

Report to the NSABB December 10, 2008



An Optimal Personnel Reliability Program (PRP) for Persons with Access to Select Agents and Toxins: WG Approach and Report Outline

- Introduction
 - Issue
 - Approach
- Vision
- Guiding Principles
- Aims and applicability of PR program
- Key features
- Specific elements
- Roles and responsibilities
- Evaluation of PR program effectiveness and impact on scientific enterprise



Vision of an Optimal PRP

 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 for an Optimal PRP

- 1. Importance of research on select agents
- 2. Role of personnel reliability programs
- Need for balance
- 4. Personal responsibility
- 5. A culture of mindful trust
- 6. Public trust
- Communication and transparency
- 8. Need for periodic evaluation

Importance of research on select agents

- Essential to public health and national security
- Underpins the development of diagnostics, treatments, and preventive measures and contributes to the development of countermeasures against potential weapons of bioterrorism
- Also important in a wider scientific context; has helped advance other fields including cell physiology, cellular signaling, and cancer biology
- However, in the wrong hands, select agents also can be used to threaten public health and security, with significant potential for harm. Therefore, it is appropriate to take steps to ensure that individuals with access to select agents are trustworthy, reliable, and dependable.

Role of personnel reliability programs

- Tool to help make certain that reasonable measures have been taken to ensure the competency of individuals with access to select agents and, to the extent possible, their intent and reliability
- Can mitigate the risk from unreliable personnel, but no program can completely eliminate the risk, due in part to the inherent imperfection of people, but also to the difficulty in screening for an individual's intent
- Nevertheless, can help to enhance security of select agent research, maintain the safety of laboratory personnel, and help to earn and maintain public trust

Need for balance

- Oversight must balance the need for security with the need for continued scientific progress
 - Underpins public health, food safety, economic viability, and national security
- Degree of oversight should be consistent with the likelihood and possible consequences of misuse of select agents and the anticipated effectiveness of a program
 - Should not unduly encumber the conduct of the science

Personal responsibility

- Ethical obligation to recognize, and help to mitigate, the risks posed by the accidental release or intentional malevolent use of these agents
- Foundation for this is:
 - Awareness of ongoing activities within the research facility
 - Recognition of one's own limitations due to physical and mental status
 - Awareness of the potential vulnerability of other individuals with access to select agents
 - Communication of information and concerns to responsible authorities



- A research program will benefit by fostering a strong culture of responsibility, trust, and awareness within the scientific community regarding work with select agents
- Trust should be coupled with recognition that no personnel reliability program is completely effective
 - Vigilance and awareness of surrounding activities and personnel are always necessary
- Default position should be one of watchful trust, not distrust, of personnel who have been cleared for work with select agents



Public trust

- Building and maintaining public trust is the responsibility of the entire scientific community
- Measures to ensure the reliability of individuals working with select agents will help to allay public concerns about such research
- Demonstrating that the scientific community is acting responsibly and proactively to protect public welfare and security will help strengthen public trust

Communication and transparency

- Efficient and effective PRP requires ongoing dialogue among the scientific community, governmental agencies, and the public
- Transparency regarding the PR measures implemented for work with select agents will help build confidence in the ability of the scientific community to responsibly conduct select agent research
 - Could also discourage those with harmful intent from attempting to divert select agents



- Assessing the effectiveness of a PRP is challenging
 - Difficult to know what was prevented due to the implementation of PR measures
- PRPs should be periodically evaluated both for effectiveness and impact on the research enterprise



Aims of an Optimal PRP

- To mitigate the risks of theft, loss, and intentional or accidental release of select agents and toxins by individuals approved for access to select agents
- To accomplish this in a manner that does not impede the progress of science



- To all individuals requiring unescorted access to select agents and toxins
- To all individuals subject to a Security Risk Assessment under the Select Agent Rules



Next Steps

- Additional Briefings
- Identify features and specific elements
- Identify roles and responsibilities
- Discuss metrics for evaluation