



**National Institutes of Health
Office of the Director
Office of Biotechnology Activities**

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

**April 29, 2009
National Institutes of Health
Building 1, Wilson Hall, Bethesda, Maryland**

MINUTES of MEETING

VOTING MEMBERS

Paul S. Keim, Ph.D., *NSABB Acting Chair*
Arturo Casadevall, M.D., Ph.D. (*via teleconference*)
Murray L. Cohen, Ph.D., M.P.H., C.I.H.
Susan A. Ehrlich, J.D., LL.M. (*via teleconference*)
Barry J. Erlick, Ph.D.
David R. Franz, D.V.M., Ph.D.
Michael J. Imperiale, Ph.D.
Stanley M. Lemon, M.D. (*via teleconference*)
Stuart B. Levy, M.D.
Mark Nance, J.D.
David A. Relman, M.D. (*via teleconference*)
James A. Roth, D.V.M., Ph.D.
Harvey Rubin, M.D.
Andrew A. Sorensen, Ph.D.
Anne K. Vidaver, Ph.D.

EX OFFICIOS/FEDERAL AGENCY DESIGNEES

Jason E. Boehm, Ph.D., U.S. Department of Commerce
Kenneth Cole, Ph.D., Office of the Special Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs
Brenda Cuccherini, Ph.D., M.P.H., Veterans Affairs
Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Disease, National Institutes of Health
Wendy Hall, Ph.D., U.S. Department of Homeland Security
Theresa Lawrence, U.S. Department of Health and Human Services
Robert Mikulak, Ph.D., U.S. Department of State
Janet K. A. Nicholson, Ph.D., Centers for Disease Control and Prevention
David G. Thomassen, Ph.D., U.S. Department of Energy
Peter Jutro, Ph.D., U.S. Environmental Protection Agency
Edward You, Federal Bureau of Investigation

NSABB EXECUTIVE DIRECTOR
ACTING DIRECTOR, OFFICE OF SCIENCE POLICY, NIH

Amy P. Patterson, M.D.

Call to Order and Review of Conflict of Interest Rules

Dr. Keim, acting chair of the National Science Advisory Board for Biosecurity (NSABB) for this meeting, convened the April 29, 2009, meeting of the NSABB at 9:00 a.m.

Dr. Patterson read into the record the rules of conduct and conflict of interest. The rules are explained in the report entitled "Standards of Ethical Conduct for Employees of the Executive Branch," which was received by each member when appointed to the NSABB. Members of the NSABB are considered Special Government Employees and were requested to review the steps to ensure that conflicts of interest are addressed. Board members are required to recuse themselves in advance of any discussion in which they believe they have a conflict of interest. Questions should be addressed to the committee management officer of the NIH Office of Biotechnology Activities, Ms. Lisa Rustin.

Introductions, Approval of the December 2008 Minutes, and Overview of Agenda

Dr. Keim welcomed NSABB members, Federal Agency representatives, and members of the public in attendance and watching via Webcast. Board members and *ex officio* representatives introduced themselves and stated their affiliations. He then reviewed the agenda for this meeting, which focused on personnel reliability. Early discussions about personnel reliability were presented by the Personnel Reliability Working Group (PRWG) at the December 2008 NSABB meeting. Since December 2008, the PRWG has met twice in person and several times via teleconference, consulted with experts, and convened a public consultation meeting on April 3, 2009. As a result of those meetings and consultations, the PRWG has continued its deliberations and presented its draft report for discussion at this meeting.

Judge Ehrlich and Dr. Erlick reviewed the minutes of the December 2008 NSABB meeting in advance of this meeting, and their suggestions were incorporated.

NSABB Motion 1

Moved by Dr. Cohen and seconded by Dr. Imperiale, the NSABB voted unanimously by voice to approve the December 2008 NSABB meeting minutes that had been distributed in advance of this meeting.

NSABB Working Group on Personnel Reliability: Overview of Deliberations and Draft Report on Personnel Reliability

Introduction

Dr. Keim provided background for the PRWG's deliberations. The NSABB charge regarding personnel reliability is to recommend to the U.S. Government strategies for enhancing personnel reliability among individuals with access to biological select agents and toxins (BSATs), while balancing the needs for both biosecurity and continued progress in the life sciences. The term "insider threat" generally refers to the misuse of pathogens by individuals who have access to them as part of their research, and may involve theft, misuse, or diversion of a BSAT by an individual with approved access. The PRWG consists of 12

voting members from the NSABB, representatives from 13 U.S. government offices and agencies, as well as representatives from the intelligence community.

