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This draft includes proposed changes that were discussed at the 4-29-09 NSABB meeting. New text is highlighted.

Enhancing Personnel Reliability among Individuals with Access to Select Agents

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

CONTENTS

ABBREVIATIONS AND ACRONYMS

APHIS	Animal and Plant Health Inspection Service
ARO	Alternate Responsible Official
CDC	Centers for Disease Control and Prevention
DoD	Department of Defense
DOE	Department of Energy
DURC	Dual Use Research of Concern
FBI	Federal Bureau of Investigation
HHS	Department of Health and Human Services
IBC	Institutional Biosafety Committee
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
PI	Principal Investigator
PRP	Personnel Reliability Program
RO	Responsible Official
SRA	Security Risk Assessment
USG	United States Government
USDA	United States Department of Agriculture

Executive Summary

NSABB charge and key considerations. In response to heightened security concerns surrounding the potential misuse of dangerous pathogens within research settings, the National Science Advisory Board for Biosecurity (NSABB) has been charged with recommending to the United States Government (USG) strategies for enhancing personnel reliability among individuals with access to select agents and toxins.[1, 2] The challenge inherent in addressing the risk of the "insider threat" to high-containment biological facilities is to effectively address biosecurity concerns without unduly hindering the pace of life sciences research. Indeed, security measures that are overly burdensome could serve as a powerful disincentive to those who wish to and will responsibly conduct research on select agents, while measures that are too weak could leave the U.S. vulnerable to those who wish to misuse select agents toward malevolent ends.

Select agent research is critical to public health and national security. Scientific research on highly pathogenic microorganisms and toxins underpins our ability to successfully combat infectious diseases affecting humans, animals and plants, and enables the development of effective countermeasures against bioterrorism threats. An in-depth understanding of biological select agents has been essential to the development of new and improved detection and diagnostic capabilities, antimicrobial and antitoxin treatments, and preventative measures. Such research has been responsible for the development of numerous vaccines, therapeutic antibodies, antimicrobial treatments, and strategies aimed at augmenting the human immune response to more effectively target pathogens. Historically, research on pathogens or toxins that are now designated select agents, such as the variola virus, has resulted in vaccines and/or therapies that have greatly reduced the rates of human morbidity and mortality across the globe, and, in turn, significantly lengthened the human lifespan. Such research conducted on plant and animal pathogens has greatly contributed to the development of a safe and nutritious food supply that is readily available at a fairly low cost. In addition, select agent research is critical to developing rapid detection and diagnostic technologies that will greatly enhance our capabilities to respond to disease outbreaks and acts of bioterrorism.

Controls on access to select agents were significantly strengthened after the anthrax mailing incident.[3] After the terrorist attacks in 2001, various laws and regulations have been enacted to more rigorously control access to select agents, including an expansion of the Select Agent Rules[4] to require that all entities that possess, use, or transport select agents must register with

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1. Meeting of the National Science Advisory Board for Biosecurity, December 10, 2008, oba.od.nih.gov/biosecurity/nsabb_past_meetings.html (accessed April 15, 2009).
2. Select Agents are biological agents and toxins that have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products, and whose possession, use, and transfer are regulated by the Select Agent Rules (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). The current *List of Select Agents and Toxins* can be found at www.cdc.gov/od/sap/docs/salist.pdf (accessed April 15, 2009).
3. Spores of *Bacillus anthracis*, the pathogen that causes the disease known as anthrax, were sent through the mail in 2001. The NSABB notes that this colloquial expression is imprecise as anthrax, the disease, was not mailed; however, the phrase "anthrax mailing" is shorthand that is commonly used to refer to the mailing of these spores.
4. The Select Agent Regulations are: *Possession of Biological Agents and Toxins*, 7 CFR Part 331; *Possession, Use, and Transfer of Select Agents and Toxins*, 9 CFR Part 121; and *Select Agents and Toxins*, 42 CFR Part 73. The text

the Centers for Disease Control and Prevention (CDC) or the U.S. Department of Agriculture (USDA) and that personnel who have access to these materials must undergo a Security Risk Assessment (SRA). The expanded Select Agent Rules also described security, inventory, and personnel training requirements. In addition, there are civil and criminal penalties for non-compliance with the Select Agent Rules.

Personnel Reliability Programs address the insider threat. Research programs that have utilized materials that are deemed sensitive from a national security perspective (i.e., nuclear and chemical weapons programs) have addressed the insider threat as a component of larger "surety" programs. Surety programs contain features aimed at ensuring that the materials are physically secure, safely handled, and properly inventoried. Surety programs also have formal personnel reliability components to help ensure that the individuals with access to sensitive materials are trustworthy and reliable. These formal Personnel Reliability Programs (PRPs) may include background investigations, security clearances, medical examinations, psychological evaluations, polygraph testing, drug and alcohol screening, credit checks, and systems of ongoing monitoring.

Select agent research poses unique security challenges. Biological select agents are unlike nuclear and chemical surety material in fundamental ways that make biological select agents unsuitable for traditional surety programs. First, current biological select agents are naturally occurring pathogens that can be isolated from natural sources, such as endemic areas, soils, or infected hosts, well beyond the safe confines of laboratory walls.[5] Even if the physical security of pathogens contained within research facilities could be fully guaranteed, these measures would at best only partially mitigate the overall risk of a harmful application of these agents. Second, whereas nuclear and chemical materials exist in discrete quantities, most biological select agents are *living* organisms that can be grown into large quantities from a minimal starting sample, manipulated in non-laboratory settings, and disseminated. These attributes make attempts to maintain accurate inventories far more challenging.

Further distinguishing biological agents from nuclear or chemical surety material are the very natures of their respective research programs. The original PRPs were implemented for federal research programs that were "born classified" and applied to participants for whom strict security measures in the workplace were routine. Conversely, virtually all research on biological select agents is unclassified,[6, 7] and much of it is conducted in university settings that have a long history of openness, national and international collaboration, and ready sharing of research materials. This culture of openness has a long and fruitful history in academia that includes research on pathogens that have only relatively recently been designated "select agents."

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of these regulations is available at www.selectagents.gov/agentToxinList.htm (accessed April 15, 2009) and the Government Printing Office, Code of Federal Regulations, www.gpoaccess.gov/cfr/ (accessed May 1, 2009).

5. The disease smallpox has been eradicated in nature but the causative agent, variola virus, exists in two facilities.

6. The Department of Health and Human Services is the largest provider of grants and contracts for select agent research and does not fund classified research. This research is aimed at developing vaccines, therapeutics, and diagnostics against diseases caused by bioterrorism agents to help first responders provide treatments to patients exposed to bioterrorism agents. See www3.niaid.nih.gov/ for more information about this research. In addition, the USDA conducts research and develops countermeasures against plant and animal pathogens. Neither the USDA nor the National Science Foundation funds or conducts any classified work.

7. The small fraction of individuals conducting classified research on select agents is subject to rigorous security and personnel reliability measures.

Mandating a national Personnel Reliability Program could have unintended consequences within the life sciences research community. Although the risk of the insider threat is uncertain, it is likely quite small based on history. Even in the open climate that is the hallmark of most life sciences research, the overwhelming majority of such research – including select agent research – has been conducted by responsible researchers toward commendable aims. The potential benefits of enhanced personnel reliability measures must be carefully weighed against the potential negative consequences that such measures would likely have on the research community. A robust and agile research enterprise that has access to a diverse workforce and spans government, private, and academic sectors provides innumerable benefits to society. The promulgation of additional reliability measures could serve as a powerful disincentive to those who wish to and would responsibly conduct research on select agents because the most talented young researchers, those with many options for research paths, may be far more likely to enter fields with less onerous regulatory requirements. Thus, a burdensome national personnel reliability program may not only drive scientists from important select agent research, but also drive select agent research out of academia and potentially out of the U.S. into countries with less stringent regulations. Furthermore, the institution of onerous reliability measures could isolate select agent researchers from the mainstream scientific community, isolation that might inhibit research and paradoxically increase the risk of the insider threat.

NSABB approach. The NSABB Working Group on Personnel Reliability was briefed on many extant personnel reliability programs, as well as safety and security measures, established for chemical, nuclear, and select agent research programs. The group reviewed extant models for ensuring personnel reliability with particular interest in the costs, impact, and effectiveness that such measures would have on the scientific enterprise, as well as the feasibility of their implementation nationally in academic settings.

