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Bridging Science and Security for Biological Research

International Science and Security

Proceedings from the Meeting, 4-5 February 2013

Association of Public and Land-grant Universities

AAAS
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BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH: INTERNATIONAL SCIENCE AND SECURITY

Meeting Report
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Disclaimer
The concerns or suggestions outlined in this report reflect the discussions at the workshop and do not necessarily represent the views of the FBI WMD Directorate; 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 FBI/WMDD/BCU

The FBI's WMD Directorate (WMDD) was created after September 11, 2001 to provide a cohesive and coordinated approach to countering WMD threats and responding to incidents if they occur. Recognizing the unique and inherent challenges to preventing bioterrorism, the FBI/WMDD/Biological Countermeasures Unit (BCU) conducts extensive outreach to the life sciences community to proactively build mutually-beneficial relationships and broaden scientists' understanding of biosecurity concerns.

About AAAS

The American Association for the Advancement of Science (AAAS) is the world's largest general scientific society and publisher of the journal, *Science* (www.sciencemag.org). AAAS was founded in 1848, and serves 262 affiliated societies and academies of science, reaching 10 million individuals. *Science* has the largest paid circulation of any peer-reviewed general science journal in the world, with an estimated total readership of 1 million. The non-profit AAAS (www.aaas.org) is open to all and fulfills its mission to "advance science and serve society" through initiatives in science policy, international programs, science education, and more.

About AAU

The Association of American Universities (AAU) is a non-profit association of 60 U.S. and two Canadian pre-eminent 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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About the Project

The Federal Bureau of Investigation (FBI) Weapons of Mass Destruction Directorate (WMDD) has developed a robust biosecurity outreach and awareness program with the scientific community. To strengthen this relationship, the FBI WMD Directorate contracted with the American Association for the Advancement of Science (AAAS) to host a series of outreach and policy meetings with research, policy, and security stakeholders and summarize important lessons learned, challenges faced, and areas for improvement of local and national-level biosecurity initiatives. In collaboration with the Association of American Universities (AAU) and Association of Public and Land-grant Universities (APLU), AAAS and the FBI WMD Directorate hosted a biosecurity outreach meeting in February 2012, entitled *Bridging Science and Security for Biological Research: A Dialogue between Universities and the Federal Bureau of Investigation*. The meeting provided opportunities for academic scientists and research administrators to build trust and enhance their relationship with the security community, with the mutual goal of jointly addressing the challenges of mitigating biosafety and biosecurity risks. One of the key findings was:

> Active communication between universities and [the] FBI could help maintain the United States' competitive advantage in research and education by helping to mitigate potential domestic and national security risks.

The second meeting, which was held in September 2012, built on this finding by providing the opportunity for scientists and research administrators to share best practices and lessons learned about the review and oversight of dual use life sciences research with each other and with the security and policy-making communities.

The third meeting, which was held in February 2013, focused on critical issues resulting from foreign scientists studying or working in the U.S., international collaboration, and U.S. scientists working in foreign countries.

Background

Much like physics and chemistry were the sciences of the 20th century, biology is expected to be the science of the 21st century. Rapid advances in biotechnology, broad application of biological research and results, and international investment in biology-related research contribute to this prediction.[1] In addition to health challenges, biology and biotechnology research address issues involving agriculture, the environment, energy, development, and national security. Further, biological research and products are a significant part of the U.S. and global economy.

However, with rapid advancement, widespread use, and investment comes the possibility of exploitation of research and results. At the 2000 annual meeting of the National Academy of Sciences, Matthew Meselson stated:

> Every major technology – metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy – has been intensively exploited, not only for peaceful purposes but also for hostile ones. Must this also happen with biotechnology, certain to be the dominant technology of the coming century?[2]

Against this backdrop, the importance of addressing issues at the nexus between biological science and security is paramount. Some of these issues are more challenging when research involves international scientists. Identifying and addressing these challenges is an important step in safeguarding science to ensure the beneficial application and use of biological research and results.

