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Bridging Science and Security for Biological Research:

A Dialogue between Universities and the Federal Bureau of Investigation

Report of a Meeting February 21-22, 2012

AAAS
ADVANCING SCIENCE, SERVING SOCIETY

ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES

BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH: A DIALOGUE BETWEEN UNIVERSITIES AND THE FEDERAL BUREAU OF INVESTIGATION

Meeting Report
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Disclaimer
The concerns or recommendations outlined in this report reflect the discussions at the workshop and do not necessarily represent the views of the AAAS Board of Directors, its Council, or membership; AAU Board of Directors or membership; or APLU Board of Directors or membership.

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About AAU
The Association of American Universities (AAU) is a nonprofit association of 59 U.S. and two Canadian preeminent public and private research universities. Founded in 1900, AAU focuses on national and institutional issues that are important to research-intensive universities, including funding for research, research and education policy, and graduate and undergraduate education.

About APLU
The Association of Public and Land-grant Universities (A·P·L·U) is a non-profit association of public research universities, land-grant institutions, and many state university systems and has member campuses in all 50 states and the U.S. territories. The nation's oldest higher education association, APLU is dedicated to advancing research, learning and engagement. Current initiatives include efforts in math and science teacher preparation; international development; institutional accountability; online education; and more.

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Background

Just over a decade ago, anthrax was sent through the mail to high profile individuals, resulting in five deaths, additional infections, and millions of dollars in cleanup costs. While in pursuit of the perpetrator, scientists from the Federal Bureau of Investigation (FBI) interacted with a few scientists from academia who possessed the knowledge and experience needed to identify the strain and potential source. At the same time, FBI agents questioned scientists with knowledge of and experience working with anthrax. These often-conflicting and contentious interactions enhanced feelings of distrust and concern among the scientific community towards law enforcement.[1] To help the organization better address incidents involving weapons of mass destruction (WMD),[2] the FBI created the WMD Directorate, whose mission is to coordinate the FBI's WMD efforts through several programs – including investigative operations, intelligence analysis, policy planning, strategic planning, and outreach to the scientific community – that address a number of issues involved in prevention and response to WMD incidents.[3]

During this period, universities and other research institutions were facing increasing demands to comply with newly created security requirements to prevent theft or illicit use of any chemical, radiological, or biological agents of national security and/or public health concern. While some of the laws and policies were in place before 2001, they were significantly enhanced after 9/11 and the anthrax letters. In addition, new laws governing transfer of funds and personnel security were enacted to prevent potential terrorists from acquiring the financial resources and capabilities that might help them cause harm to the United States. As regulations related to research were tightening, the United States began funding universities and private organizations to conduct biodefense research to develop vaccines, drugs, and diagnostic tests related to a group of pathogens and toxins, termed *select agents.*[4] In response to this increase in funding, the number of scientists and universities involved in research with select agents or their genetic material increased and several high-containment laboratories (biosafety level 3 and 4 laboratories) were built to accommodate the research.

The increased research activities led several individuals in the security and "watchdog" communities to raise concerns. In 2007, reports emerged that a Texas A&M University scientist, who did not have approval to work with select agents, became accidentally infected with brucellosis in the laboratory. In response, several congressional committees held hearings about the risks of high-containment laboratories,[5] the Government Accountability Office wrote several reports on the incident and physical security at high-containment laboratories,[6] and federal

[1] N. Hafer, C.J. Vos, K. McAllister, G. Lorenzi, C. Moore, K.M. Berger, M. Stebbins. *How Scientists View Law Enforcement. Science Progress*. 2009.
[2] WMD refers to chemical, biological, radiological, and nuclear agents that could cause mass mortality and disruption.
[3] FBI WMD Directorate. See http://www.fbi.gov/about-us/investigate/terrorism/wmd.
[4] Select Agent Program. See www.selectagent.gov.
[5] U.S. House of Representatives Committee on Energy and Commerce. *Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*. 2007. See http://democrats.energycommerce.house.gov/index.php?q=archive/110th-congress/germs-viruses-and-secrets-the-silent-proliferation-of-bio-laboratories-in-t-0.
[6] Rhodes, K. *HIGH-CONTAINMENT BIOSAFETY LABORATORIES: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*. U.S. Government Accountability Office. GAO-08-108t. 2007. See http://www.gao.gov/new.items/d08108t.pdf; Bascetta, CA. *Biological Research Laboratories: Issues Associated with the Expansion of Laboratories Funded by the National Institute of Allergy and Infectious Diseases*. U.S. Government

agencies engaged in interagency policy discussions on biosafety and biocontainment of select agent laboratories.[7]

Around the same time, Congress established the Commission on the Prevention of WMD Proliferation and Terrorism (WMD Commission) to identify the United States' activities and initiatives to prevent and respond to WMD incidents. The WMD Commission concluded that biological terrorism is more likely than nuclear terrorism[8] and that the scientific community does not have adequate expertise to evaluate security risks associated with life sciences research.[9] In response, parallel efforts were initiated in the Executive Branch and Congress to identify and reduce the risks and threats associated with research on select agents.[10] In 2010, the Executive Branch established the Federal Experts Security Advisory Panel (FESAP) to provide recommendations on the security of high-priority biological agents.[11] The FESAP, which consists of representatives from 14 U.S. government agencies, provided its recommendations on the highest priority biological agents and security measures that should be associated with those agents to the Select Agent Program.[12] These recommendations were incorporated into the most recent revision of the select agent rules, whose period of public comment recently closed.[13] In 2009, the WMD Preparedness and Response Act was introduced in Congress, containing provisions to increase security on a few select pathogens, expand scientific engagement, and improve medical countermeasure distribution.[14] Since its initial introduction, the bill has been revised and reintroduced several times.[15]

In addition to the Select Agent Program, the U.S. government established an advisory board, the National Science Advisory Board for Biosecurity (NSABB), to identify ethical and security issues associated with biological research that could be directly misused for harmful purposes.[16] The NSABB has provided recommendations on identification, oversight, education, and communication of "dual use research of concern."[17]

Accountability Office. GAO-07-0333R, 2007. See http://www.gao.gov/new.items/d07333r.pdf; Kutz, GD. *BIOSAFETY LABORATORIES: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories*. U.S. Government Accountability Office. GAO-08-1092. 2008. See http://www.gao.gov/new.items/d081092.pdf.

