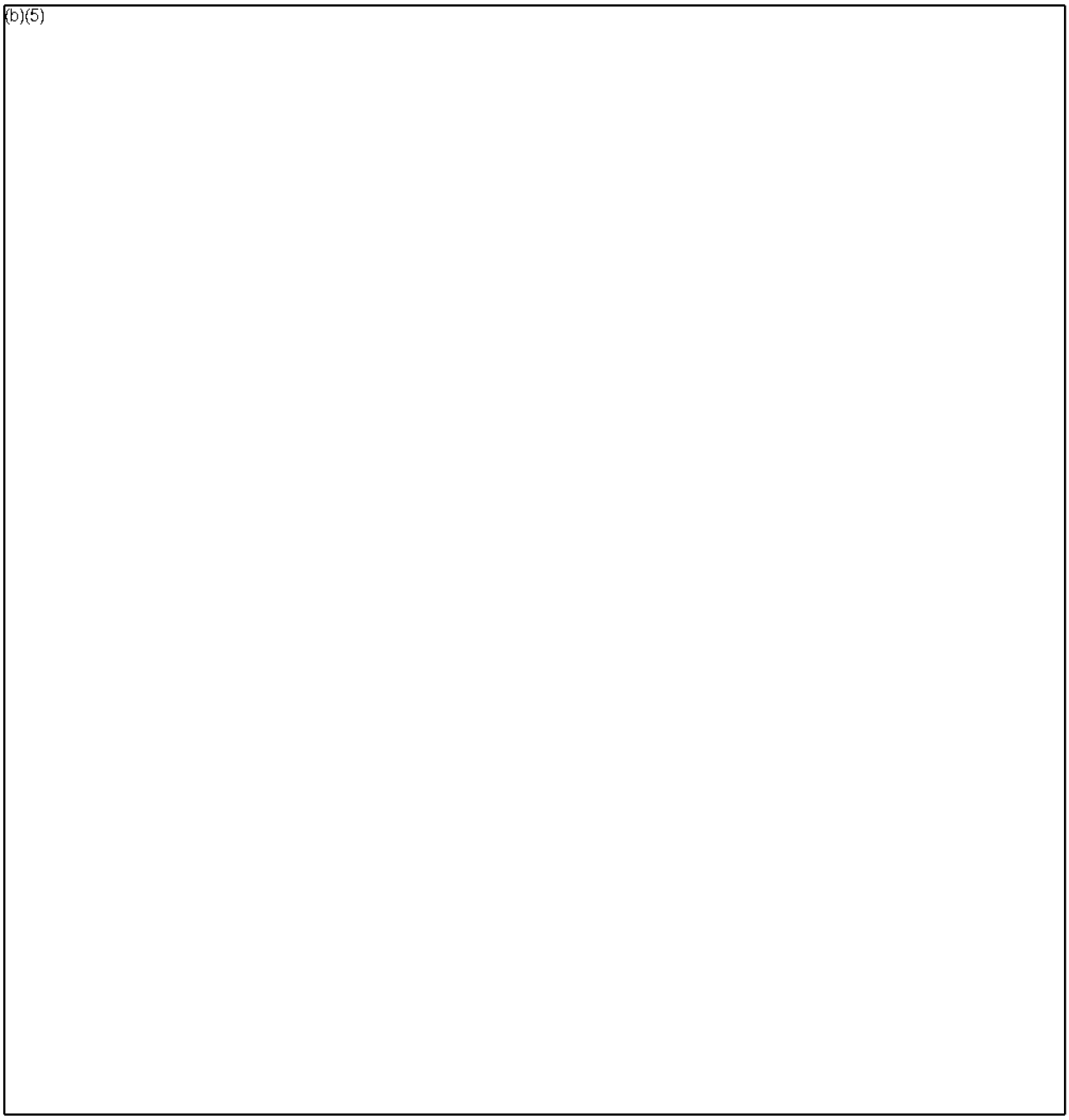


Dr. Nancy Sullivan, Biodefense Research Section, Immunology Laboratory



(b)(5)

(b)(5)

Adjournment

The Board adjourned at 2:00 p.m. on September 9, 2016. I certify that, to the best of my knowledge, the foregoing minutes of the NIAID Board of Scientific Counselors meeting are accurate and correct.

The Board has formally submitted its report to NIAID/NIH. It is our understanding that Dr. Mascola has accepted the recommendations of the Board.

10/02/2016
Date

Eric Hunter, Ph.D..
Acting Chairman
VRC Subcommittee of the Board of Scientific Counselors
NIAID

These minutes will be formally considered by the Board of Scientific Counselors at its next meeting: corrections and notations will be incorporated into the minutes of that meeting.