

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



NSABB Meeting
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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**



Controls on Access to Select Agents Have Been Strengthened

- **Following the terrorist attacks and subsequent anthrax mailings of 2001 the USG expanded the select agent regulations**
- **Select Agent Rules expanded to include all entities that possess, use, or transfer select agents**
- **Designation of institutional Responsible Officials**
- **New security, inventory, and training requirements**



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



Personnel Reliability

- **Certain research facilities have developed Personnel Reliability Programs for select agent research modeled after the historic chemical and nuclear Surety 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**



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

1. **The select agent regulations have been appropriately and significantly strengthened since 2001 to include measures that address personnel reliability**
 - **Expanded in scope**
 - **New safety, security, and training measures**
 - **SRA**
 - **Examines criminal history**
 - **Potential terrorist ties**
 - **Automatically notifies the FBI when an “approved” individual is arrested**
 - **Periodic cross-checks of approved individuals (a feature recently initiated by the FBI)**



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**



Some 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



Psychological Testing

- **Psychological screening would assess an individual's mental health, emotional stability, and sound judgment**
- **Would potentially entail:**
 - **Establishment of a psychological baseline for an individual**
 - **Written questionnaires administered and interpreted by professional**
 - **Clinical interviews**
 - **Complete access to medical records**
 - **Polygraph evaluation**



Psychological Testing

- Such tests can identify major psychological disorders
- These tests have limited ability to identify subtle deviations
- No persuasive evidence to suggest that these tests can effectively identify an individual with malevolent intent

Would be costly and problematic to implement in an academic setting as universities lack the required program infrastructure and perhaps legal expertise to deal with potential privacy concerns



National Security Clearances

- **Extensive background investigation including:**
 - ❑ Potential criminal history or terrorist ties
 - ❑ Financial history
 - ❑ Drug and alcohol use
 - ❑ Personal conduct
 - ❑ Psychological conditions
 - ❑ Foreign influences
 - ❑ Previous security violations

- **Allows considerable latitude to investigate an individual's personal life**

Expensive, time-consuming, would likely serve as a major disincentive to the select agent researchers in the academic community



Vulnerability to Coercion

- Security clearances assess certain factors that might make an individual vulnerable to coercion
- Such factors might include:
 - Excessive debt
 - Marital infidelity
 - Numerous foreign contacts
- Short of security clearances, the WG considered credit checks as a potential assessment of vulnerability

The financial histories of select agent researchers in universities would be incredibly variable and there are no objective ways to translate the information gathered from a credit check into a meaningful determination of vulnerability



Medical Examinations and Monitoring

- Medical examinations, when required by BSL-3 or BSL-4 facilities, are typically aimed at safety
- They help to ensure that individuals are able to perform duties and operate equipment (e.g. respirators)
- No evidence suggests that medical examinations and monitoring protect against the insider threat

Medical examinations and monitoring may be appropriate for safety reasons in certain facilities but go beyond the scope of personnel reliability



NSABB Findings

- 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**



Enhancing the Culture of Responsibility

- **Enforcing standard hiring practices such as verification of credentials and work history**
- **Personal contact with previous employers**
- **Consultation of publically available records of misconduct, debarment, state licensure, etc.**



Enhancing the Culture of Responsibility

- **All individuals at an institution that conducts select agent research share responsibility and should be expected to report inappropriate behaviors of co-workers**
 - **Protections must be in place to ensure that reporting is not viewed as “snitching”**
 - **There must be recognition that most inappropriate behavior is the temporary result of personal matters**
 - **Training of personnel so they are aware of their responsibilities, can recognize inappropriate behaviors, and know the reporting mechanisms, and their protections for confidentiality and fairness**



Enhancing the Culture of Responsibility

- **ROs and PIs should foster the sense that biosecurity and personnel reliability is valued and expected by:**
 - ❑ **Encouraging teamwork**
 - ❑ **Maintaining strong working relationships with personnel**
 - ❑ **Requiring the appropriate training**
 - ❑ **Being aware of the work that is being conducted within their facilities**
 - ❑ **Being attuned to changes in personalities or inappropriate behaviors and working to address potential problems early on**



Enhancing the Culture of Responsibility

- **Individuals should recognize their own limitations and be free to temporarily opt out of select agent work as needed**
 - **Individuals should:**
 - **Be aware of any changes that may affect their ability to perform their job duties**
 - **Be confident that opting out or self-reporting will not be viewed as stigmatizing and that corrective actions will not be punitive**



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 select agent list 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



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**