Globalization of Biological Research

Biological research development, and subsequent application to address societal needs often require scientists from different countries to work together to achieve research and implementation goals. Using co-authorships as a measure of international partnerships, the percentage of scientific articles co-authored by international partners has doubled since 1997. According to the National Science Foundation (NSF), approximately 50% of scientific articles from the U.S., European Union, and China have co-authors from other countries.[3] Further, some countries, such as Brazil are not only investing in biological research domestically, but also are promoting collaboration with international partners. (Brazil designates 1% of its tax revenue to research and development that is supported by

[1] National Research Council. (2009). A New Biology for the 21st Century: Ensuring the United States Leads the Coming Biology Revolution. National Academies Press. (Washington, DC).
[2] Meselson, M. 2000. The problem of biological weapons. Presentation at Symposium on Biological Weapons and Bioterrorism, National Academy of Sciences, Washington, DC, May 2.
[3] National Science Foundation. (2012) Science and Engineering Indicators 2012. Figure O-16. Available at: http://www.nsf.gov/statistics/seind12/figures_tn1.htm. Accessed March 13, 2013; National Science Foundation. (2012) Science and Engineering indicators 2012. Coauthorship and Collaboration. Available at: http://www.nsf.gov/statistics/seind12/c5/c5s4.htm#s2. Accessed March 31, 2013.

the São Paulo Research Foundation.[4] The Foundation collected approximately $500 million for research activities and international collaboration in 2012.[5])

Brazil is not unique in building its biological research enterprise. China, India, South Korea, and Singapore are among the many countries with a rapidly growing biological research capacity and workforce.[6] Countries are incentivizing their citizens, who are studying or working in other countries, to return home to head laboratories (e.g., China[7]); recruiting foreign scientists to work in their laboratories (e.g., Qatar[8]); establishing local affiliates of foreign universities (e.g., Qatar[9]); and/or partnering with local and foreign universities (e.g., Malaysia[10]). These efforts are changing the way in which education and research are supported and promoted throughout the world. Although students, post-graduate trainees, and faculty still travel to the U.S. and Europe to be educated and trained in the natural sciences, today many countries are acquiring local capacity to train new scientists and retain established scientists. These actions are often taken to build a knowledge-based economy and reverse the effects of "brain drain," which still occurs in many parts of the world.

As more countries invest in their research infrastructure, scientists from the U.S. and Europe will have greater opportunities to engage globally in collaborative research, classroom education, and laboratory training. For example, Emory University, the Georgia Institute of Technology, and Peking University have recently developed a joint Ph.D. program in biomedical engineering. In this program, students take classes and conduct research at their designated home institution and their selected secondary institution.[11] This program provides U.S. students studying and conducting research at Peking University with a stronger understanding of the Chinese bioengineering research environment and the process of collaborating with Chinese scientists.

In this environment, countries and research institutions are competing for the best and brightest scientists around the world to maintain competitiveness. At the same time, challenges that affect several countries, if not the world, are bringing scientists together

[4] FASESP. (2013). FAPESP and JSPS organize Japan-Brazil Symposium. Available at: http://www.eurekalert.org/pub_releases/2013-02/fda-faj022813.php. Accessed March 13, 2013.
[5] Ibid.
[6] National Science Foundation. (2012) Science and Engineering indicators 2012. Figure O-11. Available at: http://www.nsf.gov/statistics/seind12/figures_tn1.htm. Accessed March 13, 2013.
[7] Cai, H. (2009). Chinese Knowledge Diaspora in the Development of Chinese Research Universities. Presentation at the International Conference on Diaspora for Development. Available at: http://siteresources.worldbank.org/INTPROSPECTS/Resources/334934-1110315015165/Cai.pdf. Accessed March 13, 2013; Cai, H. (2012) "Deploying the knowledge diaspora: China's overseas talent recruitment schemes including the 111 Project" Paper presented at the annual meeting of the 55th Annual Conference of the Comparative and International Education Society, Fairmont Le Reine Elizabeth, Montreal, Quebec, Canada.
[8] For more information about the Qatar Foundation International, visit http://www.qfi.org/index.php. Accessed March 13, 2013.
[9] For more information about the Weill Cornell Medical College in Qatar, visit http://qatar-weill.cornell.edu/. Accessed March 13, 2013.
[10] Higher Education Malaysia. (2010). Twinning Degree Programs. Available at: http://jpt.mohe.gov.my/PEMASARAN/booklet%20Education%20Malaysia/MOHE%20booklet%20-%20Twinning%20Programme%20Edition%201_2010.pdf. Accessed March 13, 2013.
[11] For more information about the Georgia Institute of Technology, Emory University, Peking University Bioengineering program, visit http://www.pku.bme.gatech.edu/. Accessed March 13, 2013.