The PRWG considered the current Select Agent programs, extant frameworks for ensuring personnel reliability, and potential mechanisms for assessing "reliability," with particular emphasis on:

- costs and other burdens on institutions
- the impact on the scientific enterprise (especially research on BSATs), and
- effectiveness of any proposed personnel reliability measures

The PRWG discussed its progress at the December 2008 NSABB meeting namely,

- a briefing via teleconference by representatives of the Galveston National Biodefense Laboratory (a biosafety level [BSL] 4 facility) at the University of Texas Medical Branch regarding their proposed personnel reliability program (PRP)
- a classified briefing from the intelligence community, and
- a meeting with experts in psychological and mental health assessments.

Overview of Public Consultation on Personnel Reliability

Dr. Imperiale summarized the April 3, 2009 public consultation meeting on personnel reliability which was attended by approximately 200 individuals from the public, private, and nonprofit sectors. The goal of this meeting was for the PRWG to hear from members of the scientific community and other stakeholders about how personnel reliability is made operational, the applicability of optimal characteristics of PRPs, and related topics. The PRWG also wanted to explore the potential impact on the scientific community, including investigators and research institutions. Topics included the concept of personnel reliability and its implementation, personnel reliability measures, optimal characteristics and methods for assessing reliability, and potential benefits and consequences of PRPs.

Background presentations focused on extant PRPs from the U.S. Army and the U.S. Department of Energy (DoE), Security Risk Assessment from the Select Agent Program, planned PRPs in academia, and the PRWG's proposed optimal personnel characteristics. This public consultation meeting was videocast live and archived at www.biosecurityboard.gov (accessed by clicking on the "MEETINGS" link).

The organizing framework of the April 3, 2009 meeting was built around the optimal personnel characteristics proposed by the PRWG, which were:

- No history of scientific or professional misconduct
- Emotionally stable and capable of sound judgment
- Positive attitude toward safety and security measures, and standard operating procedures
- Free of vulnerability to coercion
- Free of felony convictions
- No domestic or international terrorist ties

Panelists focused on the first four of these characteristics, which were deemed best assessed at the local level, with the last two considered best assessed at the federal level.

The key themes and findings of this public consultation were:

- Operational aspects of PRPs include the role of the research institution's Responsible Official (RO) and that individual's qualifications, training, and responsibilities, as well as the costs of PRPs, which vary greatly based on type of institution and pre-existing infrastructure.

- Utility, applicability, and effectiveness of personnel reliability measures is based on the adequacy of current measures (although the need for certain additional measures was noted), a correlation between optimal characteristics and security, data supporting effectiveness, and personal history. It was posited that employment performance measures could be more effective. Regarding personal history, it was noted that the past might not predict the future, and, therefore, that past reliable behavior could provide a false sense of security. Also, unreliability or even misconduct in the past cannot predict that an individual will engage in bioterrorism.
- The two-person rule is resource-intensive and difficult to implement with a limited number of staff. However, many institutions have instituted a two-person rule for safety rather than security reasons. It is possible that video cameras could substitute for a second person.
- Guidance is needed regarding reporting to the U.S. government when access is restricted. Several NSABB members noted the potential for negative impacts on an individual's career, reputation and privacy, as well as concerns about liability issues and undermining the existing culture of trust.
- Engaged leadership at the local level is critical. Participants agreed that personnel reliability is best managed locally at the institutional level, and investigators must be fully engaged in personnel reliability efforts. Strong working relationships should be fostered and training is critical, especially for peer reporting.
- A balanced approach is needed. A PRP could be a disincentive to continue or to initiate research involving Select Agents; new requirements may stifle innovation. Thus, implementing any PR measures should be done cautiously, while monitoring the impacts, effectiveness, and any unintended consequences.
- Layers of accountability at the local/institutional level should include committed institutional and laboratory leadership, peer reporting, and training.
- At the federal level, effective regulatory programs should be implemented to include performance-based standards, flexibility and discretion in application, and local enforcement.
- Other issues of concern included administration of psychological assessments by a trained professional, privacy and Americans with Disability Act (ADA) issues, the impact of restricting an individual's access, and compounding the compliance burden.