[7] *Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*. 2007. See http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx

[8] Commission on the Prevention of WMD Proliferation and Terrorism, *World At Risk*. Vintage Books. 2008. See http://a.abcnews.go.com/images/TheLaw/WMD-report.pdf#http://a.abcnews.go.com/images/TheLaw/WMD-report.pdf.

[9] Senate Homeland Security and Governmental Affairs hearing, *World At Risk: A Report from the Commission on the Prevention of WMD Proliferation and Terrorism*. December 2008. See http://www.hsgac.senate.gov/hearings/world-at-risk-a-report-from-the-commission-on-the-prevention-of-weapons-of-mass-destruction-proliferation-and-terrorism

[10] President George W. Bush, *Strengthening Laboratory Biosecurity in the United States*. Executive Order 13486. 2009. See http://georgewbush-whitehouse.archives.gov/news/releases/2009/01/20090109-6.html; Department of Health and Human Service. *Report of the Working Group on Strengthening the Biosecurity of the United States*. See http://www.phe.gov/Preparedness/legal/boards/biosecurity/Documents/biosecreportfinal102309.pdf; WMD Preparedness and Response Act 2009, S.1649 and S.1649.

[11] President Barak Obama, *Optimizing the Security of Biological Select Agents and Toxins in the United States*. Executive Order 13546. 2010. See http://www.gpo.gov/fdsys/pkg/FR-2010-07-08/pdf/2010-16864.pdf.

[12] FESAP. Recommendations *Concerning the Select Agent Program*. See http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf.

[13] Select Agent Program. See http://www.selectagents.gov/.

[14] WMD Preparedness and Response Act 2009. S.1649 and S.1649.

[15] WMD Preparedness and Response Act. 2011. H.R.2356.

[16] NSABB. See http://oba.od.nih.gov/biosecurity/biosecurity.html.

[17] "Dual use research" is legitimate research that could be misapplied to cause harm. As defined by the NSABB, "dual use research of concern" is "research 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, agricultural

Recently, the NSABB and World Health Organization (WHO) have been asked to review and provide recommendations on publication of research that some consider to be of high security risk (e.g., making highly transmissible H5N1 influenza in mammals in the laboratory). One paper, submitted to SCIENCE by a Dutch research group, described mutations that enhance transmission of H5N1 influenza in ferrets and the other paper, submitted to Nature by an American research group, described mutations in H5 hemagglutinin that enhance transmission.[18] The American group worked with H5 hemagglutinin in the H1N1 virus background to minimize the risk of creating an H5N1 influenza virus that could spread rapidly between humans.[19] (Pharmaceutical products exist for H1N1 influenza virus.) The NSABB initially recommended publishing a redacted version of the papers with full release of the data to individuals and organizations with a legitimate "need to know."[20] Following this, the WHO recommended that publication of the papers should be delayed rather than be published immediately in partial form.[21] After the authors revised their papers to address the security concerns, the NSABB reviewed the papers again and concluded that the information contained in the revised versions no longer poses security risks and supported publication of the revised papers.[22] While the NSABB and WHO were conducting their reviews, the Dutch government imposed export controls on the information contained in the Dutch group's paper.[23] This issue remains unresolved at the time of this report's release.

Based on the NSABB's recommendations on oversight of "dual use research" and catalyzed by the recent events associated with the influenza papers, the U.S. government released its guidelines for the life sciences community to help them identify and minimize the risk that biological research or knowledge could be misused to cause harm.[24] These guidelines state that funding agencies, supporting research on 15 select agents, should review proposed experimental procedures for "dual use research of concern." If the proposed research raises concern, funding agencies should work with principal investigators and their institutions to develop a risk mitigation plan, which could include modifying the experimental procedures, enhancing biosafety and biosecurity measures, and/or increasing the frequency of review of the research.

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crops and other plants, animals, the environment, or materiel." See http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

[18] Fouchier, R. *Aerosol Transmission of Influenza A/H5N1 Virus in Ferrets*. Royal Society meeting on H5N1 Research: Biosafety, Biosecurity, and Bioethics. 2012 April 3-4. See http://www.voiceprompt.co.uk/royalsociety/030412/.

[19] Kawaoka, Y. *Transmission of an Influenza Virus Possessing and H5 Hemagglutinin via Respiratory Droplets in Ferrets*. Royal Society meeting on H5N1 Research: Biosafety, Biosecurity, and Bioethics. 2012 April 3-4. See http://www.voiceprompt.co.uk/royalsociety/030412/.

[20] National Institutes of Health. *Press Statement on the NSABB Review of H5N1 Research*. 10 Dec 2011; Berns KI, Casadevall A, Cohen ML, Ehrlich SA, Enquist LW, Fitch JP, Franz DR, Fraser-Liggett CM, Grant CM, Imperiale MJ, Kanabrocki J, Keim PS, Lemon SM, Levy SB, Lumpkin JR, Miller JF, Murch R, Nance ME, Osterholm MT, Relman DA, Roth JA, Vidaver AK. *Adaptations of avian flu virus are a cause for concern*. Science. 2012 Feb 10;335(6069):660-1. Epub 2012 Jan 31.