NSABB findings. During its deliberations, the NSABB Working Group on Personnel Reliability found that 1) the select agent program has been significantly strengthened since 2001 to include measures that address personnel reliability; 2) local institutions already do an extremely effective job at screening individuals requiring access to select agents as evidenced by the extremely low rate of individuals who receive unfavorable SRAs; 3) there is very little evidence that supports the effectiveness and predictive value of many additional assessments that would be conducted under PRPs with respect to the assessments' ability to detect the traits or individuals who pose an insider threat; and 4) engaged institutional leadership has been cited often as the most effective way to mitigate the risk of an insider threat.

NSABB recommendations. In light of these findings, the NSABB recommends the following:

1. **It is appropriate to enhance extant personnel reliability measures, but the promulgation of a formal, national Personnel Reliability Program is unnecessary at this time.** The NSABB has concluded that 1) the select agent regulations have already been significantly strengthened to appropriately address the possibility of an insider threat; 2) there is currently insufficient evidence of the effectiveness of PRP measures towards mitigating the risk of an insider threat to warrant the additional, significant burden on research institutions; and 3) a PRP is likely to have unintended and detrimental

consequences for the scientific enterprise that in the future could result in more harm to public health and safety and to national security than an insider threat poses.

2. **The current SRA process should be strengthened.** The SRA is a valuable federal-level check of an individual's possible criminal history and potential terrorist ties. To further strengthen the SRA, the federal government should continue to identify potential weaknesses and gaps in the information-gathering process, and adjust the procedures as necessary. However, the SRA should remain a timely process so as not to impede the recruitment of researchers, including foreign researchers. In its full report, the NSABB has noted several examples of how the SRA process could be strengthened.

3. **The culture of responsibility and accountability should be enhanced at institutions that conduct select agent research.** Though persuasive evidence is lacking that PRP assessment instruments can effectively identify individuals who pose an insider threat, enhancing the culture of responsibility and accountability among individuals with access to select agents and toxins is a way to strengthen personnel reliability. This can be accomplished without any significant expenditure of resources or disruptions of research, and was noted by many whom the NSABB consulted as being the best defense against the insider threat.

   In this context, the NSABB identified a goal that every institution that conducts research on select agents should strive toward, as well as a set of Guiding Principles for the responsible conduct of research on select agents and toxins that underpin the issue of personnel reliability. In addition, the NSABB identifies several specific practices and approaches for enhancing the culture of reliability and accountability at the institutional level.

4. **Professional societies should continue to encourage an ongoing dialogue about personnel reliability to maintain vigilance about biosecurity issues throughout the research community and to foster community-based solutions.** Many professional societies have done a commendable job engaging their respective communities both in the U.S. and internationally about Dual Use Research of Concern (DURC).[8] These societies should now strengthen their conversations about maintaining personnel reliability as they promote a culture of research responsibility and vigilance about DURC and other biosecurity issues. Outreach and education efforts will be essential to enhancing the culture of research responsibility outlined above as this culture will be fostered by individuals who are knowledgeable about the insider threat, trained in appropriate security measures, and have a clear understanding of their role within a select agent research facility. Professional societies are well-positioned to undertake these

[8] National Science Advisory Board for Biosecurity, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (Washington, DC: 2007). Dual use research of concern is described on page 17 of this report as "[r]esearch that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel." The NSABB report can be accessed at oba.od.nih.gov/biosecurity/biosecurity_documents.html (accessed May 5, 2009).

outreach and education efforts and to equip researchers with the tools required to strengthen vigilance about biosecurity at the local level.

5. **The *List of Select Agents and Toxins*[9] 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. Consequently, the risk that they might pose to public, animal and plant health and safety varies significantly depending on the agent, and yet the same stringent controls apply across the board, making it unnecessarily very difficult to conduct vital research on these important biological organisms by hindering the ability of less pathogenic select agents to be used for legitimate research purposes.

   The select agent list is reviewed every two years in recognition of the emergence of new potential agents. These compulsory reviews should continue with greater consideration for removing agents that research and management show to be of lower risk. The NSABB recognizes that the decision to remove agents from the list should not be taken lightly and will require much consideration from the scientific and public policy-making communities. Though certain agents may be removed from the *List of Select Agents*, research using these strains is and would still be conducted at the appropriate biosafety level with all the specified safety and security precautions. While there is a process to remove attenuated (or weakened) strains of select agents that pose little or no risk to public health and national security from the list, the process is considered burdensome, time-consuming and inhibitory to research. The process thus needs reconsideration.

[9] The current *List of Select Agents and Toxins* can be found at www.selectagents.gov/resources/List of Select Agents and Toxins_111708.pdf (accessed May 8, 2009).

Introduction:

Purpose of this report. The National Science Advisory Board for Biosecurity (NSABB) was charged with recommending to the United States Government (USG) strategies for enhancing personnel reliability among individuals with access to biological select agents and toxins.[10] The challenge is to develop policies aimed at mitigating the risk of misuse of select agents by individuals who have access to them as part of their jobs, education, or training, the so-called "insider threat," and appropriately address biosecurity concerns without unduly hindering the pace of life sciences research. This report is intended to provide guidance to the USG as it designs such policies, and sets forth the NSABB's recommendations for enhancing personnel reliability by building on the existing Select Agent Program and calling for renewed sense of responsibility and accountability among researchers at the institutional level.

The critical role of select agent research. Protecting public health and safety and maintaining national security depend in large part on a robust and agile life sciences research enterprise that utilizes a diverse workforce spanning government, private, and academic sectors. Some of this research focuses on certain highly pathogenic organisms and toxins designated as "biological select agents." Research on these agents, and the mechanisms by which they cause disease or harm, underpins our ability to successfully combat infectious diseases affecting humans, animals, and plants, and is essential to the development of new and improved diagnostics, treatments, and preventative measures for a variety of infectious diseases, including the development of vaccines, therapeutic antibodies, antimicrobial treatments, and strategies aimed at augmenting the human immune response to more effectively target pathogens. Historically, research on pathogens or toxins that are now designated select agents, such as the variola virus, has resulted in vaccines and/or therapies that have greatly reduced the rates of human morbidity and mortality across the globe and, in turn, significantly lengthened the human lifespan. Research on other select agents shows promise of providing insights into emerging infectious diseases as well as other non-infectious diseases. Such research conducted on plant and animal pathogens has greatly contributed to the development of a safe and nutritious food supply that is readily available at a fairly low cost. A thriving select agent research enterprise broadly supports public health and safety, agricultural and commercial development, and economic competitiveness, as well as national security.

Such research also enables the development of effective countermeasures against bioterrorism threats because an in-depth understanding of biological select agents is essential to the development of new and improved detection and diagnostic technologies, antimicrobial and antitoxin treatments, and preventative measures, all of which will greatly enhance our capabilities not only to respond to acts of bioterrorism and to disease outbreaks but to develop

[10.] Select agents are biological agents and toxins that have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products, and whose possession, use, and transfer are regulated by the Select Agent Rules (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). The current *List of Select Agents and Toxins* can be found at www.selectagents.gov/resources/List of Select Agents and Toxins_111708.pdf (accessed May 8, 2009).

beneficent uses. For example, anthrax lethal toxin has been shown to inhibit tumor angiogenesis and may have broad implications as an anti-tumor agent.[11]

The insider threat. In 2001, spores of *Bacillus anthracis* were sent to victims via the U.S. Postal Service, resulting in 22 infections, five deaths, extensive social disruption, and enormous costs for the emergency response, remediation, and subsequent investigation. The well-publicized FBI investigation that followed, which focused on U.S. scientists,[12] has resulted in renewed scrutiny of laboratory security. In turn, these heightened concerns surrounding the potential misuse of dangerous pathogens within research settings has resulted in calls to reexamine, and potentially enhance, the laboratory security measures aimed at ensuring personnel reliability among individuals with access to biological select agents and toxins.