NSABB Draft Report: Enhancing Personnel Reliability Among Individuals with Access to Select Agents

Dr. Keim enumerated the PRWG's overarching considerations regarding personnel reliability, including the possibility that an overly burdensome PRP could serve as a powerful disincentive for individuals who wish to conduct Select Agent research responsibly. On the other hand, security measures that are too weak could leave the United States vulnerable to individuals or groups who wish to misuse Select Agents. It was agreed that Select Agent research is critical to public health and safety, agricultural and commercial development, economic competitiveness, and national security, and that a thriving Select Agent research community that develops vaccines, therapies, and diagnostic tools is the best defense against natural disease outbreaks as well as bioterrorism.

The PRWG noted that Select Agents represent a unique security challenge. BSATs are fundamentally different from chemical and nuclear material in that most BSATs are naturally occurring, many can be isolated from natural sources, and many are living organisms that can be cultured from a minimal starting sample. The nature of research using BSATs poses a challenge, in part because much of this research is conducted in academic settings with a history of openness and collaboration, and because the majority

of biological Select Agent research is unclassified. Because of these unique characteristics, Select Agent research requires a different approach to security than has been applied traditionally to chemical and nuclear material.

The PRWG also noted that controls on access to BSATs have been continuously strengthened. Following the terrorist attacks and subsequent anthrax mailings of 2001, the U.S. government expanded the Select Agent regulations to include all entities that possess, use, or transfer Select Agents, and new security, inventory, and training requirements have been enacted. The USA PATRIOT Act and the Bioterrorism Response Act define certain individuals who are not permitted access to BSATs. In addition, a Security Risk Assessment (SRA) is required for all individuals with unescorted access to Select Agents; individuals provide fingerprints and disclose such information as criminal history, drug use, mental health history, service history, and citizenship.

The PRWG believed that mandating a national PRP could have unintended consequences. Such a PRP could be a powerful discouraging factor for young researchers who wish to begin a career in Select Agent research and could drive Select Agent research overseas to countries with less stringent standards and regulations, thereby isolating Select Agent researchers from the mainstream scientific community and potentially compromising the quality of this research. A mandated PRP, therefore, could result in a decreased ability to recruit top scientific talent and in a U.S. Select Agent research enterprise that is less robust, less diverse, and less responsive, and characterized by a decreased ability to recruit top scientific talent. Such restrictions could diminish the capacity to develop vaccines, treatments, and countermeasures, and all of these possibilities could lead to decreased security.

The PRWG reviewed and evaluated the utility of several personnel reliability measures. Insofar as the use of psychological testing is part of a PRP, the PRWG found that such tests can identify major psychological disorders but that they have limited ability to identify subtle deviations. In addition, no persuasive evidence suggests that these tests can effectively identify an individual with malevolent intent. They also would be costly and problematic to implement in an academic setting because universities lack the required program infrastructure to address and resolve potential privacy concerns. National security clearances were deemed expensive and time-consuming, and the PRWG determined they would likely be a major obstacle in conducting Select Agent research in the academic community. Regarding the use of credit checks to predict an individual's vulnerability to coercion, the PRWG noted that the financial histories of Select Agent researchers in universities would be incredibly variable. In addition, no objective means exist to translate the information gathered from a credit check into a relevant determination of vulnerability. While medical examinations and monitoring may be appropriate for safety reasons in certain facilities, the PRWG stated that those measures go beyond the scope of personnel reliability.

The PRWG reported the following findings:

1. The Select Agent regulations have been appropriately and significantly strengthened since 2001 to include measures that address personnel reliability.
2. Local institutions already screen individuals who require access to Select Agents.
3. Little evidence exists regarding the effectiveness and predictive value of personnel reliability measures with respect to their ability to identify individuals who may pose an insider threat.
4. Engaged leadership at the institutional level has been cited often as the most effective way to mitigate the risk of an insider threat.

Dr. Keim presented the PRWG's suggested vision statement regarding personnel reliability: "The goal of every institution that conducts research on Select Agents should be that personnel approved for access to Select Agents and toxins are behaving in a responsible and trustworthy manner that upholds public health and safety, national security, and the integrity of the scientific enterprise." In addition, the PRWG suggested the following guiding principles regarding personnel reliability in research on Select Agents:

1. Research on Select Agents is essential to public health and national security.
2. Personnel reliability measures can reduce but not eliminate an insider threat.