[21] Cohen, J. *WHO Group: H5N1 Papers Should Be Published In Full*. Science. 2012 Feb 24;335(6071):899-900. World Health Organization. *Public Health, Influenza Experts Agree H5N1 Research Critical, but Extend Delay*. 2012 Feb 17. See http://www.who.int/mediacentre/news/releases/2012/h5n1_research_20120217/en/index.html.

[22] National Science Advisory Board for Biosecurity. *Statement of the NSABB. March 29-30, 2012 Meeting of the National Science Advisory Board for Biosecurity to Review Revised Manuscripts on Transmissibility of A/H5N1 Influenza Virus.* See http://oba.od.nih.gov/oba/biosecurity/PDF/NSABB_Statement_March_2012_Meeting.pdf.

[23] Greenfieldboyce, N. *Bird Flu Studies Mired in Export Control Law Limbo.* NPR. 2012 April 10. See http://www.npr.org/blogs/health/2012/04/10/150311034/bird-flu-studies-mired-in-export-control-law-limbo.

[24] *U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern*. See http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf.

The Universities' Challenge

Against this backdrop, universities have experienced increasing compliance requirements (beyond security requirements) on biological research, while having to contend with an indirect cost rate that has remained at the same level since the early 1990s.[25] These requirements encompass a wide range of issues, including managing conflicts of interest, research integrity, export control, human and animal subjects protection, and environmental stewardship. Many universities spend significant administrative and financial resources to simply comply with guidelines, regulations, and laws that apply to biological research. During the past two years, the Association of American Universities (AAU) and Association of Public and Land-grant Universities (APLU) have initiated efforts to better understand the total financial costs of conducting research at educational institutions.[26] AAU and APLU have found that the cost of complying with unfunded research requirements has, in several cases, doubled or even quadrupled over the past five years. In addition, several universities cited a significant amount of their general operating funds going towards research compliance. This redirection of support away from education, general facility maintenance, direct costs of research, and other core university functions may adversely affect the entire education and research environment at academic institutions.

Institutions receiving federal funding from agencies, such as the National Institutes of Health (NIH), are required to review research involving recombinant DNA, experimental animals, and human subjects. Life scientists must adhere to training requirements, regulations, and guidance on a number of ethical topics, such as research on human and animal test subjects, conflicts of interest, intellectual property, mentorship, and authorship.[27] Scientists are also required to receive training on the safe and secure handling of radioactive materials, hazardous chemicals, and biological agents. Universities are required to conduct personnel verification and clearance of scientists who work with certain chemicals, radioactive materials, and biological select agents deemed to be security risks. Universities must also comply with a number of laws and regulations that apply to all employees, including export control and immigration laws. (The challenges associated with export control and immigration laws are exacerbated with foreign scientists.)

Beyond research compliance, universities face serious challenges to the safety and security of all students and personnel. Universities must ensure that their security measures sufficiently address these everyday concerns, which can include threats of campus violence, attacks on scientists working with animals and facilities that house experimental animals, and cyber crimes.[28] Institutions have responded by establishing "threat assessment" groups, consisting of key individuals from the university and neighboring community, to discuss potential risks or threats

[25] Council on Governmental Relations. *Federal Regulatory Changes Since 1991*. See http://www.cogr.edu/viewDoc.cfm?DocID=151793.
[26] AAU, APLU, COGR. Regulatory and Financial Reform of Federal Research Policy. Recommendations to the NRC Committee on Research Universities. 21 Jan 2011.
[27] U.S. Department of Health and Human Services, Public Health Services Grant Application (PHS398), Assurances and Certification section (Part III-10).
[28] AAAS, AAU, APLU. Competing Responsibilities: Addressing the Security Risks of Biological Research in Academia. Workshop Report. 2010.

and mitigation strategies. The members of threat assessment groups can vary based on the threat, but often, they include campus police, local police, and university officials.

FBI Biosecurity Outreach

The countermeasures section of the WMD Directorate has implemented a successful biosecurity outreach program.[29] Through this program, the FBI and its WMD Coordinators from each of its 56 field offices in the U.S. have reached out to members of the scientific community to build trust and relationships among these organizations. These Coordinators stand ready to help scientific institutions minimize real and perceived threats before an incident occurs and deal with the consequences of an incident that has taken place.

The goal of the FBI outreach program is to establish strong relationships between the WMD Coordinators and key officials from research institutions to prevent and mitigate potential threats involving biological agents. FBI WMD Coordinators have initiated a series of dialogues and outreach activities with universities, the private sector, and amateur biologists to build trust and open lines of communication between the FBI and these groups. Outreach activities include table top exercises and case studies to facilitate discussion about differences in mission, roles and responsibilities, and perceptions of incidents. These efforts highlight and build on a shared goal of serving the public good.

Since 2009, several local FBI WMD Coordinators have developed strong relationships with university officials in their region and have received invitations to participate in emergency response exercises for select agent laboratories. The outreach has also resulted in communication about questionable and/or suspicious incidents that have occurred at universities. However, negative perceptions associated with the FBI and their approaches and methods still prohibit or limit complete and open communication between some universities and their local WMD Coordinator. Consequently, the FBI continues its outreach program by engaging with research institutions, individually or through partnering with different scientific or educational organizations on issues that plague the institutions daily and by using constructive, not alarming, methods. This approach has gained the FBI's WMD Directorate interested partners and audiences from a number of sectors within the scientific community. The approach also underscores the mutual benefit of partnerships between the scientific community and FBI.