The "insider threat" generally refers to the misuse of these pathogens by an individual who has access to them as part of his or her job. The scenarios that illustrate the insider threat are numerous, but they can generally be described as involving the theft, misuse, or diversion of a select agent by an individual who had been approved to have access to them. Some examples of the "insider" include an individual with malevolent intent who infiltrates a research facility under the guise of a legitimate researcher, only to steal, release or divert select agents, or an individual with access to select agents who is coerced into providing access or expertise to unauthorized individuals with malevolent intent.

Controls on access to select agents were significantly strengthened after the anthrax mailing incident.[13] Following the terrorist attacks of 2001 and the subsequent anthrax mailings, the USG substantially expanded the scope of the select agent regulations and added measures aimed at ensuring personnel reliability. Prior to 2001, the Select Agent Regulations were largely focused on shipping, requiring individuals and facilities that ship or receive select agents and toxins to register with, and report each transfer to, the Centers for Disease Control and Prevention (CDC) or the United States Department of Agriculture (USDA). The current Select Agent Rules[14] were expanded by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*[15] (Bioterrorism Response Act) to require that all entities that possess or use (in addition to transport) select agents must register with the CDC or USDA.

[11.] Randall W. Alfano et al., "Potent inhibition of tumor angiogenesis by the matrix metalloproteinase-activated anthrax lethal toxin," *Cell Cycle* 7, no. 6 (2008): 745-49, www.landesbioscience.com/journals/cc/article/5627/ (accessed May 8, 2009).

[12.] In 2008 the Department of Justice announced its intention to seek a grand jury indictment against a U.S. scientist working in a federal research facility. These charges were not filed as the scientist took his own life. See DOJ Press Release, "Transcript of Amerithrax Investigation Press Conference," August 6, 2008, www.usdoj.gov/opa/pr/2008/August/08-opa-697.html (accessed April 30, 2009). To date, no further details regarding the anthrax mailings investigation have been made public and the NSABB was not briefed on the personnel reliability aspects of the investigation.

[13.] Spores of *Bacillus anthracis*, the pathogen that causes the disease known as anthrax, were sent through the mail in 2001. The NSABB notes that this colloquial expression is imprecise as anthrax, the disease, was not mailed; however, the phrase "anthrax mailing" is shorthand that is commonly used to refer to the mailing of these spores.

[14.] 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

[15.] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Public Law 107-188, 107th Congress, 2nd Sess. (June 12, 2002), frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ188.107.pdf (accessed May 8, 2009).

Both the Bioterrorism Response Act and the 2001 USA PATRIOT Act[16] address the concept of personnel reliability by declaring that certain types of individuals are prohibited from having access to select agents. Generally, a restricted or prohibited person is an individual who has committed a felony or been convicted of using illegal drugs, has engaged in terrorist activities, has a history of mental illness, or is a citizen from a country designated as a state-sponsor of terrorism. The specific restricted and prohibited categories are as follows:

Restricted and Prohibited Categories

A restricted person under the USA PATRIOT Act (18 U.S.C. 175b):

- is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- is a fugitive from justice;
- is an unlawful user of any controlled substance as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);
- is an alien illegally or unlawfully in the United States;
- has been adjudicated as a mental defective or committed to any mental institution;
- is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism; or
- has been discharged from the Armed Services of the United States under dishonorable conditions.

A prohibited category under the Bioterrorism Response Act includes an individual reasonably suspected by any federal law-enforcement or intelligence agency of:

- Committing a crime specified in 18 U.S.C. 2332b(g)(5);
- Having a knowing involvement with an organization that engages in domestic or international terrorism as defined in 18 U.S.C. 2331 or with any other organization that engages in intentional crimes of violence; or
- Being an agent of a foreign power as defined in 50 U.S.C. 1801.

Under the current Select Agent Rules implemented by the U.S. Department of Health and Human Services (HHS)/CDC and USDA/APHIS (Animal and Plant Health Inspection Service), an individual requiring unescorted access to select agents as part of his or her job must have a Security Risk Assessment (SRA) by which his or her potential status as a restricted or prohibited person is evaluated. A favorable SRA is required for access to select agents. An individual must provide fingerprints and disclose aspects of possible criminal history, use of illicit drugs, mental-health history, and whether dishonorably discharged from the U.S. Armed Services.[17] Additional information is collected from naturalized citizens and permanent residents regarding immigration status and country of birth. Federal databases are then utilized to examine an individual's possible criminal background, potential terrorist ties, and immigration status (see databases in Appendix B). Additional investigation is conducted if necessary.

16. *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001*, Public Law 107-56, 107th Cong., 2nd Sess. (October 26, 2001) frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ056.107.pdf (accessed May 8, 2009).

17. Information is collected on the FBI form *Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information*, also known as FD-961, available at www.fbi.gov/terrorinfo/bioterrorfd961.htm (accessed May 8, 2009).

An individual granted access to select agents must undergo a new SRA every five years. Responsible Officials (ROs) and Alternate Responsible Officials (AROs) who oversee select agent research programs must obtain a favorable SRA each time the certificate of select agent registration is renewed. In addition, the FBI is automatically notified when an individual with a favorable SRA is arrested and fingerprinted or checked against criminal databases for whatever reason. The FBI also monitors individuals with favorable SRAs for criminal activity or terrorist ties by periodically cross-checking their names and fingerprints against federal databases. Access to select agents can be denied, limited, or revoked at any time by the institutional RO or ARO, the CDC, or the USDA if deemed appropriate. These decisions can be appealed.

The current Select Agent Rules also describe security, inventory, and personnel training requirements. In addition, there are civil and criminal penalties for non-compliance with the Select Agent Rules. Compliance with these regulations is critical as institutions and individual scientists engaged in select agent research have much at stake, including the safety of laboratory personnel, the safety of the public and the environment, and the public's confidence and trust in their ability to conduct such work safely and responsibly.

A focus on "biosurety" and personnel reliability. Historically, the concept of personnel reliability in research settings has been addressed as a constituent of larger surety programs. Surety programs were first implemented to prevent unauthorized access to chemical and nuclear weapons-related agents, and typically consist of four major components: (1) physical security, (2) safety, (3) personnel reliability, and (4) agent/material accountability.[18, 19, 20] "Physical security" describes both the structures and the individuals that secure and restrict access to sensitive materials. "Safety" encompasses the standards, practices, specialized equipment, and laboratory design features that help to ensure the safe handling of such agents, and protect the health of research personnel, the public, and the environment. "Personnel reliability" measures aim to ensure that individuals granted access to sensitive materials are trustworthy, responsible, and stable, and can competently perform their duties. "Agent accountability" involves procedures for maintaining accurate inventories and transfer records.

"Biosurety" is a term coined to describe the application of surety principles to research involving biological agents.[21] Although not labeled as such, some aspects of biosurety are currently addressed in life sciences research in the form of guidelines, manuals and best practices. For example, the CDC-NIH (National Institutes of Health) manual *Biosafety in Microbiological and*

[18.] Gretchen L. Demmin, "Biosurety" in *Medical Aspects of Biological Warfare*, ed. Martha K. Lenhart, 543–58 (Washington, DC: Defense Dept., Army, Office of the Surgeon General, Borden Institute, 2007).

[19.] Kathleen Carr et al, "Implementation of Biosurety Systems in a Department of Defense Medical Research Laboratory," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 2, no. 1 (2004): 7–16, www.liebertonline.com/doi/abs/10.1089/153871304322964291 (accessed May 8, 2009).

[20.] Ross H. Pastel et al, "Clinical Laboratories, the Select Agent Program, and Biological Surety (Biosurety)," *Clinics in Laboratory Medicine*, 26 (2006): 299–312, www.sciencedirect.com/science/article/B75HR-4K991CB-5/2/17d59bd962ece152a61c4fc391c231b5 (accessed May 8, 2009).

[21.] The term "biosurety" stems from a historically weapons-related concept of surety that also encompasses the concept of quality assurance for weapons delivery. As such, "biosurety" is a misnomer in the life sciences context as, in accordance with the Biological Weapons Convention, the U.S. does not develop biological weapons. Accordingly, select agent research is not conducted to develop bio-weapons or with the intent of enhancing offensive capabilities. This report minimizes the use of the term "biosurety" to avoid the implication that such programs are weapons-related and focuses instead on personnel reliability.