to solve problems jointly. As globalization in the biological sciences and biotechnology grows, scientists and research institutions face increasing challenges to their ability to conduct, support, and/or oversee research activities that involve international dimensions. Implicit in this process is the need to ensure compliance with all relevant regulations (in all countries involved) and prevent inappropriate use of research knowledge or materials for any reason. Preventing use of biological materials to inflict harm on individuals and populations is an ethical, safety, and security concern. During the past decade, international efforts have begun to encourage the development of a common conceptual understanding of ethics, research integrity, biosafety, and biosecurity.

Cross-disciplinary Research in Biology

The life sciences are becoming increasingly cross-disciplinary and multi-dimensional. For over a decade, engineers and non-life scientists (i.e., physical, chemical, computer, and material scientists) have designed new tools and techniques to study a wide range of biological questions, opening opportunities for new, more complex research on biological systems.

For example, the fields of computational biology and bioinformatics apply techniques from computer science and applied mathematics to the life sciences to analyze large amounts of biological data and study biological systems. Today, the many fields of '–omics' is a direct result of this convergence of computer and mathematical sciences with the biological sciences to study biological processes, protein interactions, and genetic interactions at a systems level.

Synthetic biology is another example where engineering concepts are applied to the life sciences to create new, predictable biological processes or systems. Many efforts are currently underway to promote synthetic biology and to identify and minimize any associated ethical, environmental, safety, or security risks. The International Genetically Engineered Machine (iGEM) competition was established by engineers who asked whether biological systems could be built using individual parts (i.e., gene-encoding plasmids) and whether the function of a biological system could be predicted based on its individual parts.[12] The competition started with a month-long course at MIT in 2003.[13] Since then, it has grown to include approximately 190 teams from the U.S., Asia, Europe, and Central and South America. In addition, iGEM established a high school competition in 2012.

Challenges of Biological Research with International Dimensions

The simultaneous shift towards greater globalization and cross-disciplinarity in the biological sciences and biotechnology holds great promise, but also has elicited

[12] According to iGEM leadership, biological systems can be built using individual biological parts but the function of those systems cannot necessarily be predicted based on the individual components.
[13] For more information about iGEM, visit http://igem.org/Main_Page. Accessed March 13, 2013.

significant concerns.[14] The promise of addressing local, national, regional, and global challenges using low-cost, new approaches raises hope for many in less-developed countries. At the same time, bioethicists and security experts have raised concerns about the inappropriate use of research results and biological materials. The laws and regulatory requirements might vary greatly between countries and result in significant impediments to supporting international collaborations, hosting foreign scientists, or encouraging scientists to train or work in foreign laboratories. Research institutions and scientists encounter many problems in supporting research efforts with international components that go beyond the persistent and challenging issues of visas and export controls. The following discussion will focus on these broader problems.

When working with foreign counterparts, research institutions and scientists face challenges of jurisdiction and governance, culture, scientific infrastructure, and politics. Biosafety and occupational safety, protection of human subjects, research integrity, conflict of interest, biosecurity concepts, intellectual property protections, and other ethical issues are particularly difficult to address with foreign colleagues because of differences in definitions, language, and socio-cultural context. Research administrators and scientists actively work to identify and resolve differences in regulatory infrastructures and concepts of responsible research practice to facilitate educational and research experiences. Institutions can spend years working with their foreign counterparts to ensure that their institutional processes are at the same level; an example could be ensuring that a foreign collaborating institution has been certified by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). Further, U.S. universities train their U.S. and foreign life sciences graduate students about research integrity and bioethics. However, these training programs often vary between doctoral programs within and between institutions.

