

Enhancing Personnel Reliability among Individuals with Access to Select Agents





NSABB Charge: Personnel Reliability

- **Recommend to the USG strategies for enhancing personnel reliability (PR) among individuals with access to biological select agents and toxins**
- **Balance the needs for both biosecurity and continued progress in the life sciences**



The “Insider Threat”

- **Generally refers to the misuse of pathogens by individuals who have access to them as part of their job**
- **May involve theft, misuse, or diversion of a select agent by an individual who is approved to access them**



Working Group Established

Voting Members

- Dennis Kasper (Chair)
- Arturo Casadevall
- Murray Cohen
- Barry Erlick
- Susan Ehrlich
- Claire Fraser-Liggett
- Mike Imperiale
- Paul Keim
- Stan Lemon
- David Relman
- Andrew Sorensen
- Anne Vidaver

Agency Representatives

- FBI
- OGC
- State Dept.
- Dept. of Defense
- OSTP
- NIH
- DHS
- EPA
- USDA
- ODNI
- DHHS
- CDC
- Dept. of Energy
- Intelligence Community



Working Group Approach

- **The WG considered:**
 - The current Select Agent Programs
 - Extant frameworks for ensuring PR
 - Potential mechanisms for assessing “reliability”
- **The WG particularly considered:**
 - Costs and other burdens on institutions
 - Impact on the scientific enterprise, especially research on select agents
 - Effectiveness of any proposed PR measures



Working Group Approach

- **WG briefings:**
 - **HHS Select Agent Program**
 - **Dept. of Defense (Army Biological Personnel Reliability Program)**
 - **Dept. of Energy (Select Agent Human Reliability Program)**
 - **NIH Intramural Research Program**
 - **CDC Intramural Research Program**
 - **Battelle Biomedical Research Center**
 - **Intelligence Community (Security clearances)**
 - **Galveston National Lab (BSL-4 facility) at UTMB, proposed PRP**
 - **Classified briefing from the intelligence community**
- **Discussion of PR with:**
 - **Selected participants at USG-WHO International Roundtable on Dual Use Research**
 - **Experts in psychological/mental health assessments**



Working Group Approach: Public Consultation

- **Explore potential impact on the scientific community**
 - **Investigators**
 - **Research institutions and organizations**
- **Topics**
 - **Concept of personnel reliability and its implementation**
 - **Personnel reliability measures**
 - **Optimal characteristics and methods for assessing reliability**
 - **Potential benefits and consequences of personnel reliability programs**

Public Consultation

■ April 3, 2009

- Presentations, videocast, podcasts at www.biosecurityboard.gov

■ ~200 attendees

- Public
- Private
- Non-profit

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NSABB - Past Meetings

April 2009 Meeting - April 3

Agenda and Webcasts

- [Agenda](#) [Webcast](#)
- Minutes will be posted once they are available.

Presentation Materials

Background and Introduction to the Personnel Reliability Issue

- [Understanding and Improving Laboratory Security, Personnel Reliability, and Safety](#) [Diane DiEulis, Ph.D.](#)
Office of Science and Technology Policy

Panel 1 - Extant Models of Personnel Reliability Programs

- [The Army Biological Personnel Reliability Program \(BPRP\)](#) [John Humpton](#)
Combating WMD and Proliferation Policy Division G-3/5/7, Headquarters, Department of the Army
- [LLNL Select Agent Human Reliability Program](#) [Eric Gard, Ph.D.](#)
Global Security Directorate, Lawrence Livermore National Laboratory
- [Bioterrorism Risk Assessment Group](#) [John Stovers](#)

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Public Consultation: Organizing framework

- **Background presentations on extant personnel reliability measures**
 - Army
 - DOE
 - CDC and DOJ/CJIS
 - UTMB, Galveston National Lab
- **Expert panelists**
 - Select agent and other biomedical research
 - Biosafety
 - Research administration
 - Responsible conduct of research
 - Psychiatry and psychometric research