The Meeting

AAAS, in collaboration with the AAU, APLU, and FBI, convened a meeting to encourage dialogue and communication among officials from leading research universities (including vice presidents of research or compliance, environmental health and safety officials, biosafety officials), senior faculty and FBI WMD Coordinators about security risks associated with biological research. The meeting was held at AAU and AAAS headquarters in Washington, DC on February 21-23, 2012. The formal meeting was on February 21-22, 2012 and FBI

[29] FBI Academic Biosecurity Workshops. See http://academicbiosecurityworkshop.org/; Edward Lempinen. *FBI, AAAS Collaborate on Ambitious Outreach to Biotech Researchers and DIY Biologists.* 1 April 2011.

Coordinators toured two University of Maryland research facilities on February 23, 2012. This opportunity offered university officials a chance to understand the roles and responsibilities of the FBI and university employees in challenging biosecurity situations, as well as providing FBI Coordinators an opportunity to understand better the challenges facing universities and view actual biology laboratories.[30]

The goals of the meeting were to:

- Facilitate open communication between the security and the scientific communities about the risks of biological research and how to balance the costs and benefits of mitigating those risks;
- Determine how the university and security communities can work together to address the risks of misuse of biological research, theft of biological agents, or accidental exposure, while supporting critical research progress;
- Develop and disseminate to both the security and academic communities recommendations for building a collaborative framework for policies that reflect the balance of risk and benefit while ensuring critical biological research can be pursued in the US; and
- Develop and disseminate to the scientific community and policy-makers possible solutions that could address the potential risks of biological research at the local or national level.

To encourage interaction and discussion, the meeting was held as not-for-attribution. However, we were able to capture the major themes and policy-relevant issues that were raised at the meeting. The following summary highlights these points. The *Emerging Themes* and *Policy and Programmatic Suggestions* section are followed by three appendices that include the meeting agenda, list of participants, and description of the choice-based table top exercise.

[30] Although several FBI WMD Coordinators have worked in biology laboratories, not all have.

Emerging Themes

In the current economic and security climate, universities in the United States are facing serious challenges in ensuring that they can provide a safe and secure environment for scientists to conduct high-quality research. Research universities operate in partnership with the federal government, accepting federal funds to conduct basic and applied research, ultimately to benefit society. The average research university hosts hundreds of research projects that involve scientists from diverse disciplines (e.g., physical, life, computer, engineering, mathematical, chemical, and social sciences) and countries, and provide necessary laboratory training to undergraduate and graduate students. However, partnerships with the government have become more costly over time; over the past 30-40 years, concerns about ethical, safe, and secure practices related to research have led to the creation of laws, regulations, and guidance to minimize or eliminate those concerns. Since the early 1990s, the number of compliance requirements for research programs has steadily increased, with a sizable jump after the 2001 terrorist attacks, but the amount of indirect costs allotted to universities to comply with those requirements has remained constant.[31]

This situation has led to a "tipping point" of compliance and research where universities are beginning to question whether or not they can afford to pursue certain types of research. Of particular relevance to the present workshop, the requirements to enhance biological, chemical, and radiological security have raised the cost for compliance significantly. The laws, regulations, or guidance for enhancing security of certain materials often contain common requirements for which different processes, documentation, and audits must be conducted. As an example of this, the select agent rules, Nuclear Regulatory Commission rules for working with cesium irradiators, and chemical security rules all require personnel to undergo some type of background review and approval process. However, the processes by which scientists are approved (or cleared) differ among regulating agencies and/or requirements, leading to increased administrative effort by universities to get individual scientists approved to work in the laboratory with hazardous materials.[32]

In an environment where compliance requirements are becoming increasingly burdensome to research universities, routine communication and cooperation among researchers, students, institutional officials, support staff, and law enforcement can establish a safe, ethical, and secure research and educational environment at universities. The following discussion categorizes comments made by meeting participants into four major sections: Cost of Compliance; Balancing Research and Security; the University and FBI Relationships; and Gaps and Challenges. This discussion precedes the section outlining policy and programmatic suggestions made by meeting participants.

[31] Council on Governmental Relations. *Federal Regulatory Changes Since 1991*. See http://www.cogr.edu/viewDoc.cfm?DocID=151793; AAU, APLU, COGR. Regulatory and Financial Reform of Federal Research Policy. Recommendations to the NRC Committee on Research Universities. 21 Jan 2011.

[32] AAAS, AAU, APLU. Competing Responsibilities: Addressing the Security Risks of Biological Research in Academia. Workshop Report. 2010.

Cost of Compliance

- For the past 3 years, representatives of the U.S. government have inquired about the costs of complying with the select agent rules. While some institutions have been able to provide this information, many cannot because the security measures instituted at universities address both the national and domestic security concerns. This attempt to quantify the cost for complying with specific national security requirements often does not include the cost of not conducting the research, not including foreign researchers or supporting collaboration, and under-investing in non-life science programs at the university.

- An important goal is the need for balancing bureaucracy and increased paperwork with real enhancements to security. Many participants and members of the broader scientific community voiced the need for a demonstrable link between the current compliance environment, which occupies approximately 42% of researchers' time doing paperwork,[33] and security.

- A major concern of workshop participants was the prohibitive regulations that are not based on evidence (e.g., counting vials of biological agents). The lack of evidence-based security measures was considered a major barrier in gaining buy-in by scientists and university officials. Scientists seek to understand the demonstrable outcomes towards enhancing security of any measures that are implemented.

- The amount of time and man-hours involved in implementing security measures (e.g., export controls) was also considered prohibitive to research and collaboration. The underlying premise was that the research should be conducted and information should be shared because of their importance in addressing health and biodefense needs.