Research administrators and scientists who are familiar with the research environment in which their foreign colleagues train and work are well-equipped to identify and resolve potential regulatory or behavioral differences. However, changing political and regulatory environments can complicate efforts to resolve operational problems. For example, when India changed its intellectual property rights from process- to product-based, Indian scientists had to be retrained on the new definition. This change affected how Indian scientists viewed intellectual property rights, which could have affected their interactions with foreign partners. In addition to legal changes, the relative stability of a country might correlate with the stability of its regulatory infrastructure and perceptions of risk. For example, scientists living in a fairly unstable country might be more likely to work on research that has a high likelihood of success and can be conducted within a short timeframe because of the unpredictable political and funding situation.

[14] National Research Council. (2006). Globalization, Biosecurity, and the Future of the Life Sciences. National Academies Press. (Washington, DC).

Institutional Biosafety and Biosecurity Programs

The concepts of biosafety (i.e., measures to prevent accidental exposure or release of pathogens and toxins) and biosecurity (i.e., measures to prevent intentional theft, loss, or misuse of materials, technology, or expertise to cause deliberate harm) often get lost in translation from English because many languages have one word to describe both terms. To address this difference, many national and international organizations have coined the term "biorisk management" to jointly describe biosafety and biosecurity.[15] Although instructive at the institutional level, it does not specifically address biosecurity from a law enforcement perspective. From this perspective, biosecurity encompasses the broad range of security threats institutions face, beyond pathogen or toxin-specific risk assessment. These threats include personnel security and the "insider threat"; theft, loss, and/or misuse of biological pathogens or toxins; cyber attack; animal rights extremism; theft of intellectual property; and bioterrorism.

Despite the efforts of national and international biosafety organizations to promote "biorisk management," many countries do not rank intentional theft or misuse of harmful pathogens as high as more pressing national priorities. Many countries view political uncertainty, social unrest, availability of food and clean water, infectious disease, and other significant challenges above the risk of bioterrorism or biological weapons.

However, a few countries have developed biological weapons in the past and terrorist organizations have expressed an interest in using biology to cause harm. To facilitate national and international efforts at countering biological threats arising from misuse or theft of research, the scientific community has been recruited to prevent inappropriate use of biology and encourage the maximal benefit of research results to society. For example, the BWC has become a forum wherein scientists can engage on security issues and promote self-governance approaches for minimizing misuse of research or theft of harmful pathogens.[16] As scientists develop and implement cost-effective approaches to prevent accidental or intentional release, concepts of biosafety and biosecurity will change to reflect safety standards and security best-practices, respectively, employed in less-developed countries.

FBI Biosecurity and Outreach Programs

The FBI contributes to the U.S. Government's efforts to reduce the risk of bioterrorism by enforcing the federal statutes that prohibit development, production, or stockpiling of biological weapons. To accomplish these functions, the Biological Countermeasures Unit

[15] Centers for Disease Control and Prevention. (2009). Biosafety in Microbiological and Biomedical Laboratories (5th Edition). Available at: http://www.cdc.gov/biosafety/publications/bmbl5/. Accessed March 13, 2013; World Health Organization. (2006). Biorisk management: Laboratory biosecurity guidance. Available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/. Accessed March 13, 2013; CEN Workshop Agreement, CWA15793. (2011) Laboratory Biorisk Management. Available at: ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf. Accessed March 13, 2013.

[16] For more information about the Biological Weapons and Toxins Convention, visit http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument.

(BCU) of the FBI's WMD Directorate has developed biosecurity initiatives that focus on acquisition or exploitation of biological material, technology, and expertise to intentionally cause harm.

The BCU has established a successful biosecurity outreach program, the goal of which is to establish strong, sustainable relationships with officials and scientists from research institutions to prevent and mitigate potential threats that they might encounter. The primary way in which the FBI engages with the scientific community is through their Academic Biosecurity Workshops.[17] FBI WMD Coordinators conduct the workshops using a series of dialogues and exercises to bring relevant academic, health, first responder, law enforcement, and industry experts together to: 1) promote an understanding of their respective roles and responsibilities, capabilities, and resources; and 2) develop feasible, implementable threat mitigation strategies. The WMD Coordinators offer a point of contact at the local level and provide local support and security expertise. These efforts build on a shared goal of serving the public good.

