

**NSABB Public Consultation on Personnel Reliability Among  
Individuals with Access to Select Agents**

**Bethesda Marriott  
5151 Pooks Hill Rd., Bethesda, MD**

**April 3, 2009  
8:00 am – 5:15 pm**

**Agenda**

**8:00 am Welcome and Opening Remarks**

*Dennis Kasper, M.D., NSABB Chair*

William Ellery Channing Professor of Medicine and Professor of Microbiology and Molecular Genetics, Harvard Medical School

**8:15 am Background and Introduction to the Personnel Reliability Issue**

*Diane DiEuliis, Ph.D.*

Assistant Director, Office of Science and Technology Policy, Executive Office of the President

**8:30 am**

**Panel I – “Extant Models of Personnel Reliability Programs”**

Moderators:

*Michael J. Imperiale, Ph.D.*

NSABB Member and Professor, Department of Microbiology and Immunology, University of Michigan Medical School

*Anne K. Vidaver, Ph.D.*

NSABB Member and Professor and Head, Department of Plant Pathology, University of Nebraska-Lincoln

Background: Two extant Federal personnel reliability programs will be described, including the various components of these programs. In addition, representatives from the CDC and the FBI will describe certain features of the Select Agent Program that address personnel reliability. Finally, a representative of the Galveston National Laboratory will speak to some of the personnel reliability measures that they are putting into place.

Presenters:

*John Humpton*

Combating WMD and Proliferation Policy Division G-3/5/7, Headquarters, Department of the Army

*Eric Gard, Ph.D.*

Global Security Directorate, Lawrence Livermore National Laboratory

*John Stovers*

Bioterrorism Risk Assessments, Criminal Justice Information Services, FBI

*Robbin Weyant, Ph.D.*

Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC

*Stan Lemon, M.D.*

NSABB Member and Director, Institute for Human Infections and Immunity and Professor, Departments of Microbiology & Immunology and Internal Medicine, University of Texas Medical Branch/Galveston National Laboratory

**9:30 am**      **Plenary Discussion of Panel I Topics**

**10:00 am**      Break

**10:20 am**      **Presentation – “Optimal Personnel Characteristics”**

*Dennis Kasper, M.D.*

Background: In conceptualizing an optimal personnel reliability program, the NSABB working group identified a number of personnel characteristics that these programs should assess in determining whether individuals should be permitted to work with Select Agents. Some of the characteristics would be assessed by the Federal government and others are more appropriately assessed at the local level by institutions. The focus of today’s meeting is on the personnel characteristics that institutions would be best positioned to assess. These include scientific and professional integrity, emotional stability and capacity for sound judgment, freedom from vulnerability to coercion, and a positive attitude regarding safety and security measures and standard operating procedures. Dr. Kasper will also briefly review the vision, guiding principles, and aims and applicability of an optimal PRP that were discussed at the December 10, 2008 NSABB meeting.

10:45 am

**Panel II – “Optimal Personnel Characteristics – Scientific and Professional Integrity and Compliance with Biosafety and Biosecurity Standards”**

Moderators:

*Murray L. Cohen, Ph.D., M.P.H., C.I.H.*

NSABB Member and President and Chairman, Frontline Healthcare Workers,® Safety Foundation, Ltd.

*Barry J. Erlick, Ph.D.*

NSABB Member and President, BJE Associates, Inc.; Affiliate Professor, Auburn University; Adjunct Professor, Kansas State University

Background: Because of the potential harm that can come from the misuse or mishandling of Select Agents, individuals working with these agents must adhere assiduously to security rules and safety standards and, conversely, not exhibit a demonstrable propensity for dishonesty or disregard for professional and other generally accepted standards. Hence, individuals working with Select Agents should not have a history of breaches of scientific integrity (such as falsification or fabrication of data or plagiarism) nor a history of failing to adhere to generally accepted professional standards of conduct or a history of sanctions by professional associations or licensing bodies. The focus of this panel will be on the following characteristics:

- No history of scientific or professional misconduct in the workplace
- Positive attitude toward safety and security measures and standard operating procedures

Discussion questions:

- What are the hallmarks of scientific and professional integrity?
- What behaviors involve breaches of scientific and professional integrity?
- How can scientific and professional integrity be assessed in objective ways so as to be meaningful for assessing personnel reliability?
- What are hallmarks of a positive attitude toward safety and security?
- What are the indicators of a problematic attitude toward these matters?
- How should a PRP assess these attitudes toward safety and security (employment records, military service records, peer reporting, monitoring by supervisors)?