Biomedical Laboratories and the *NIH Guidelines for Research Involving Recombinant DNA Molecules* describe biosafety practices and procedures for work with pathogens and recombinant organisms as well as some security practices. Personnel reliability and agent accountability are addressed to some extent by the current Select Agent Rules, as discussed above, with the SRA and by requirements for recordkeeping.

Certain research facilities (notably federal) have instituted formal Personnel Reliability Programs (PRPs) to provide additional measures to help ensure that individuals with access to select agents meet additional standards of reliability. Current PRPs are modeled after those within the traditional surety programs and may include extensive background investigations with interviews of character references, security clearances, medical evaluations that may include a review of complete medical records, psychological testing, drug and alcohol testing, polygraph examinations, credit checks, and a comprehensive review of service and employment records. PRPs usually also involve formal mechanisms for ongoing monitoring that can include requirements for self-reporting, peer-reporting, ongoing monitoring by supervisors, and penalties for noncompliance. Individuals enrolled in a PRP typically undergo periodic reassessments including annual physical examinations, random drug tests, re-evaluation of medical records and medications, recurring psychological evaluations, and renewal of security clearances. Importantly, personnel reliability measures can help to mitigate, but not to eliminate the risk of an insider threat.

Select agent research poses unique security challenges. Biological select agents are unlike nuclear and chemical surety material in fundamental ways that make them less-suited for traditional surety programs. First, current biological select agents are naturally occurring pathogens that can be isolated from natural sources well beyond the safe confines of laboratory walls.[22] Consequently, even if the physical security of pathogens contained within research facilities could be fully guaranteed, these measures would at best only partially mitigate the overall risk of harmful application of these agents. Second, whereas nuclear and chemical materials exist in discrete quantities, most biological select agents are *living* organisms that can be grown into large quantities from a minimal starting sample, manipulated in non-laboratory settings, and disseminated. These attributes make attempts to maintain accurate inventories far more challenging.

Further distinguishing biological agents from nuclear or chemical surety material are the very natures of their respective research programs. The original PRPs were implemented for federal research programs that were "born classified" and applied to participants for whom strict security measures in the workplace were routine. Even PRPs that have been developed more recently for biological select agents have been implemented in facilities that already are more accustomed to more strict oversight by agencies that have unique research cultures, notably the U.S. Department of Energy (DOE) and Department of Defense (DoD), which stem from their long histories with surety programs. Conversely, virtually all research on biological select agents is unclassified,[23, 24] and much of it is conducted in university settings that have a long history of

[22] The disease smallpox has been eradicated in nature but the causative agent, variola virus, exists in two facilities.

[23] The Department of Health and Human Services (HHS) is the largest provider of grants and contracts for select agent research and does not fund classified research. This research is aimed at developing vaccines, therapeutics, and diagnostics against diseases caused by bioterrorism agents to help first responders treat patients exposed to

openness, national and international collaboration, and ready sharing of research materials. This culture of openness has a long and fruitful history in academia that includes research on pathogens that only relatively recently have been designated "select agents."

Mandating a national Personnel Reliability Program could have unintended consequences within the life sciences research community.

Although the risk of the insider threat is uncertain, it is very likely to be quite small based on history. Even in the open climate that is the hallmark of most life sciences research, the overwhelming majority of such research – including select agent research – has been conducted by responsible researchers toward commendable aims. The potential benefits of enhanced personnel reliability measures must be carefully weighed against the more likely negative consequences that such measures could have on the research community. A robust and agile research enterprise that comprises a diverse workforce, and spans government, private, and academic sectors provides innumerable benefits to society. The promulgation of additional reliability measures could serve as a powerful disincentive to those who wish to and would responsibly conduct research on select agents because the most talented young researchers, those with many options for research paths, may be far more likely to enter fields with less onerous regulatory requirements. Thus, a burdensome national personnel reliability program may not only drive scientists from important select agent research, but also drive select agent research out of academia and potentially out of the U.S. into countries with less stringent regulations.

Paradoxically, measures aimed at enhancing the biosecurity of select agent research could have the unintended consequence of actually decreasing national security if such measures diminished the capacity for the U.S. to prepare for, and respond to, emerging threats (including naturally occurring disease outbreaks as well as bioterrorism) by diminishing the U.S.' ability to recruit top scientists and develop vaccines, treatments, and other countermeasures. Furthermore, the institution of reliability measures could isolate select agent researchers from the mainstream scientific community, and such isolation might increase the risk of the insider threat.

NSABB approach. To address its charge, the NSABB formed a Working Group on Personnel Reliability (see Appendix A). This group examined the current federal Select Agent Program as well as formal Personnel Reliability Programs that have been established for nuclear, chemical, and biological select agent research. It also was briefed on the following extant programs for ensuring reliability, including:

- HHS Select Agents Program;
- CDC intramural research program;
- DoD/Department of the Army Biological Personnel Reliability Program;
- DOE Select Agent Human Reliability Program;
- NIH Biological Surety Program for intramural research;

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bioterrorism agents. See www3.niaid.nih.gov (accessed May 5, 2009) for more information about this research. In addition, the USDA conducts research and develops countermeasures against plant and animal pathogens. Neither the USDA nor the National Science Foundation funds or conducts any classified work.

[24.] The small fraction of individuals conducting classified research on select agents is subject to rigorous security and personnel reliability measures.

- Battelle Biomedical Research Center; and
- Galveston National Lab (BSL-4 facility) at the University of Texas Medical Branch.

In addition, the Working Group consulted with:

- The intelligence community with regard to security clearances;
- Selected participants in the U.S. Government-World Health Organization International Roundtable on Dual Use Research (November 2008) on the topic of personnel reliability; and
- Experts in psychological and mental health assessments.

The group considered extant models and expert perspectives with particular interest in the costs, impacts, and effectiveness that such measures would have on the scientific enterprise, as well as the feasibility of their implementation nationally, in academic settings.

In addition, the NSABB solicited broad public input and stakeholder perspectives at the Public Consultation Meeting on Personnel Reliability held on April 3, 2009 (see Appendix C).

NSABB Findings:

During its deliberations, and broad public and expert consultations, the NSABB identified a number of important findings.

1. **The select agent regulations have been appropriately and significantly strengthened since 2001 to include measures that address personnel reliability.** The current Select Agent Regulations are substantially different since the terrorist attacks and anthrax mailings of 2001. They have been expanded in scope to encompass possession and use, and include requirements for the registration of agents and toxins; designation of an institutional Responsible Official; implementation of security and safety measures to deter theft, loss, or release of select agents and toxins; training of staff; record keeping; and assessment of security risk for all individuals who request access to select agents and toxins.

   Importantly, the requirement for a Security Risk Assessment (SRA) addresses many key aspects of personnel reliability. The SRA utilizes federal databases to learn an individual's possible criminal history and potential terrorist ties, and ascertain whether an individual falls into the restricted or prohibited categories described above. While the NSABB was initially concerned that, between SRA renewals, individuals with access to select agents could fall into a prohibited category (possibly for several years) without being detected,[25] it learned that not only is the FBI automatically notified when individuals with access to select agents are arrested, but that the FBI has recently begun periodically (~ 6 months) cross-checking the names of approved individuals with specified databases to identify if an individual with access to select agents slides into a restricted category between SRA renewals.

[25.] Currently, an SRA is valid for five years unless otherwise terminated by the entity, CDC, or USDA. ROs, AROs, and individuals who own or control the entity must obtain SRA approval each time the select agent certificate of registration is renewed. Certificates of registration are valid for a maximum of three years.

2. **Local institutions already screen individuals requiring access to select agents.** In most if not all institutions, an individual requiring access to select agents is pre-screened prior to hiring or prior to requesting an SRA. Data presented to the NSABB by the CDC demonstrate that fewer than 1% of applicants who submit to the SRA process have been determined to fall into restricted or prohibited category.[26] The extremely low rate of individuals who receive unfavorable SRAs suggests that unsuitable individuals are effectively "pre-screened" by the human resources departments and other hiring offices within institutions, are deemed inappropriate to have access to select agents by the institutional Responsible Official, or are deterred by the prospect of an SRA.