The tangible benefits generated by these engagements are evident by the increasing number of requests for workshops by research institutions. In addition, this model has garnered international attention; requests for assistance to implement similar academic workshops have come from both the law enforcement and academic communities of foreign nations.

The Meeting

In February 2013, the American Association for the Advancement of Science (AAAS), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and Federal Bureau of Investigation (FBI) convened a meeting of scientists, research administrators, and biosecurity experts to share information about problems encountered while supporting international collaboration, education and research of foreign scientists in the U.S., and training of U.S. scientists abroad.

The ***goals*** of the meeting were:

- To identify current challenges in addressing safety, security, and ethics while conducting or enabling biological research with foreign students, faculty, staff, or collaborating partners;
- To discuss current strategies or needs for promoting a common understanding of biosecurity risks and mitigation measures, and how they relate to safety and ethical risks and mitigation strategies of biological and biotechnological research;
- To identify strategies for enabling international scientific collaboration within the existing biological sciences and security environment; and

[17]Edward Lempinen. (2011) *FBI, AAAS Collaborate on Ambitious Outreach to Biotech Researchers and DIY Biologists.* Available at: http://www.aaas.org/news/releases/2011/0401fbi_biosecurity.shtml?sa_campaign=Internal_Ads/AAAS/AAAS_News/2011-04-01/jump_page. Accessed October 17, 2012.

- To identify ways in which the research community and FBI can work together to address these challenges.

Meeting participants were asked to consider the following issues:

- Challenges that research institutions face with foreign scientists working in the U.S., international collaborations, and American scientists working in foreign institutions;
- Current practices or procedures that overcome one or more of these challenges;
- Gaps in understanding or process that need to be addressed to ensure that interactions between scientists are safe, secure, ethical, and scientifically useful and/or productive; and
- Specific action items to gather more information about what is needed to improve the current situation or to help alleviate existing problems.

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 presented at the meeting. The following summary highlights these points. The *Emerging Themes, Problems and Possible Approaches,* and *Suggested Action Items* sections are followed by two appendices that include the meeting agenda and list of participants.

Emerging Themes

Efforts to link scientists globally through education and research are often met with operational challenges that either delay or prevent partnerships or foreign training from occurring. The most prevalent difficulties involve visa, export control, and customs issues. These issues have been, and continue to be, vigorously debated by the scientific, security, and policy communities. Beyond these widespread and pervasive issues, scientists and research administrators encounter many other problems with supporting the education of foreign scientists in the U.S., international research collaboration, and training of U.S. scientists and students at foreign institutions. These problems tend to focus on the rules and responsibilities governing research in different countries and the level of familiarity and trust between scientists from different countries.

Although these issues are critically important to ensuring a productive, mutually beneficial, ethical, safe, and secure research environment, very few concerted efforts have been developed to address these problems in a system-wide manner. Several intergovernmental organizations have initiated activities to harmonize the principles and practices of research integrity or research ethics.[18] Similarly, several nongovernmental organizations, including the AAAS[19] and national academies of sciences,[20] have developed programs to address ethical, safety, and security issues internationally. Operationally, however, research institutions have to identify and resolve problems on a case-by-case basis. This approach is more costly for the institution, and limits the identification of common problems and sharing of best practices to address those problems.

Adding a layer of complexity is the increasingly cross-disciplinary nature of life sciences research, as evidenced by the merging of biological and non-biological disciplines (e.g., engineering, physical, chemical, computer, and materials sciences) to develop new research tools, study complex research questions, and produce novel applications. One recent example of this is synthetic biology, which was created by computer scientists and engineers who wondered whether "biological parts" could be used to develop more complex systems, much like a computer. Research of this type raises concern because common standards, best practices, or regulatory requirements for research ethics, laboratory biosafety, and laboratory biosecurity often do not extend to non-life scientists working with biological materials.