- The increasingly complex and demanding regulatory environment has lead researchers and institutions to ask about the point at which the burden of required security measures outweighs the interest and means to conduct research on animal, plant, and human pathogens and preparedness initiatives.

- Participants discussed the inherent challenge between prescriptive and performance-based regulations and guidance and how they are interpreted by different agencies and inspectors. This challenge raised considerable concern by both university representatives and FBI WMD Coordinators because multiple interpretations of regulations results in variability of implementation of security measures, some of which may not be based on best practices or evidence of efficacy.

- Guidance is voluntary and subject to multiple interpretations; however, both universities and federal agencies may treat guidance as if it were regulation or law. Guidance is often included in grant or contractual agreements and used by inspectors to assess compliance.

[33] Federal Demonstration Partnership (FDP) Faculty Burden survey. See http://sites.nationalacademies.org/PGA/fdp/index.htm.

This has effectively increased the number of requirements with which universities must comply to remain in good standing with their funding contracts.

- Despite the concerns and disparity of multiple interpretations of regulations and guidance, participants stressed the need for flexibility in implementing processes and procedures to comply with those rules. They discouraged the use of "one size fits all" approach to compliance.

- Security measures that meet legal or regulatory requirements do not necessarily meet standards for ensuring safety and security of laboratories.

- Participants raised concerns about public disclosure and open records laws as problematic for ensuring security at universities. Some requests have included a list of all scientists working in high containment laboratories, the pathogens they study, and the experimental animals included in their studies. Such a list would place the researchers and facilities at risk for domestic or national security threats, including risks posed by aggressive animal rights groups and activist organizations.

- In the current economic climate, project funding is highly competitive and several well-established and formerly successful laboratories have closed because the laboratory heads could no longer secure funding. The pressure to succeed in this environment is increasing, which causes ethical dilemmas in acquiring funding and fully complying with regulatory requirements.

- Over a third of the scientific and engineering workforce – including students, fellows, and faculty – at universities are from outside the United States. A few institutions have found that the regulatory burden of allowing foreign nationals to participate in certain research activities may be cost and time prohibitive. Consequently, some institutions have chosen not to support some research proposals to ensure they can provide quality education and research opportunities to American citizens and foreign nationals.

- Many researchers maintain collaborations with colleagues from other countries. Differences in regulatory requirements between international partners often causes additional burden on institutions. They must work harder to resolve differences and, if possible, ensure compliance with all relevant laws, regulations, and guidance.

- Cultural nuances affect the understanding and implementation of regulations. In addition, international activities affect the scientific culture at U.S. universities.

Balancing Research and Security

- All biological research is associated with risk. However, not all risks should be treated the same. Research involves a wide variety of risks, including safety, environmental consequences, ethical dilemmas, physical security, intellectual property infringement, and risks to the institution and laboratory's reputations.

- In general, research administrators are more familiar with the broad range of risks associated with research than faculty and students, who may be more familiar with risks of only their own research.

- Both university representatives and FBI WMD Coordinators stated that the most immediate security risks are cyber security, individual security, and vulnerability of an institution or individual to an assault. This is especially true for the conduct or communication of research with a high potential of risk to the university or its personnel.

- University officials were concerned that their researchers may be in danger because of the information they possess (i.e., knowledge about specific pathogens, both function and physical location of strains).

- Familiarity of researchers with security issues helps promote a culture of transparency within the university, which promotes the building of trust between scientists and university officials, assessing and reporting unusual behavior, and accepting and adopting common norms in ethics, safety, and security. This culture of transparency inherently promotes a culture of responsibility and ultimately, a culture of compliance, safety, and security. Neither the FBI nor university officials want to promote distrust within and between laboratories.

- Laboratory staff have an essential role in establishing and maintaining a safe and secure research environment. Principal investigators are responsible for complying with all regulatory requirements, assessing and minimizing occupational risk, ensuring appropriate training of personnel, and developing and supporting standard operating procedures for the laboratory and research institution.

- A number of research administrators may be involved if an incident or breech in an experimental protocol occurs. A combination of legally mandated oversight bodies – including Institutional Biosafety Committees, Institutional Review Board, and Institutional Animal Care and Use Committee - principal investigator(s), and/or relevant laboratory staff may be involved in addressing and resolving the incident. These oversight committees may also include scientists and engineers from non-life science disciplines if the problem in question involves multidisciplinary research.

- Meeting participants highlighted risk assessment as a significant challenge when trying to balance research initiatives and security concerns. Scientists stated that they felt they did not have enough information on which to base an assessment of the potential that their research, which was conducted with beneficial intent, can be misused by an individual with malicious intent. Although providing classified information to scientists to help them assess potential risks of personnel and experiments is not feasible, members of the security community did recognize the dilemma with which scientists have been confronted.

Personnel Security

"Skills do not equal character, degrees do not equal trustworthiness"

- The key to personnel security is to be familiar with "normal behavior" of staff. This familiarity will help researchers identify when staff exhibit unusual behavior. Non-punitive mechanisms for expressing concerns about unusual behavior may help scientists opt out of experimental activities during difficult times or help researchers report behavior of potential security and safety concern. However, these mechanisms are not uniform among universities.

- The first stage of assessing personnel is at employment. However, former employers may not discuss negative aspects of individuals because institutions are concerned about potential litigation. Very often, problem employees that leave their institutions in poor standing prevent former employers from informing prospective employers by signing nondisclosure agreements. In light of this, a referral to the former employer's general counsel is a universal signal of concern.

- Research administrators may be able to discuss potential problems with individual staff or their counterparts. However, the legality of these inquiries is questionable.

- A high degree of variability in employment screening exists among universities. Some universities screen individuals from certain countries, while others screen individuals working with certain biological, chemical, or radiological materials.