   Moreover, most BSL-4 laboratories already implement reliability measures that go beyond the SRA if not formal PRPs. For example, the newly constructed Galveston National Laboratory, one of only two full suit BSL-4 facilities being operated in a non-federal setting, is developing a reliability program that would integrate reliability assessments by its departments of human resources and employee health, and its biosafety officer. Many BSL-3 laboratories also have enhanced safety and security measures as well as additional personnel training and monitoring requirements.

3. **There is little evidence regarding the effectiveness and predictive value of personnel reliability measures with respect to their ability to identify individuals who may pose an insider threat.** In light of the NSABB's first two findings, i.e., that the SRA has been strengthened and that local institutions appear to be doing an effective job screening individuals, the NSABB carefully considered and extensively debated whether additional reliability measures, or a formal national Personnel Reliability Program for select agent research, were appropriate. In this context, it carefully examined the numerous assessments that are employed by formal Personnel Reliability Programs, including extensive background investigations with interviews of character references, security clearances, medical evaluations including review of complete medical records, psychological testing, drug and alcohol testing, polygraph examinations, credit checks, comprehensive review of service and employment records, and provisions for ongoing monitoring.

   As a prelude to identifying optimal features of a personnel reliability program, the NSABB identified a number of optimal personnel characteristics that underlie trustworthy, responsible behavior. It then sought to identify methodologies to assess these characteristics, especially those using the various assessments commonly utilized in PRPs. The optimal personnel characteristics were:
   - Free of felony convictions;
   - No domestic or international terrorist ties;
   - No history of scientific or professional misconduct in the workplace;
   - Emotional stability and capacity for sound judgment;

[26.] Robbin S. Weyant and John Stovers, "NSABB Briefing: Security Risk Assessments for Possession, Use, and Transfer of Select Agents," (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, United States of America, April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Weyant.pdf (accessed May 5, 2009).

- Positive attitude toward safety and security measures, and standard operating procedures; and
- Free of vulnerability to coercion.

The NSABB considers these to be reasonable characteristics for individuals with access to select agents and toxins. It found, however, that some of the characteristics were exceedingly difficult to measure in any objective way and that it was unclear whether these characteristics were suitable surrogates (or predictors) for not posing an insider threat. Furthermore, as it considered the potential utility of the various assessments commonly utilized in PRPs, it found little evidence to suggest that personnel reliability assessments going beyond the SRA and other institutional background checks that are already in place would correlate with, or effectively identify, an insider threat. In addition, as was the case with the optimal personnel characteristics, there were no objective criteria for translating the information gathered from a given assessment into a determination of reliability.

While the NSABB considered all of the commonly used personnel reliability assessments, it focused considerable attention on the three assessments common to most PRPs:

Psychological testing. In particular, the NSABB vigorously debated whether to recommend psychological assessments for individuals with access to select agents. These tests would largely aim to assess an individual's personality attributes and capacity for sound judgment and emotional stability. Such screening would entail the establishment of a psychological baseline for an individual and require questionnaire-based assessments, interviews and evaluations by trained professionals, and access to complete medical records. Such tests would need to be conducted periodically to identify significant changes in an individual's mental health. The strength of such psychological assessments is in their ability to identify major psychological disorders; however, their ability to identify more subtle deviations or concerns is more problematic. Moreover, identifying an individual with malevolent intent appears, if not impossible, at least extremely difficult.

These types of assessments appear to have value under certain circumstances, however. A battery of psychological tests often detects major mental illness, and some psychological profiling is conducted for certain elite military units.[27] Psychological tests are also routinely used as a component of the employment screening process in other high stress or security-related settings, such as for airline pilots[28] or within the nuclear industry. Indeed, some BSL-4 facilities require (or are considering) psychological assessments for their employees,[29] but

[27.] Charles A. Morgan, III, "Psychological Assessment in the Selection of Personnel for Specialized Roles in Government: Where does it fit in? What role might it play?" (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, U.S.A., April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Morgan.pdf (accessed May 5, 2009).
[28.] Jeff Baker, "Psychological Assessment," (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, U.S.A., April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Baker.pdf (accessed May 5, 2009).
[29.] Stanley M. Lemon, "Managing Personnel Reliability at the Galveston National Laboratory University of Texas Medical Branch," (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, U.S.A., April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Lemon.pdf (accessed May 5, 2009).

individuals in these high-containment laboratories operate under severe, and often continual, pressure and stress, so these assessments are typically aimed at biosafety.

Additionally, psychological tests employed for the purpose of mitigating the insider threat (particularly in academia) would be extremely resource-intensive and they lack persuasive evidence for effectiveness or their predictive value. Moreover, most universities lack the appropriate program infrastructure to effectively implement these features or to deal with their associated legal and/or privacy concerns.

National security clearances. Some PRPs require individuals to obtain a national security clearance. A security clearance investigation examines an individual's possible criminal history and potential terrorist ties, but it also evaluates an individual's financial history, drug and alcohol use, personal conduct, psychological conditions, potential for foreign influence, and previous security violations or misuse of information technology. Such investigations allow considerably more latitude to investigate an individual's personal life, acquaintances, affiliations, business partners and other factors than PRPs that do not require a clearance.

In addition to assessing one's possible criminal history and terrorist ties (which are also addressed by the current SRA), security clearances attempt to identify factors that might make an individual vulnerable to coercion. However, not only is quantifying–or even describing–one's "vulnerability to coercion" exceedingly difficult, there are certain behaviors that might make an individual vulnerable to coercion, e.g., excessive debt, marital infidelity, or numerous foreign contacts, but none of these factors, either singly or in combination, necessarily indicate that an individual would be susceptible to coercion. Not only is the assessment of the factors that may contribute to an individual's vulnerability quite challenging but determining how these vulnerabilities translate into a security risk is inexact at best.

Short of national security clearances, which are expensive, typically take months to complete, and would likely serve as a major disincentive to researchers in the academic community, the NSABB considered individual components of a security clearance to assess one's vulnerability, such as credit checks. It concluded that, while an individual with large debt might be willing to provide access to select agents in exchange for financial consideration, and while credit checks are commonly employed and may already be conducted by some hiring offices, mandating credit checks as part of a larger reliability program for select agent research is problematic because there are no objective ways to translate the information into any meaningful measure of reliability. The types of individuals who conduct select agent research range from graduate students and post-doctoral trainees to laboratory technicians to tenured professors, all of whom are at different stages in their professional and personal lives. The variability in the financial histories of select agent researchers suggests that credit checks, as an assessment of vulnerability, are essentially meaningless. Moreover, state and local legislation may prohibit credit checks being used in the employment process.

Medical examinations. Many PRPs require individuals to undergo medical examinations. These examinations are conducted largely for biosafety reasons to ensure that individuals are physically able to perform duties or safely operate laboratory equipment, e.g., respirators. These examinations are appropriate, for safety reasons, for BSL-4 and BSL-3 facilities but such assessments are beyond the scope of personnel reliability and no evidence suggests that such examinations would protect against the 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.** During the NSABB's deliberations and consultations, the concept of engaged institutional leadership was noted repeatedly as critically important to ensuring personnel reliability. Leadership that values security, fosters a sense of vigilance and responsibility among personnel, and encourages teamwork, camaraderie, and close personal working relationships was mentioned consistently as one of the most effective and feasible ways to enhance personnel reliability. Indeed, it was suggested that engaged leadership and teamwork may be more effective than the formal assessments conducted under PRPs.

NSABB Recommendations:

In light of these findings, the NSABB recommends the following:

1. **It is appropriate to enhance personnel reliability measures for individuals with access to select agents, but the promulgation of a formal, national Personnel Reliability Program is unnecessary at this time.** First, the select agent regulations already have been significantly strengthened to appropriately address the possibility of an insider threat. Second, a PRP is likely to have unintended but nevertheless detrimental consequences for the scientific enterprise, especially in academia, that, in the future, could well result in more harm to public health and safety and to national security than an insider threat. Finally, there is insufficient evidence of the effectiveness of personnel reliability measures to warrant the additional, significant burden on research institutions.