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[18] For more information about the 2nd World Congress on Research Integrity and resulting statement, visit http://www.singaporestatement.org/. Accessed March 13, 2013; For more information about the United Nations Education, Scientific, and Cultural Organization's Ethics efforts, visit http://www.unesco.org/new/en/social-and-human-sciences/themes/about-ethics/. Accessed March 13, 2013; For more information about the International Council for Science's efforts on responsibilities of scientists, visit http://www.icsu.org/news-centre/press-releases/press-releases-2011/responsibilities-of-scientists-underlined-by-scientific-community/responsibilities-of-scientists-underlined-by-scientific-community. Accessed March 13, 2013.

[19] AAAS. International Engagement: Responsible Science for a Safer Society. Available at: http://cstsp.aaas.org/InternationalMeeting/home.html. Accessed March 13, 2013.

[20] InterAcademy Panel. Biosecurity Activities. Available at: http://www.interacademies.net/10941.aspx?catGroupId=1&CFVTopics=9. Accessed March 13, 2013.

These overarching issues of immigration and customs controls, national differences, and best practices for responsible science provide the broader context within which international science and security concerns exist. During the meeting, several general themes emerged from the discussions:

- Researchers know how to design and conduct scientific projects with their foreign colleagues. However, scientists and research administrators are much less familiar with the *process* of international collaboration. The process of collaboration includes such actions as preparing and complying with contracts, ensuring the necessary certifications (e.g., for animal care and use, hazardous materials), and implementing institutional policies and measures to ensure compliance with relevant laws and regulations.

- The formation of large international efforts focused on specific scientific challenges, such as the Human Genome Organization (HUGO) and HIV vaccine research and development, are more advanced than the development of standards of practice for all biological research.

- A stakeholder forum wherein research administrators share information about research practices could enable the development of common standards and policies for biological research.

- Clearly defined roles, responsibilities, and expectations of scientists are fundamental to ensuring a productive, safe, secure, and ethical research environment.

- The FBI is a unique national law enforcement agency because it actively seeks partnerships with the scientific community to minimize security risks associated with biological research. In addition, the agency provides local points of contact for research institutions through the FBI WMD Coordinator program.

- Background checks are often required for employment and routinely required for access to regulated research materials (i.e., the U.S. Federal Select Agent Program). Ineffective background checks could result in two undesirable consequences – a scientist with selfish or harmful motivations is not properly vetted or research and collaboration are inappropriately stifled because of lack of available information to carry out background checks.
    - Equivalent background information is not readily available for vetting foreign scientists who have not spent a sufficient amount of time in the U.S. To increase the utility of background checks, they must be conducted to the same level for U.S. and foreign scientists.
    - Vetting scientists from other countries is very challenging. U.S. scientists and research administrators must rely on trusted colleagues in different countries to evaluate the technical ability, behavior, and background of foreign scientists.

- Developing common standards of research practice between U.S. and foreign scientists is critical for ensuring that research is conducted in a safe, secure, and ethical manner. The best way to promote common standards of research practice is through face-to-face interactions.

In addition to the themes listed above, meeting participants identified problems and possible approaches for addressing those problems, which are described in the *Problems and Possible Approaches* section. Participants also suggested informational or programmatic needs to ensure all scientists are conducting research in a safe, secure, and ethical manner. These needs are provided in the *Suggested Action Items* section of this report.

Problems and Practical Approaches

Throughout the meeting, participants described their experiences with U.S. scientists working in other countries, foreign scientists working in the U.S., and the institutional infrastructure needed to support international collaborations. During the discussions, participants shared difficulties they have encountered at their institutions and approaches they have used to solve some of these problems. The following discussion presents specific problems and possible solutions identified during the meeting.

Problem: Biosafety, Biosecurity, Ethics, and Research Integrity

- Meeting participants highlighted the importance that intent plays in the dual use life sciences issue.
- Some meeting participants suggested that comprehension of biosafety, biosecurity, ethics, and research integrity concepts is highly dependent on the research and governance infrastructure within which scientists are trained.
- Several participants acknowledged that students often encounter different standards of research practice in the laboratory than in formal training programs.
- U.S. scientists who conduct research overseas do not necessarily receive periodic training for biosafety, laboratory biosecurity, broader security issues, ethics, and research integrity.
- Participants questioned the efficacy of formal responsible conduct of research (RCR) training in encouraging ethical behavior.