Panelists:

- Investigator perspective

*Dennis Metzger, Ph.D.*

Professor and Theobald Smith Endowed Chair, and Director, Center for Immunology and Microbial Disease, Albany Medical College

- Federal representative

*John Dahlberg, Ph.D.*

Director, Division of Investigative Oversight, HHS Office of Research Integrity

- Biosafety

*Debra Hunt, Dr.P.H.*

Director, Biological Safety, Duke University

- Education about the responsible conduct of research  
*Nicholas Steneck, Ph.D.*  
Director, Research Ethics and Integrity Program, University of Michigan Institute for Clinical and Health Research & Professor Emeritus of History, University of Michigan
- Senior Research Administrator  
*Brian Herman, Ph.D.*  
Vice President for Research and Professor, Cellular and Structural Biology, University of Texas Health Science Center
- Private sector  
*Eric Utt, Ph.D.*  
Director, Worldwide Public Affairs and Policy, Pfizer Inc.

**12:15 pm** Lunch

**1:15 pm** Plenary Discussion of Panel II Topics

**2:30 pm**

**Panel III – “Optimal Personnel Characteristics - Emotionally Stable and Capable of Sound Judgment; Free of Vulnerability to Coercion”**

Moderators:

*Susan A. Ehrlich, J.D.*

NSABB Member and Judge (Retired), Arizona Court of Appeals

*Paul S. Keim, Ph.D.*

NSABB Member and Division Director, Pathogen Genomics, Translational Genomics Research Institute; Cowden Endowed Chair in Microbiology, Northern Arizona University

Background: The NSABB Working Group considered emotional stability and sound judgment to be critically important characteristics because an individual’s mental and emotional status may impact his/her ability to focus, perform job-related duties, and to make sound decisions. As assessments of mental stability and judgment are subjective and potentially stigmatizing, confidentiality regarding determinations of mental status is an important consideration. The Working Group also recognized that an individual’s ability to make sound decisions can fluctuate based on social and emotional factors, and hence a personnel reliability program should be sufficiently flexible to enable rapid recognition of such changes and suspend and restore access to Select Agents as appropriate. In addition, a person who is generally capable of sound judgment and otherwise trustworthy may be vulnerable to external coercion based on various influences in their life. The panel discussion will focus on the importance and assessment of these characteristics:

- Emotionally stable and capable of sound judgment
- Free of vulnerability to coercion

Discussion questions:

- How should mental and emotional stability be assessed?

- At what junctures should mental and emotional stability be assessed? Upon commencing work with Select Agents? Only when there is a potential problem?
- How should a PRP encourage individuals to report emotional stress and personal problems in a way that is not seen as stigmatizing?
- What role do supervisors and peers play in these assessments?
- Should there be a mechanism for appealing PRP decisions based on mental status?
- What life style elements can make one vulnerable to coercion?
- How should a PRP identify and assess these elements on an ongoing basis?
- How should knowledge of potential vulnerabilities of coercion be factored into decisions about personnel reliability?

Panelists

- Investigator perspective

*Fred Sparling, M.D.*

Director, Southeast Regional Center for Excellence in Emerging Infections and Biodefense (SERCEB)

- Psychological assessment expert perspective

*C. Andy Morgan, M.D.*

Associate Professor, Department of Psychiatry, Yale University

*Jeff Baker, Ph.D., ABPP*

Professor, Division of Rehabilitation Sciences and Chief Psychologist, Aviation Medicine, Anesthesiology, Orthopedic Surgery, University of Texas Medical Branch

- Think tank perspective

*Amy Smithson, Ph.D.*

Senior Fellow, James Martin Center for Nonproliferation Studies

**3:30 pm** Break

**3:45 pm** **Plenary Discussion of Panel III Topics**

**4:45 pm**

**Plenary Discussion**

Moderator:

*Dennis Kasper, M.D.*

- Are there additional optimal personnel characteristics that should be assessed?
- Comments on vision statement, guiding principles, aims and applicability?
- How should the effectiveness of a Personnel Reliability Program be evaluated?

**5:15 pm** **Wrap-up and Concluding Remarks, Meeting Adjournment**