   The NSABB recommends an approach to personnel reliability that augments the current Security Risk Assessment process of the Select Agent Regulations, combined with an enhanced culture of research responsibility and accountability at the institutional level. A singular approach to personnel reliability, e.g., a federally mandated PRP across the select agent research community, is neither appropriate nor useful at this time. However, institutions that are engaged in select agent research should review their employment practices and other existing select agent personnel reliability-related policies to determine whether there is a need to implement additional personnel reliability measures. If deemed useful and appropriate at the local level, such institutions should be able to establish a formal PRP at their discretion. Institutions that implement additional reliability measures or a formal program then should monitor the costs, impact, and general effectiveness so that they can inform the greater communities of the advisability and feasibility of a national program.

2. **The current SRA process should be strengthened.** The SRA is a valuable federal check of an individual's possible criminal history and potential terrorist ties. To further strengthen the SRA, the government should continue to identify potential weaknesses or gaps in the information gathering process, and reinforce the assessment as necessary.

   During the NSABB deliberations, the following actions were identified as but some examples of how the SRA process could be strengthened:

   - Incorporate into the SRA process the periodic cross-checking of individuals with favorable SRAs against federal databases. The FBI has recently begun checking the names of individuals with favorable SRAs against the Counterterrorism Watchlist and other databases approximately every six months. This is a valuable practice that should be formally incorporated into the SRA process to ensure its continuation.

   - ~~Expand the SRA prohibition regarding terrorism. Currently, one of the SRA prohibitions against access to select agent access specifies individuals who are under investigation for a federal crime of terrorism that transcends national boundaries but excludes individuals within the U.S. who are reasonably suspected of committing crimes of domestic terrorism. Domestic terrorism should be added as a prohibition.~~ Rationale for striking text: On 5-20-09, NSABB staff were informed by the FBI that this bullet is unnecessary because the Department of Justice has reviewed the Bioterrorism Response Act and determined that the prohibitor "Committing a crime specified in 18 U.S.C 2332b(g)(5)" already includes both domestic and international crimes of terrorism.

   - Strengthen screening of foreign individuals. Training and recruiting students and scientists from foreign countries is critical. Indeed, select agent research is a global endeavor and international collaborations and connections are important and must be fostered.[30] The U.S. should continue to welcome foreign researchers, and the SRA process should continue to accommodate foreign personnel. Nonetheless, although it may be difficult to gather information about foreign-born individuals, it is imperative that the screening of foreign individuals be as rigorous as the screening of U.S.-born individuals. The USG should make the necessary modifications to the SRA process to ensure that the screening of foreign personnel be rigorous and timely, and does not impede the ability to recruit foreign researchers. Within the current SRA framework, foreign personnel who have been provided with favorable SRAs should be periodically checked against immigration records. This check could possibly be conducted concurrently with the aforementioned 6-month Counterterrorism Watchlist check and would identify any changes in the status of those approved foreign individuals.

[30.] National Research Council, *Globalization, Biosecurity, and the Future of the Life Sciences* (Washington, DC: The National Academies Press, 2006), www.nap.edu/catalog.php?record_id=11567 (accessed May 8, 2009).

- Clarify the reference to "mental defective" on the SRA form. The current form required to initiate the SRA[31] contains questions regarding an individual's possible criminal record, unlawful use of controlled substances, and history of mental illness, as well as citizenship, and country of origins. Notably, Question 12e asks whether individuals have been "adjudicated as a mental defective." This terminology is not commonly understood and should be clarified by including on the FD-961 form the citation to and definition in 27 C.F.R. 478.11 so that an individual understands what information is being requested.

3. **The culture of responsibility and accountability should be enhanced at institutions that conduct select agent research.** Although persuasive evidence is lacking regarding the effectiveness of extant personnel reliability measures for accurately identifying and/or screening out individuals who may pose an insider threat, enhancing the culture of responsibility and accountability among individuals with access to select agents and toxins is a way to strengthen personnel reliability. This can be accomplished without any significant expenditure of resources or disruptions of research, and was noted by many whom the NSABB consulted as being the best defense against the insider threat.

   In this context, the NSABB identified a vision:

   As part of the responsible conduct of research, 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 furtherance of that vision, the NSABB developed a set of Guiding Principles for the responsible conduct of research on select agents and toxins that underpin the issue of personnel reliability. Research institutions should consider these principles as they address personnel reliability in their select agent research programs. The full text of the Guiding Principles can be found in Appendix D; the topics of the various principles are as follows:

[31.] Information is collected on the FBI form *Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information*, also known as FD-961, available at www.fbi.gov/terrorinfo/bioterrorfd961.htm (accessed May 8, 2009).

Guiding Principles for the Responsible Conduct of Research on Select Agents (abridged version)

- Research on select agents is essential to public health and national security.
- Personnel Reliability measures can reduce but never eliminate the insider threat.
- The implementation of reliability measures for select agent research must balance the need for security with the need for continued scientific progress.
- Individuals with access to select agents and toxins have an ethical obligation to recognize, and help to mitigate, the risks posed by the accidental release or intentional malevolent use of these agents.
- Select agent research programs will benefit by fostering a strong culture of responsibility, trust, and awareness within the scientific community regarding work with select agents.
- Building and maintaining public trust is the responsibility of the entire scientific community.
- Any personnel reliability measures that are implemented should be evaluated for effectiveness and impact on the research enterprise.
- ROs, principal investigators, supervisors, and managers should be actively engaged in the oversight of research being conducted in their laboratories and facilities.
- The continued awareness of individuals who have been approved for access to select agents should become a routine aspect of responsibly conducting select agent research.
- Fairness and confidentiality to the extent feasible will foster self- and peer-reporting, which have been widely suggested as effective personnel reliability measures.
- Individuals who have a clear understanding of their responsibilities are the foundation of a safe and secure select agent research enterprise.

An enhanced culture of responsibility and accountability can be achieved in many ways that are not mutually exclusive. For example, there is value in assessing prior work history and performance as a predictor of future conduct. Standard hiring practices–such as the verification of credentials, work history, and job performance–should be applied to persons with unescorted access to select agents and toxins. This should occur either at the point of hiring or at the point of requesting access to select agents, and this should be conducted in a rigorous and thorough manner. For example, there should be personal follow-up with previous employers and other relevant institutional personnel, such as institutional biosafety committee (IBC) staff rather than simply relying on letters of reference. As well, publicly available records about scientific misconduct, debarment, state licensure, etcetera, can be checked.

Another important aspect of enhancing the culture of responsibility and accountability is to raise the level of awareness about dual use research of concern, the importance of biosecurity, the risk of the insider threat, and the need for vigilance and reporting of concerns about biosecurity. All individuals in an institution that conducts research with select agents, not just those with access to select agents, must be aware of surrounding activities and understand that it is their individual and collective responsibility to report if a colleague

appears to be behaving in ways that are inappropriate for work with select agents. It will be important to dispel any notion that peer-reporting is "snitching" about one's colleagues or constitutes an otherwise inappropriate or negative activity, and, in fact, in most cases, any inappropriate behavior is likely to be the temporary result of a personal matter, e.g., the illness or death of a loved one or a divorce. This can and should be addressed through training of personnel about their responsibilities in this regard, what should be reported and to whom, and what protections are in place for the reporter and the subject of the report. There should be procedures that protect against frivolous or retaliatory reporting and also that maintain confidentiality and privacy to the extent possible. Indeed, many institutions already have processes for reporting problems in the workplace that could incorporate peer-reporting with respect to select agent research. These procedures are important to maintaining a culture of research responsibility and should be used to encourage peer-reporting and protect whistle-blowers and those who report concerns made in good faith. The NSABB notes that students or researchers may be reluctant to report on more senior scientists or supervisors. Therefore, it should be made clear at the outset to whom individuals should report if there are concerns about senior-level individuals.