- Principal investigators play an important role in vetting, mentoring, and monitoring their laboratory personnel. They are responsible for the safe and secure operations of their laboratory, training their staff and students, establishing an environment that promotes trust and transparency, and empowering members of the laboratory to report any unusual behavior. If alerted to questionable behavior, principal investigators are responsible for determining how to resolve the situation.

Assessing Risk and Minimizing the Potential for Misuse

- The issue of "dual use research" (i.e., legitimate research that could be misused to cause harm) is an ethical and security issue, and not intuitive. Research ethics and good laboratory management are linked and principal investigators are responsible for training their laboratory staff in ethical conduct and leading by example.

- Anecdotes used to describe the potential for misuse often seem like "urban myths" to scientists and university officials because the actual security risks that "dual use research" present are not communicated effectively to the scientific community. In fact, almost no information is available linking the assessment of potential "dual use" to an actual situation where someone with ill intent has tried to replicate the experiment in question.

- Most universities do not have mechanisms to review the "dual use" potential of experiments. However, some universities do include the "eight screening questions" in their review of research. These "screening questions" are the list of experiments described by the NSABB as experiments with "dual use potential of concern."[34] Only a few universities have stand alone review mechanisms; other universities include the review of "dual use" potential as part of their Institutional Biosafety Committee assessments.

- Reviews conducted at universities are most often based on the checklist of experiments rather than an understanding of the concept of potential misuse of experiments to cause harm. This raises questions about what information is needed by scientists and university officials to assess the actual risks rather than perceived risks of conducting and communicating the research and to perform a cost-benefit analysis.

- The *process* by which scientists and research administrators assess and manage biosecurity risks throughout a project (from research design to communication) is valuable for teaching and reinforcing the concept that legitimate research could be misused for harmful purposes. Engaging scientists in this process may also help to minimize risks early on in the research and prevent the possibility of redaction of information at the publication stage.

The University and FBI Relationship

- The university and FBI have common goals, which are to protect public safety. However, their approaches and perspectives are quite different. Although tensions between these communities exist, the FBI WMD Directorate, with its mission to proactively counter threats and minimize risks, has begun to build trust, lines of communication, and relationships with the universities and other research institutions to fulfill their common mission.

- The FBI wants scientists to intuitively assess "normal" and "unusual" behavior of laboratory personnel and the surrounding situation. They believe that such assessments can help reduce the likelihood that security problems might arise at universities.

- Building trust and cooperation between the university and law enforcement communities is critical to minimizing both domestic and national security risks. Continued engagement

[34] 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,* June 2007. See http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf. The experiments are: enhance the harmful consequences of a biological agent or toxin; disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification; confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies; increase the stability , transmissibility , or the ability to disseminate a biological agent or toxin; alter the host range or tropism of a biological agent or toxin; enhance the susceptibility of a host population; generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

and dialogue between these communities enhances their familiarity of each other and increases the likelihood of building trust and collaboration.

- When to include the FBI if a potential problem arises and who should reach out to the FBI (i.e., should scientists contact the FBI directly or should they work with other university officials first) are challenging questions that need to be addressed. Several university officials and scientists expressed concerns about the possibility of negative repercussions of informing the FBI about potential problems. However, establishing and clearly communicating the appropriate processes and procedures for contacting and interacting with law enforcement to university employees could help alleviate these concerns.

- The FBI's ability to act on information is bounded by statutory authority. They would not carry out interviews and investigative operations on university property without informing and coordinating with relevant university officials and/or campus police. The FBI and local law enforcement have the ability to monitor individuals who pose specific threats to the institution or researchers. They can also discretely help minimize the risk that research facilities and individuals could become targets by raising awareness about identifying unusual interactions or behaviors and protecting one's self.

- The FBI agents who attended the meeting described their immediate procedural actions after being alerted to a potential problem. The FBI WMD Coordinators rely on the researcher or university representative's perspective about the individual or problems involved to gain a better understanding of the situation. They do not want to raise alarms if the situation doesn't warrant such a response.

- The FBI does not want to be inundated with notifications, but at the same time being involved early in a potential incident may allow them to help minimize risks to individuals, facilities, and the institution as a whole (including protecting the institution's reputation).

- If a potential problem arises, involving key institutional stakeholders (e.g., members of review bodies, campus police, health and safety office, and scientific and educational leaders), the local FBI WMD Coordinator, and representatives from other agencies (e.g., public health departments, funding agencies, and regulatory organizations) could help resolve the problem in a mutually acceptable way. **The conclusion is that active communication between universities and FBI could help maintain the United States' competitive advantage in research and education by helping to mitigate potential domestic and national security risks.**

Gaps and Challenges

Several specific gaps and challenges that were highlighted at the meeting are listed below:

- Communication among researchers, university officials (including deans and chairs of departments), law enforcement, regulators, and the public about the potential risks of research, methods for reducing the risks, and ways of responsibly communicating the benefits and risks to a broader audience.

- Multiple interpretations of complex regulatory requirements by inspectors from different funding and regulatory agencies.

- Neglect of other university responsibilities because of the increasing costs of complying with security requirements at institutions.

- The threshold of when to involve the FBI in a potential research or laboratory problem and who should be allowed to call the FBI if a problem has been identified (i.e., can students or faculty members anonymously report problems or should they first report to university officials).

- Tensions that exist between the scientific and law enforcement communities because of concerns about adverse consequences of contacting the FBI to seek advice or share information about a potential problem.

- Key information to help scientists assess the risk that their research could be misused for harmful purposes or that individuals in their laboratory or department may have malicious intent.

Specific solutions provided by meeting participants during and after the highly interactive discussion are presented in the *Policy and Programmatic Suggestions* section.

