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 agents 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.

   - 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.

   - 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

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[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).

[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).

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:

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 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. Although 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 appropriate 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 unduly complex, burdensome, time-consuming and inhibitory to research. The process thus needs reconsideration.

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[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).

[redacted]

From: [redacted]
Sent: Monday, January 24, 2011 9:55 AM
To: [redacted]
Cc: [redacted]

Subject: RE: article

FYI.

I will be meeting with [redacted] of the American Association for the Advancement of Science (AAAS) to discuss ways for [redacted] to also partner closely with AAAS after the NSHEAB meeting on 2/2/11.

[redacted]

A/UC [redacted]
FBIHQ
[redacted]
[redacted] (desk)
[redacted] cell)
[redacted]@ic.fbi.gov [redacted]
[redacted]@fbi.sgov.gov [redacted]

b6
b7C
b7E

From: Anthony Boccanfuso [mailto[redacted]@uidp.net]
Sent: Monday, January 24, 2011 9:40 AM
To: [redacted]
Subject: article

Dear [redacted]

I assume you saw this...

Science, Law Enforcement Build Biotech Bridges

Genspace President Ellen Jorgensen (*left*) and FBI Supervisory Special Agent Edward H. You (*right*).

With scientists working to create new life forms and amateur biology clubs springing up nationwide, it stands to reason that the U.S. security community would be concerned that one

rogue researcher or one innocent error might create a grave problem.

But before uneasiness could turn to conflict, the FBI, working closely with AAAS, embraced a new strategy. The Bureau held conferences with university and private sector researchers, attended synthetic biology science fairs, and spent time with do-it-yourself (DIY) biologists. The message, though tailored for each audience, was consistent.

"We want science and security communities to come to an understanding to promote a culture of responsibility," says Edward H. You, an experienced researcher and now the FBI supervisory special agent guiding the outreach effort. By bringing those communities together, "we can...identify what some of the risks and gaps might be, and then come up with strategies that make sense to both communities to mitigate those risks and gaps."

A certain amount of uneasiness was inevitable after the deadly blitz of anthrax letters that followed the 9/11 terror attacks and, more recently, the stunning advances and increasing accessibility of biotech research. In research published last May in *Science*, genomics pioneer J. Craig Venter announced development of the first cell controlled by a synthetic genome. That breakthrough underscored that biotech will likely create unpredictable implications for science and society.

In a recent appearance at AAAS, bioethicist Thomas H. Murray said synthetic biology—fundamentally altering life or creating new life forms—offers "mind-boggling" possible benefi ts, from production of new pharmaceuticals to cleaning up oil spills. But, he added, the benefi ts must be weighed against bioterrorism and other hard-to-define risks.

"If I didn't think the potential benefits . . . were massive, there would be no point in having this conversation," said Murray, president and chief executive officer of the Hastings Center, in the annual AAAS-Hitachi Lecture on Science & Society on 28 October.

Finding the best balance of benefits and risks is the rationale for the collaboration between the FBI and AAAS, said AAAS biosecurity expert Kavita Berger, an associate program director in the Center for Science, Technology and Security Policy.

Just a few years ago, Berger contributed to a survey of researchers that found only a third were comfortable sharing their research with agents, and a mere 14% felt comfortable with the FBI having a role in monitoring research.

But if science and security couldn't build a working relationship, she thought, then policy-makers, acting out of mistrust or fear, might impose rules that impede research without affecting real security concerns.

Collaboration, she said, is "ultimately going to be a lot more productive and a lot more useful in reaching the end goals of security and science."

In professional conferences organized by the FBI and AAAS, You and Berger have had agents and researchers work through simulated problems related to biotech and biosecurity. In the process, they learned about each other's values, perspectives, and practices.

Now the uneasiness is giving way to closer interaction between researchers and law enforcement, with major universities offering to host the conferences. "We're seeing a paradigm shift," said You, who had worked in gene therapy and cancer research before joining the FBI.