Another way to enhance the culture is by building a strong sense of team within laboratories that work with select agents and toxins. ROs and principal investigators (PIs) play a critically important role in setting an appropriate tone regarding biosecurity and personnel reliability. They should work to build and foster strong working relationships with individuals with access to select agents. This will not only help to build a sense of trust and responsibility that will foster peer-reporting, but it will also help the RO and PI in being able to recognize behavior changes that may presage a reliability or a biosecurity problem. The importance of ROs and PIs who are engaged in the work that is being conducted and attuned to the personnel with access to select agents was a recurring theme in NSABB discussions as being one of the most effective personnel reliability measures

Another important aspect of responsibility and accountability is the recognition by individuals with access to select agents of their own limitations and of a choice to temporarily opt out of select agent work when and while necessary. An individual's ability to make sound decisions regarding select agents and to properly perform job duties can be negatively affected by a variety of factors, including medication and illness, stress, and other factors in one's personal life. Individuals must be aware of changes that may affect their ability to work with select agents and opt-out as appropriate. Importantly, opting out or self-reporting a problem should not be viewed as stigmatizing, and corrective actions should not be or be seen as punitive. As such, confidentiality and privacy must be maintained by supervisors to the extent possible. Again, training of individuals as to what should be reported and to whom, and the protections in place for the individual, is essential.

4. **Professional societies should continue to encourage an ongoing dialogue about personnel reliability to maintain vigilance about biosecurity issues throughout the research community and to foster community-based solutions.** Professional societies have done a commendable job engaging their respective communities both in the U.S. and

internationally about Dual Use Research of Concern.[32] These societies should now strengthen their conversations about maintaining personnel reliability and continue to promote a culture of research responsibility and vigilance about biosecurity issues. Outreach and education efforts will be essential to enhancing the culture of research responsibility outlined above as this culture will be fostered by individuals who are knowledgeable about the insider threat, trained in appropriate security measures, and have a clear understanding of their role within a select agent research facility. Professional societies are well-positioned to undertake these outreach and education efforts and to equip researchers with the tools required to strengthen vigilance toward biosecurity at the local level.

5. **The *List of Select Agents and Toxins*[33] 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. Consequently, the risk that they might pose to public, animal and plant health and safety varies significantly depending on the agent, and yet the same stringent controls apply across the board, making it unnecessarily very difficult to conduct vital research on these important biological organisms by hindering the ability of less pathogenic select agents to be used for legitimate research purposes.

The select agent list is reviewed every two years in recognition of the emergence of new potential agents. These compulsory reviews should continue with greater consideration for removing agents that research and management show to be of lower risk. The NSABB recognizes that the decision to remove agents from the list should not be taken lightly and will require much consideration from the scientific and public policy-making communities. Though certain agents may be removed from the *List of Select Agents*, research using these strains is and would still be conducted at the appropriate biosafety level with all the specified safety and security precautions. While there is a process to remove attenuated (or weakened) strains of select agents that pose little or no risk to public health and national security from the list, the process is considered burdensome, time-consuming and inhibitory to research. The process thus needs reconsideration.

[32.] National Science Advisory Board for Biosecurity, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (Washington, DC: 2007). Dual use research of concern is described on page 17 of this report as "[r]esearch that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel." The NSABB report can be accessed at oba.od.nih.gov/biosecurity/biosecurity_documents.html (accessed May 5, 2009).

[33.] The current *List of Select Agents and Toxins* can be found www.selectagents.gov/resources/List of Select Agents and Toxins_111708.pdf (accessed May 8, 2009).

Appendix A

National Science Advisory Board for Biosecurity Roster

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Appendix B

Federal databases that are searched for the Security Risk Assessment conducted under the Select Agent Program

- National Crime Information Center (NCIC) Files
  - Foreign Fugitive File
  - Deported Felon File
  - Protection Order File
  - Wanted Person File
  - U.S. Secret Service Protective File
  - SENTRY File (Bureau of Prisons)
  - Convicted Person on Supervised Release File
  - Convicted Sexual Offender Registry
  - Violent Gang and Terrorist Organizations File

- Interstate Identification Index: State/Local criminal history

- Foreign Terrorist Tracking Task Force
  - Terrorist Screening Center Database (TSDB)
  - Transportation Security Administration (TSA)'s No Fly and Selectee databases

- Automated Case Support (ACS): FBI case file database

- Bureau of Immigration and Customs Enforcement's Law Enforcement Support Center databases (for foreign-born candidates)
  - Central Index System (CIS)
  - Computer Linked Application Information Management System (CLAIMS)
  - Deportable Alien Control System (DACS)
  - National Automated Immigration Lookout System (NAILS II)
  - Nonimmigrant Information System (NIIS)
  - Student and Exchange Visitor Information System (SEVIS)
  - Redesigned Naturalization Application Casework System (RNACS)
  - Refugee, Asylum, and Parole System (RAPS)
  - Enforcement Case Tracking System (ENFORCE)
  - Treasury Enforcement Communications System (TECS)

Appendix C

National Science Advisory Board for Biosecurity (NSABB)
Public Consultation on Personnel Reliability
April 3, 2009

Overview

In recognition of the potential impact of its recommendations for enhancing personnel reliability among individuals with access to select agents and toxins, the NSABB Working Group on Personnel Reliability (WG) convened a public meeting to engage the scientific community, research and policy organizations, and other interested stakeholders in a discussion of the personnel reliability issue, methods for assessing reliability, and the potential benefits and consequences of implementing reliability measures or programs. The public consultation was held at the Bethesda Marriott in Bethesda, Maryland, on April 3, 2009.

Approximately 180-200 individuals attended the public consultation, bringing a variety of perspectives and backgrounds and representing the public, private, and non-profit sectors, including industry, academia, and the federal government. The meeting was organized as a series of panels that focused on the assessment of optimal personnel characteristics identified by the NSABB WG as underlying the trustworthy and responsible behavior of individuals with access to select agents. In particular, the focus was on characteristics that were deemed to be best assessed at the local, institutional level. Fifteen invited speakers with expertise in the areas of select agent and other biomedical research, personnel reliability programs, biosafety, research administration, the responsible conduct of research, and psychiatry and psychometric research joined members of the NSABB Working Group on three panels. These panels collectively addressed current and existing models of personnel reliability programs (PRPs) and how to address the optimal characteristics that PRPs may assess when determining whether individuals should be permitted to work with select agents (i.e., 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). After panelist remarks, there was ample time for a plenary discussion of the issues.

The agenda for this meeting follows this overview. More information, including slides of panelist presentations and a link to a videocast of the meeting, can be found at oba.od.nih.gov/biosecurity/nsabb_past_meetings.html.

Themes and Issues

The panelist presentations and subsequent plenary discussions raised many thoughtful issues and suggestions, and identified a number of important concerns. Following are some highlights of the discussions; they are not meant to be an exhaustive list, but rather reflect some of the recurring themes and issues, including those that appeared to elicit general support from among the meeting participants.

- **Interest in the operational aspects of personnel reliability programs.** Several commenting audience members indicated that they had already or were in the process of developing a PRP at their institution. There were questions and comments about the role of Responsible Officials in a PRP, including discussion about the appropriate qualifications and training of such individuals and the extent of their roles and responsibilities regarding the determination of reliability of individuals with access to select agents. It was noted that some ROs serve a purely administrative role in the determination of reliability, while others make substantive judgments based on input from experts. There were also questions about the costs of implementing PRPs, and it was noted that costs can vary greatly depending on the type of institution and the existing infrastructure for making suitability determinations.

- **Questions about the utility, applicability, and effectiveness of personnel reliability measures.** A number of concerns were raised regarding the issue of whether additional personnel reliability measures are needed to protect against the insider threat. Certain individuals questioned whether any proven correlation exists between the optimal characteristics being considered by the NSABB and increased lab security, i.e., whether a breach of scientific integrity really would mean that a person is likely to pose an insider threat. A number of those who commented made note of the paucity of data regarding the effectiveness of the assessments conducted in extant personnel reliability programs for identifying insider threats, particularly psychological assessments, drug and alcohol testing, and credit checks. There were also differing opinions voiced regarding the utility of a person's history in predicting future actions. It was noted that people who commit scientific fraud often have a history of minor infractions, and also that persons with characteristics that may be associated with unreliability are not necessarily going to engage in bioterrorism. Others of those who commented noted that surveillance of job performance, rather than predictive profiling, is likely to be more effective and that focusing on past behavior may provide a false sense of security about a person's reliability.

- **General lack of support for the two-person rule.** Several comments were made regarding the "two-person rule" as both a biosafety and biosecurity provision. Audience members and panelists from institutions that have implemented some variant of the two-person rule indicated that the measure can be very resource-intensive. In addition, some of those who commented focused on the difficulty of implementing the two-person rule at smaller facilities due to smaller numbers of people.