Policy and Programmatic Suggestions

The following are a list of suggestions, made by meeting participants, to address several of the gaps and challenges highlighted in the previous section. With one exception, the suggestions are categorized into four groups – Compliance Requirements, Risks, Reporting, and Outreach. These suggestions are not consensus recommendations and do not suggest ease of implementation.

1. Universities and the U.S. government should support a stronger link between the life sciences and national security community to develop a cadre of scientists who can conduct research to address biodefense and preparedness initiatives and provide scientific input about assessing the benefits and risks of research.

Compliance Requirements

2. The U.S. government should conduct research on regulations to develop evidence-based security measures that provide a demonstrable link between implementation of these measures and enhanced security. The costs should not outweigh the benefits of implementing the security measures.

3. The U.S. government should share best practices and evidence-based interpretations of requirements with regulatory and funding agencies and universities. These interpretations should become "gold standards" for complying with security requirements.

4. The U.S. government should initiate efforts to harmonize duplicative requirements found in biological, chemical, and radiological regulations and guidance to allow universities to maximally invest in ethics, safety, and security and reduce administrative burden of complying with the many duplicative security requirements.

5. The U.S. government should coordinate inspections of laboratory facilities using common interpretations of regulations and guidance. Inspectors should have the requisite knowledge and experience in the subject matter of the regulation or guidance.

6. The U.S. government should consider developing an electronic mechanism for inputting results from laboratory inspections.

7. The U.S. government should improve export control policies and sample and information sharing requirements to enable research and reduce the costs of compliance.

Risks

8. The U.S. government should develop a mechanism to translate actual security risks and threats to the laboratory context, and convey information that university officials and scientists may need to assess the risk and likelihood that research could be misused for

harmful purposes and the behavior and trustworthiness of laboratory staff working with high-risk research.

9. The FBI and other security officials should provide guidelines to help universities identify "red flags" in the research environment.

10. The FBI should continue to work collaboratively with university officials to minimize risk.

11. Principal investigators should designate and empower laboratory coordinators as points of contact for training, and monitoring and reporting of adverse incidents that may occur in the laboratory. The cost of employing personnel whose sole job is to coordinate training, monitor staff, and report incidents may be prohibitive to several laboratories. However, investigators may be able to hire laboratory coordinators if funding is provided or made available in grants.

12. Universities, department chairs, and principal investigators should train all incoming scientists – regardless of discipline or country of origin – about university, departmental, and laboratory standard operating procedures and ethical, safety, and security framework. Such training should occur at the beginning of their employment/training period and should have an ongoing professional development program, as well, taking into account cultural differences that may be relevant to foreign scientists.

13. The U.S. government should develop an effective and safe mechanism to allow prospective and former employers to speak honestly about candidate employees. This may help regulatory and funding agencies disclose any security concerns when prospective employees are seeking approval to work on biological, chemical, and radiological hazards.

Reporting

14. Universities should create a mechanism or a safe place where individuals can speak with colleagues about potential concerns and report concerning behavior without any individuals involved incurring punitive consequences unless warranted by their actions.

15. Universities should establish processes to allow scientists to temporarily opt out of laboratory work if they feel like they cannot work safely because of a personal situation or illness without incurring any negative consequences. To encourage scientists to temporary opt out when they cannot work safely in the laboratory, universities should provide clear parameters for ensuring that the principal investigator can fulfill grant or contract award commitments, and students can complete their dissertation research.

16. Universities should establish processes to ensure that the FBI and representatives from regulating agencies can directly interact with individuals possessing the most knowledge and information about the problem in question.

Outreach

17. Working together, the FBI and university officials should identify areas where tensions still exist, the reasons for their existence, and ways in which those tensions can be overcome to encourage trust and communication. This suggestion supports the need for more dialogue between the university and FBI communities.

18. Universities should establish processes to help build enduring relationships between the FBI, campus police, and the research arm of the university.

19. More scientists should be included in outreach activities with the FBI WMD Coordinators and university officials.

20. Universities and the FBI should develop communication strategies that link benefits and risks of research and promote thoughtful, careful interaction between both communities to resolve domestic and national security risks.

21. Universities should develop thoughtful communication strategies to minimize the consequences of media reports about situations that might arise in the laboratory.

Appendix 1:
Meeting Agenda

BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH:
A DIALOGUE BETWEEN UNIVERSITIES AND THE FEDERAL BUREAU OF INVESTIGATION

February 21-22, 2012
Washington, DC

Agenda

Day 1 (February 21, 2012)
Location: ICI Urban Bistro, Hotel Sofitel Washington DC

6:30 – 9:00 **Reception and Dinner**

7:30 – 8:30 **Dinner Speaker**

Welcome: *Norman Neureiter, Ph.D.,* American Association for the Advancement of Science

Moderator: *Hunter Rawlings, Ph.D.,* Association of American Universities

Speaker: *Vahid Majidi, Ph.D.,* Federal Bureau of Investigation, WMD Directorate

Day 2 (February 22, 2012)
Location: Association of American Universities Conference Room,
1200 New York Ave, NW, Washington, DC 20005

8:00-8:30 **Registration and Breakfast**

8:30-9:30 **Current State of University-based Biological Research: Environment, Compliance Requirements, and Risks**

Moderator: *Carrie Wolinetz, Ph.D.,* Association of American Universities

Panelist: *James Casey, J.D.,* The University of Texas at San Antonio

Respondent: *Supervisory Special Agent Edward You,* Federal Bureau of Investigation

9:30-11:00 **Minimizing Risk of Biological Research: Needs, Compliance Requirements, and Policy Suggestions**