3. Implementation of personnel reliability measures must balance the need for security with the need for scientific progress.
4. Individuals with access to Select Agents have an ethical obligation to mitigate the risks posed by their accidental or intentional release.
5. Select Agent research programs will benefit by fostering a strong culture of responsibility, trust, and awareness.
6. Building and maintaining the public trust is the responsibility of the entire scientific community.
7. ROs, principal investigators, and supervisors should be actively engaged in the research being conducted in their facilities.
8. The continued awareness of individuals who have been approved for access to Select Agents should become a routine aspect of conducting Select Agent research.
9. Fairness and confidentiality will foster self and peer reporting, which have been widely suggested as effective personnel reliability measures.
10. Individuals must have a clear understanding of their responsibilities.

Taking all their research and consultation together, the PRWG offered the following recommendations for consideration and discussion by the NSABB:

1. It is appropriate to enhance personnel reliability measures for individuals with access to Select Agents. However, promulgation of a formal, national PRP is unnecessary at this time because the Select Agent rules already have been significantly strengthened, a PRP would likely have unintended detrimental consequences, and there is insufficient evidence of the effectiveness of PRP measures to warrant the additional burden on research institutions.
2. The current SRA process should be strengthened. The U.S. government should continue to identify potential weaknesses and gaps in the information gathering process and reinforce the assessment as needed. The NSABB proposes:
 - Formally incorporating into the SRA the periodic crosschecking of "approved" individuals
 - Expanding the SRA prohibition to include domestic terrorism
 - Strengthening the screening of foreign individuals in a way that ensures the process remains timely
 - Clarifying the reference to "mental defective" on the SRA form
3. The culture of responsibility and accountability should be enhanced at institutions that conduct Select Agent research. Many experts noted this as the best defense against an insider threat, and it can be accomplished without expending significant resources or disrupting research progress.
4. Professional societies should continue to encourage an ongoing dialogue about personnel reliability and to foster community-based solutions. Societies have done a commendable job engaging their communities about dual use research of concern, and they should continue to promote a culture of research responsibility and vigilance regarding personnel reliability.
5. The Select Agent list should be reduced or stratified. The currently designated "Select Agents" differ significantly in degree of pathogenicity and ability to be used as agents of bioterrorism; however, the same stringent controls are applied to all Select Agents, making it unnecessarily difficult to conduct research on many important organisms.

Public Comment

The following comments about the draft PRWG report were presented during the public comment portion of this NSABB meeting.

- The report contains no reference to the PRWG having examined the large body of evidence of the 50-year history of military PRPs in the nuclear field.

- The report makes the assumption that laboratories are a low risk for the malevolent acquisition of materials and that the primary route would be cultivating a BSAT from nature. However, the empirical evidence is to the opposite, i.e., the common route of acquisition has been theft or acquisition from laboratory stocks.
- A next step is for the NSABB to study a whistle-blower protection system, which should be in place so scientists can report suspicious or unusual behaviors.
- A next step is for the NSABB to recommend concentration on education and outreach. Unless the vision and guiding principles are widely communicated and made the focus of attention starting at the graduate level, they will have minimal impact.
- The number of events is a very small dataset, so that a finding of "no evidence of effectiveness" for possible PRP measures does not necessarily mean "no effectiveness." The NSABB should investigate the existence of predictive models.
- Several speakers commended the NSABB report for highlighting the importance of peer reporting. They added that it will be important to work out the details of how the model should be implemented.
- The report should emphasize that, for the most part, scientists are responsible people who have been conducting research responsibly.
- Where PRP programs have been tried (e.g., the U.S. Department of Defense), secrets have not necessarily been more safe.

NSABB Discussion of Draft Report

The following comments about the PRWG draft report were offered during the NSABB discussion.

The PRWG report should encourage an emphasis on outreach and education and how to reach the entire scientific community about personnel reliability; the majority of the scientific community is oblivious to this issue. As the scope of research increases and more biologists enter this field, the possibility remains small but nonetheless increases that agents derived from nature will be used malevolently.