Public Consultation: Themes and Issues

- Operational aspects of a PRP
- Utility, applicability & effectiveness of PR measures
- Engaged leadership at the local level is critical
- A balanced approach is needed
- General lack of support for the two-person rule
- Reporting, training, and privacy





**NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY**

Enhancing Personnel Reliability among Individuals with Access to Select Agents



**Report of the
National Science Advisory Board for Biosecurity
(NSABB)**

May 2009



Overarching Considerations

- **An overly burdensome PRP could serve as a powerful disincentive for those who wish to responsibly conduct select agent research**
- **Security measure that are too weak could leave the US vulnerable to those who wish to misuse select agents toward malevolent ends**



Select Agent Research is Critical

- **Public health and safety**
- **Agricultural and commercial development**
- **Economic competitiveness**
- **National security**
 - **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**



Select Agents are a Unique Security Challenge

- **Biological agents are fundamentally different from chemical and nuclear material**
 - **Most biological select agents are naturally occurring pathogens and many can be isolated from natural sources**
 - **Many biological select agents are living organisms that can be cultured from a minimal starting sample**



Select Agents are a Unique Security Challenge

- **The nature of research using biological select agents poses a challenge**
 - A long and fruitful history of research on these pathogens that have only recently been deemed “select agents”
 - Much of this research is conducted in academic settings with a history of openness and collaboration
 - The vast majority of biological select agent research is unclassified
- **Select agent research requires a different approach to security than the one that has been traditionally applied to chemical and nuclear material**



NSABB Findings

- 1. The select agent regulations have been appropriately and significantly strengthened since 2001 to include measures that address personnel reliability**
 - Select agent rules were expanded to include all entities that possess, use, and transfer select agents**
 - New safety, security, training, and inventory requirements**
 - Designation of institutional Responsible Officials**



Controls on Access to Select Agents Have Been Strengthened

- **New regulations address personnel reliability:**
 - **USA PATRIOT Act**
 - **Bioterrorism Response Act**
- **These laws define certain individuals who are not permitted access to select agents**
- **The restricted and prohibited categories include individuals with:**
 - **Felony convictions**
 - **Convictions for illegal drug use**
 - **Terrorist ties**
 - **History of mental illness**
 - **A dishonorable discharge from the Armed Services**
 - **Citizenship from a country designated a state-sponsor of terrorism**



Controls on Access to Select Agents Have Been Strengthened

- **Security Risk Assessment (SRA)**

- Required for all individuals with unescorted access to select agents
- Individuals provide fingerprints and disclose information about criminal history, drug use, mental health history, service history, citizenship, etc.
- Criminal background check using federal databases to identify if individuals fall into restricted or prohibited categories
- Individuals with favorable SRAs are periodically cross-checked with databases
- The FBI is automatically notified of the arrest of an individual with a favorable SRA



NSABB Findings

2. Local institutions already screen individuals requiring access to select agents

- Most institutions pre-screen individuals prior to hiring for or transferring into select agent duties
- An extremely low rate of individuals receive unfavorable SRAs suggesting effective prescreening by human resources departments
- Many BSL-3 labs have enhanced safety, security, training, and monitoring requirements
- BSL-4 facilities require additional safety, security and training measures; most implement reliability measures



NSABB Findings

- 3. There is little evidence regarding the effectiveness and predictive value of PR measures with respect to their ability to identify individuals who may pose an insider threat**



Personnel Reliability Programs

- **PRP features may include:**
 - ❑ **Extensive background investigations**
 - ❑ **Security clearances**
 - ❑ **Medical examinations and records evaluations**
 - ❑ **Psychological screening**
 - ❑ **Drug and alcohol testing**
 - ❑ **Polygraph examinations**
 - ❑ **Credit checks**
 - ❑ **Comprehensive review of service and employment records**
 - ❑ **Mechanisms for ongoing monitoring**



Optimal Characteristics Were Exceedingly Difficult to Assess

Optimal Personnel Characteristics:

- Free of felony convictions
 - No domestic or international terrorist ties
 - No history of scientific or professional misconduct in the workplace
 - Emotionally stable and capable of sound judgment
 - A positive attitude toward safety, security, and SOPs
 - Free of vulnerability to coercion
- The NSABB examined methodologies commonly used by PRPs to assess these characteristics
 - Though reasonable characteristics, it became unclear whether they were surrogates for, or predictors of “reliability”
 - No objective criteria for translating the information gathered from an assessment into a determination of reliability
 - Little evidence to suggest that any assessments can identify an insider threat



Mandating a National PRP Could Have Unintended Consequences

- **A PRP could:**
 - **Be a powerful disincentive for young researchers who wish to enter into select agent research**
 - **Drive select agent research overseas to countries with less stringent regulations**
 - **Isolate select agent researchers from the mainstream scientific community**
- **This could result in:**
 - **A US select agent research enterprise that is less robust, less diverse, and less responsive**
 - **Decreased ability to recruit top scientific talent**
 - **Diminished capacity to develop vaccines, treatments and countermeasures**
 - **Decreased security**



NSABB Findings

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- 4. Engaged leadership at the institutional level has been cited often as the most effective way to mitigate the risk of an insider threat**
- **It was noted repeatedly by experts with experience running select agent labs or PRPs that successful programs require leadership that:**
 - Values security
 - Encourages teamwork
 - Fosters vigilance regarding personnel reliability and security
 - Maintains close personal relationships with researchers
 - Remains “tuned in”



NSABB Findings

- 1. The Select Agent regulations have already been significantly strengthened**
- 2. Local institutions already screen individuals**
- 3. There is little evidence supporting the effectiveness and predictive value of the additional assessments that would be conducted under a PRP**
- 4. Engaged leadership is a critical component for ensuring reliability**



NSABB Recommendations

- 1. It is appropriate to enhance personnel reliability measures for individuals with access to select agents**

But promulgation of a formal, national PRP is unnecessary at this time

- The select agent rules have already been significantly strengthened**
- A PRP would be likely to have unintended detrimental consequences**
- There is insufficient evidence of the effectiveness of PRP measures to warrant the additional burden on research institutions**



NSABB Recommendations

2. The current SRA process should be strengthened

- The USG should continue to identify potential weaknesses or gaps in the information gathering process and reinforce the assessment as needed
- The NSABB suggests:
 - Formally incorporating into the SRA the periodic cross-checking of “approved” individuals
 - Expanding the SRA prohibition to include domestic terrorism
 - Strengthening the screening of foreign individuals (in a way that still ensures that the process remains timely)
 - Clarifying the reference to “mental defective” on the SRA form



NSABB Recommendations

- 3. The culture of responsibility and accountability should be enhanced at institutions that conduct select agent research**

This was noted by many whom the NSABB consulted as the best defense against the insider threat and can be accomplished without any significant expenditure of resources or disrupting research progress



Vision Statement

- **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**



Guiding Principles

1. **Research on select agents is essential to public health and national security**
2. **PR measures can reduce but not eliminate the insider threat**
3. **Implementation of PR 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, PIs, 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 PR measures**
10. **Individuals must have a clear understanding of their responsibilities**



NSABB Recommendations

- 4. Professional societies should continue to encourage an ongoing dialogue about personnel reliability and foster community-based solutions**

Societies have done a commendable job engaging their communities about DURC and should continue to promote a culture of research responsibility and vigilance toward personnel reliability



NSABB Recommendations

5. The *List of Select Agents and Toxins* should be reduced or stratified

The currently designated “select agents” differ significantly in degree of pathogenicity and ability to be utilized as an agent of bioterrorism

Yet the same stringent controls are applied equally to all select agents making it unnecessarily difficult to conduct research on many important organisms

Research using any strains that are removed from the list will still be conducted at the appropriate biosafety level with all the appropriate safety and security precautions



NSABB Recommendations

- 1. Personnel reliability can be enhanced but a formal PRP is not needed at this time**
- 2. The current SRA should be strengthened**
- 3. The culture of research responsibility and accountability should be enhanced within the select agent research community**
- 4. Professional societies should engage their communities on personnel reliability**
- 5. The select agent list should be shortened**