Moderator: *Kavita Berger, Ph.D.,* American Association for the Advancement of Science

Panelists: *Mark Denison, M.D.,* Vanderbilt University
Ara Tahmassian, Ph.D., Boston University
JP Riordan, Federal Bureau of Investigation

Respondent: *Laura Kwinn, Ph.D.,* Department of Health and Human Services

11:00-11:30 Break

11:30-12:30 **Case Studies: Different Perspectives to One Situation**

Moderator: *Kathleen Vogel, Ph.D.,* Cornell Univeristy

Panelists: *William Mellon, Ph.D.,* University of Wisconsin-Madison
Special Agent Douglas Raubal, Milwaukee Field Office

12:30-1:30 Lunch

1:30-3:30 **Table Top Exercise: Small Group Discussions**

4:00-5:00 **Reporting of Exercise, Prevalent Issues Raised, and Policy Suggestions**

5:00 **Adjourn**

Day 3: Laboratory Visit Day for FBI Coordinators (February 23, 2012)

8:00 **Departure from the Hotel Sofitel to the University of Maryland College Park**

9:00-10:30 **Avrum Gudelsky Veterinary Center**

10:45-11:45 **Maryland NanoCenter**

Noon **Departure from the University of Maryland College Park to the Hotel Sofitel**

Appendix 2:
Meeting Participants

Mark Barnes, J.D.
Chief Research Compliance Officer and
Senior Associate Provost
Harvard University

Steven Beaudoin
Director of Environmental Health and
Safety
University of Chicago

Kenneth Berns, M.D., Ph.D.
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Owner
DeckPrism, Law Offices of Steven Cash

Cary Cooper, Ph.D.
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Professor of Molecular Biology and
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James (Jim) Walker, Ph.D.
Assocaite Vice President for Research
University of Iowa

Jamie Willard-Smith, Ph.D.
Biosafety Officer/RO
Michigan State University

Jerry Zamzow
Director, Office of Responsible Research
Iowa State University

Appendix 3:
Table Top Exercise

The objectives of the exercise were:

- To understand the roles and responsibilities of university officials, scientists, and FBI;
- To become familiar with how university officials, scientists, and the FBI approach and address different problems that might arise from biological research;
- To identify important issues caused by or affecting compliance requirements and risk mitigation strategies; and
- To identify opportunities for initiating or expanding relationships among the scientific, university, and law enforcement communities.

There were no right and no wrong answers.

Background Scenario

While this scenario was not based on real events, it was designed to mimic possible real life situations.

The Laboratory
The Principal Investigator was Professor Rhea Searcher. She was a tenured professor at State University; specialized in virology and immunology; focused on development of a Dengue Virus vaccine; received grants from the National Institutes of Health (NIH) for her research; acquired prior approval for her research from the Institutional Biosafety Committee (IBC) and Institutional Animal Care and Use Committee (IACUC); employed undergraduate and graduate students, research technicians, and post-doctoral fellows; and conducted research in a biosafety level 2 (BSL2) laboratory.

The post-doctoral fellow was Mandip. He was from a foreign country and previously had conducted research to study the strains of Dengue commonly found in Asia.

The graduate students were Amy, Shane, and Molly. Amy was a fifth year doctoral student in virology and her dissertation involved viral recombination. Shane was a third year doctoral student in virology and immunology. Molly was a first year doctoral student in virology.

The undergraduate students were Rahid, Joe, Megan, and Rebecca. They were involved in various small research projects and often helped Mandip, Amy, Shane, and Molly. Under the supervision of Amy, Megan conducted research for an undergraduate honors thesis.

The laboratory technicians were Adam and Sara. Adam worked in the laboratory for over 6 years, but was leaving. Sara just joined the laboratory and took Adam's place.

The Project
Dr. Searcher and her laboratory were conducting basic research studies to develop a single vaccine against all four, naturally-occurring strains of Dengue virus. Dengue virus is considered a re-emerging disease, whose distribution is dependent on its vector, the *Aedes aegypti* mosquito. The female mosquito picks up and transmits the virus when feeding from humans or non-human primates. Transmission between monkeys and humans may occur, but its role in causing outbreaks is uncertain. When a person is infected with more than one strain, they may suffer from the very severe disease, Dengue Hemorrhagic Fever.

Dr. Searcher's projects involved genetic manipulation of viral DNA and used of experimental animals.

The Experiment
Amy was using genetic engineering (i.e., recombinant DNA techniques) to create a candidate vaccine against Dengue virus. Shane was creating experimental mice that mimic the symptoms and immunological response seen in humans infected with multiple strains of Dengue Virus. Mandip oversaw Amy and Shane's research progress.

Amy's experiment included three sets of mice:

Experimental group: 4 groups of 5 mice each were treated with the candidate vaccine.
Negative control group: 4 groups of 2 mice each were the control group and did not receive the vaccine (but were injected with the buffer solution)
Positive control group: 4 groups of 2 mice each infected with one strain of Dengue virus.

Amy collected samples at four time points after the initial infection. One group of mice from both sets was humanely sacrificed at each time point.

Initial Results
The candidate vaccine seemed to be safe and effective and did not cause disease in the experimental mice. Mice infected with the candidate vaccine developed immune responses that protected against all four strains of Dengue virus. Dr. Searcher asked Amy to repeat the experiment to ensure that her initial results were accurate.

Choices

Throughout the scenario, the University and FBI WMD Coordinator needed to make decisions on how to proceed in challenging or threatening situations. There were several different pathways/scenarios that could have been taken.

The pathways prompted the group to decide whether or not the University and FBI should work together to address a particularly challenging security problem and why. The scenarios included animal rights extremism, vandalism, bioterrorism, or acts of negligence.