The recommendation to remove some Select Agents from the Select Agent list is important; for example, one strain of Rift Valley Fever is still on the Select Agent list. The effect of changes to the Select Agent list on the scientific community would be significant, but removal of a Select Agent from the list does not compromise safety or security because research on the agent still would be conducted under the proper BSL conditions, and granting exceptions from the Select Agent list allows a wider use of these agents in the proper setting. When agents are on the list, however, it becomes almost impossible to conduct research; for example, private companies will not use a Select Agent to produce a vaccine or therapeutic.

The SRA is similar to a national PRP, so strengthening the SRA would be appropriate. The PRWG noted its concern that foreign visiting researchers would be most affected by more intensive and extensive investigations, in part due to the delay and costs of such investigations.

The phrase "anthrax mailings" is not accurate. It was decided to change the terminology in the report to "anthrax letter attacks (*anthracis* spores)."

Several NSABB members expressed concern about whistle-blower protections, particularly about a junior investigator reporting a senior investigator or a superior. It was decided to modify and strengthen the relevant language.

Prompted by a question from an observer, the NSABB discussed the types of suspicions and evidence that might legitimately point to the possibility that someone is poised to do harm. In many cases, such evidence will be scant and will not be adequate for formal processes. It was observed that most universities have an ombudsman or similar process for the lodging of complaints and that such person then decides whether a formal investigation is needed. A team approach among scientists and safety officers is essential to the safety of the research enterprise and to the researchers' careers. Dr. Rubin agreed to draft a statement to be added to the report regarding the use of already existing resources within the university. Judge Ehrlich agreed to review Dr. Rubin's draft statement, adding the idea that there should be no adverse consequences for good-faith reporting.

Dr. Franz offered to review the draft report for any appropriate additions related to global and international issues.

NSABB members had varying views on whether to include a statement in the report that the PRWG was not briefed on personnel reliability aspects of the investigation into the anthrax letter attacks because it was unknown whether the lack of such a briefing might represent a gap in the working group's knowledge. No specific action was taken on this issue.

Dr. Franz proposed to add the phrase "both in the U.S. and internationally" on page 14 of the draft report, at the end of the first full sentence under recommendation #4. This wording was accepted and was included as part of the vote on the draft report.

Dr. Keim noted that amendments to this draft report (to clarify or enhance meaning) would be forthcoming for a vote during a future public teleconference. The nine suggested amendments will touch on the following issues:

- Adding language about the anthrax spores in letters
- Further underscoring a culture of responsibility in peer reporting, including the possibilities of retaliation and frivolous reporting
- Encouraging outreach and education at both local and federal levels
- Strengthening acknowledgement of the international component for which Dr. Franz and Dr. Levy will provide wording
- Communicating the 50 years of scientific responsibility and integrity
- Adding a statement that no PRP will ensure 100 percent security
- Screening for the SRA being as expeditious as possible
- Softening assertions about naturally occurring pathogens
- Strengthening language about removing attenuated strains of species from the Select Agent list

NSABB Motion 2

Moved by Dr. Erlick and seconded by Dr. Cohen, the Board voted to approve the NSABB draft report on personnel reliability, with the understanding that approximately nine minor amendments would be made to be voted on during a future public teleconference. The vote to approve the draft report on personnel reliability was 14 in favor, 0 opposed, and 0 abstentions.

Closing Remarks and Adjournment

Dr. Keim thanked the members of the NSABB and everyone else present for their insightful comments. He adjourned the meeting at 12:00 p.m.

The next NSABB meeting will be held on December 3, 2009.

Date:

December 23, 2009



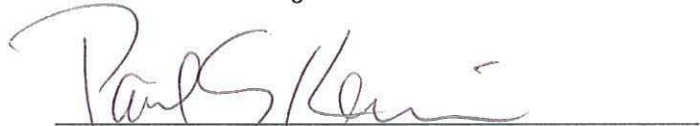
Amy P. Patterson, M.D.
Executive Director
National Science Advisory Board for Biosecurity, and
Acting Director
Office of Science Policy
National Institutes of Health

I hereby acknowledge that, to the best of my knowledge, the foregoing Minutes and Attachments are accurate and complete.

These Minutes will be formally considered by the NSABB at a subsequent meeting; any corrections or notations will be incorporated into the Minutes after that meeting.

Date:

January 4th 2010



Paul S. Keim, Ph.D.
Acting Chair
National Science Advisory Board for Biosecurity