- **Reporting to U.S. Government (USG) when an individual's access to select agents has been restricted.** Some of the discussion and commentary centered on the need for guidance on reporting the restriction of a person's access to select agents, particularly on what to report, to whom, and when and whether the reasoning and procedures leading to the decision are to be disclosed. Those who commented were concerned with adversely affecting a person's career and reputation, as well as privacy and liability issues. Attendees and panelists also noted that reporting requirements may undermine the culture of trust critical to the dynamics of a successful laboratory group

- **Engaged leadership at the local level is critical to a successful PRP.** It was noted repeatedly throughout the public consultation that personnel reliability is best managed locally as an

institutional responsibility. In addition, many of those who commented touched on the need for principal investigators (PIs) to be engaged with their staffs and attuned to all of the activities in their laboratories. Comments regarding the benefits of increased or enhanced engagement of leadership included ensuring that researchers are not conducting inappropriate side projects and fostering a team dynamic that can enhance safety and reduce the instance of isolated or "lone ranger" researchers. Audience members and panelists noted that strong working relationships, both among laboratory personnel and between the PI and the personnel, may be much more effective than a formal PRP in having a potential reliability issue recognized and managed. For example, some audience members commented that maintaining an awareness of employee stress levels and other risk factors or behavior that is of potential concern can play an important role in employee conduct and laboratory dynamics; stress was cited as the most common motivator for scientific misconduct. Several of the attendees also related the need to train supervisors to recognize and address behavior of concern early and to train laboratory personnel about what to report, when, to whom, and what privacy and confidentiality provisions are in place.

- **A balanced approach is needed when considering a PRP.** Several attendees were concerned that the implementation of onerous new requirements for personnel reliability may stifle innovation and serve as a disincentive for people to enter or stay in the field of select agent research. One panelist noted that his organization's PRP has been a "culture shock" for people entering his laboratory. Other audience members and panelists reported that their facilities have found it more difficult to recruit researchers into programs with more restrictive guidelines. During the commentary, it was also noted repeatedly that PRPs and their assessment measures or instruments need to be monitored for their impact, effectiveness, and unintended consequences. Above all, the sentiment was to proceed with caution towards a solution that is as least burdensome as possible and that does not attempt solve a problem that is difficult to define by employing methods for which there is little evidence of effectiveness.

- **Layers of accountability.** A number of people who commented noted that multiple layers of accountability are needed to effectively address personnel reliability and select agent research at the institutional and federal levels. Those whose comments focused on local or institutional accountability stressed the need for committed institutional and laboratory leadership. Peer reporting was noted as one of the most valuable aspects of a potential PRP, as peers may often observe the first indicators of a problem. It was also noted that instituting peer-reporting requirements would likely be a major paradigm shift for academia but that training on peer reporting is essential. Several audience members and panelists also voiced concern about coping with the compounding compliance burden from multiple regulations, no matter how well-founded the regulation may be. It was noted that most effective regulatory programs advance performance-based standards, allow for flexibility and discretion in application**,** and provide for local enforcement.

- **Other issues of concern regarding PRPs.**
  - Regarding the use of psychological assessments in a PRP, several comments were made that these instruments and tests should be administered and analyzed by an appropriately trained professional.

- It was noted that, depending on the underlying reason given, restricting an individual's access to select agents could raise Americans with Disabilities Act issues for the institution.
- Although privacy and confidentiality concerns were voiced by several attendees and panelists, it was also noted that full disclosure to a PRP authority may lessen an individual's vulnerability to coercion.
- Concerns were also raised regarding the impact of restricting an individual's access to select agents. It was stressed that the denial of access to select agents should result in a reassignment of duties, not the loss of a job absent security issues. It was noted, however, that to a graduate student, the loss of a project can result in a major career disruption. In both cases, restricting access could serve as a disincentive for self-reporting.

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 it is putting in 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

Stanley M. 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"

Moderator:

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 E. 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**

Appendix D

Guiding Principles for the Responsible Conduct of Research on Select Agents

- **Research on Select Agents is essential to public health and safety and to national security.** It underpins the development of diagnostics, treatments, and preventative measures for some of the most highly pathogenic microorganisms and toxins, and contributes to the development of countermeasures against potential weapons of bioterrorism. Knowledge gained from research on select agents is also important in a wider scientific context, and has helped advance other fields, including cell physiology, cellular signaling, and cancer biology. This research should be conducted in a responsible manner by conscientious individuals.

- **Personnel reliability measures can reduce but never eliminate the insider threat.** Personnel reliability programs and measures are tools to help ensure, to the extent possible, that individuals with access to select agents are trustworthy and reliable. Effective approaches to enhancing reliability can mitigate the risk of the insider threat, but no program can completely eliminate the risk. This is due in part to the inherent imperfection of people, as well as to the difficulty of screening for an individual's intent or predicting individual behavior.

- **The implementation of reliability measures for select agent research must balance the need for security with the need for continued scientific progress, which underpins public health and safety, food security, commercial and economic viability, and national security.** The degree of oversight should be consistent with the likelihood and possible consequences of a misuse of select agents and the anticipated effectiveness of a program, and should not unduly encumber the conduct of the robust scientific enterprise that is critical to the future of the U.S.

- **Individuals with access to select agents and toxins have an ethical obligation to recognize, and help to mitigate, the risks posed by the accidental release or intentional malevolent use of these agents**. The foundation for this is a continual awareness of ongoing activities within the research facility, recognition of one's own limitations due to physical and emotional status that can be addressed without punitive measures, and communication of information and concerns to responsible authorities without fear of sanctions.

- **Select agent research programs 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 the recognition that no personnel reliability measures are completely effective, so vigilance and awareness of surrounding activities and personnel are always necessary. Thus the default position should be one of mindful trust, not distrust, of personnel who have been cleared for work with select agents.

- **Building and maintaining public trust is the responsibility of the entire scientific community.** Taking measures to ensure the reliability of individuals working with select agents and toxins will help to allay public concerns about such research. It will strengthen public trust regarding select agent research by demonstrating that the scientific community is acting responsibly and proactively to protect public welfare and security. Transparency regarding the personnel reliability measures implemented for work with select agents will help build confidence in the ability of the scientific community to conscientiously conduct select agent research and could deter those with harmful intent from attempting to divert select agents.

- **Any personnel reliability measures that are implemented should be evaluated for effectiveness and impact on the research enterprise.** Assessing the effectiveness of personnel reliability measures is challenging since it cannot usually be known what was prevented due to the implementation of personnel reliability measures. Nonetheless, measures aimed an enhancing personnel reliability should be periodically evaluated both for effectiveness and impact on the research enterprise.

- **ROs, PIs, supervisors, and managers should be actively engaged in the oversight of research being conducted in their laboratories and facilities.** Institutional leadership that is attuned to potentially questionable behavior or activities can identify problems early and take steps to mitigate risks. At the same time, it is important for institutional leadership to set a tone that laboratory safety and security is highly valued and expected, particularly from researchers who work with select agents.

- **The continued awareness of individuals who have been approved for access to select agents should become a routine aspect of responsibly conducting select agent research.** Supervisors, peers, and individuals who conduct select agent research are best-positioned to recognize potentially problematic behavior, and should have the ability to recognize, and willingness to report, such behaviors.

- **Fairness and confidentiality to the extent feasible will foster self- and peer-reporting, which have been widely suggested as effective personnel reliability measures.** A select agent research program should enable the temporary suspension of select agent access in a manner that is neither stigmatizing nor punitive. For example, suspension of access to select agents not due to security issues should result in a re-assignment of duties rather than the loss of a job. Reporting, whether by self or peers, should be confidential and private to the maximum extent possible. Assurance that personal information remains as private as possible can allay concerns or embarrassment that may be associated with the reporting of particularly sensitive information or personal circumstances that affect one's ability to concentrate or perform duties.

- **Individuals who have a clear understanding of their responsibilities are the foundation of a safe and secure select agent research enterprise.** Maintaining personnel reliability hinges in large part on the ability of personnel to recognize suspicious or problematic behavior and their willingness to report such behavior. A culture of research responsibility that is underpinned by effective training will encourage the early identification of potentially problematic behavior.