Approach: To address problems involving responsible behavior, meeting participants suggested the following approaches:

- Scientists could be educated about a wide range of risks, including biosafety, laboratory biosecurity, broader security concerns (e.g., targeting of facilities by animal rights extremists, safeguarding computer systems that control laboratory facilities, and elicitation), information-sharing, human and animal subjects, falsification, fraud, and plagiarism.
- Research institutions could develop formal training programs that involves mentorship by well-established researchers to ensure all scientists, both U.S. and foreign, have the same understanding of research-related risks, mitigation strategies, and behavioral expectations.
- The scientific and regulatory communities could develop biosecurity practices that are based on the needs of different scientific communities.
- Funding agencies could invite grant applicants to describe how they would resolve safety, security, or ethical concerns arising from unexpected research results. However, this requirement should not impose an additional regulatory burden on research institutions and scientists.
- The U.S. Government could establish an inclusive policy development process that involves ongoing communication with stakeholders, assistance to stakeholders to facilitate compliance with existing or forthcoming policies, and

iterative improvements to policy documents based on lessons learned through these stakeholder interactions.

- The scientific community could replicate the process through which the DIYBio community, in collaboration with the Wilson Center,[21] developed community norms. This process encouraged amateur biologists to brainstorm potential risks of their research activities, consider normative behaviors to either prevent or minimize those risks, and engage security experts (i.e., local FBI WMD Coordinators) to understand security concerns.
- Research institutions could develop courses that address differences between attitudes and ethical frameworks of scientists educated and trained in different countries to facilitate a common understanding of acceptable behavior.
- Research institutions could implement training programs that focus on scientists' roles and responsibilities to themselves and their co-workers, institution, and community to encourage safe, secure, and ethical behavior.
- Research institutions could include the social impacts of science in education and training programs.
- Research institutions could use scientific examples that reflect the research capacity in other countries in training programs to describe behavioral concepts to foreign researchers.
- The scientific community could identify and promote a common conceptual understanding of responsible research conduct.
- Research institutions could use international documents on research integrity to promote common research norms. The International Council for Science (ICSU);[22] World Science Forum, the 2nd World Conference on Research Integrity;[23] Organization for Economic Cooperation and Development (OECD);[24] and United Nations Education, Scientific, and Cultural Organization (UNESCO)[25] have produced documents promoting common principals for research integrity.
- Research institutions could raise awareness among faculty about common principles and practices that promote a safe, secure, and ethical research environment.
- Research institutions could support a regimented process for laboratory training that provides personalized instruction and establishes a consistent institutional process and structure for high-risk research. The training could include assessing a trainee's ability to communicate in English, conducting informal psychological evaluations, and observing a trainee's attitudes in the laboratory.
- Research institutions could conduct routine training and periodic assessments of scientists. To achieve this, research that seeks to better understand the

[21] Kuiken, T. (2010). Responsible Science for Do-It-Yourself Biologists: New Initiative Launched on Biosafety . Available at: http://www.synbioproject.org/process/assets/files/6424/diypressrelease.pdf. Accessed March 13, 2013.
[22] For more information about the International Council for Science's efforts on responsibilities of scientists, visit http://www.icsu.org/news-centre/press-releases/press-releases-2011/responsibilities-of-scientists-underlined-by-scientific-community/responsibilities-of-scientists-underlined-by-scientific-community. Accessed March 13, 2013.
[23] For more information about the 2nd World Congress on Research Integrity and resulting statement, visit http://www.singaporestatement.org/. Accessed March 13, 2013.
[24] For more information about the Organization for Economic Cooperation and Development's collection of codes of conduct, visit http://virtualbiosecuritycenter.org/codes-of-ethics. Accessed March 13, 2013.
[25] For more information about the United Nations Education, Scientific, and Cultural Organization's Ethics efforts, visit http://www.unesco.org/new/en/social-and-human-sciences/themes/about-ethics/. Accessed March 13, 2013.

psychological and behavioral characteristics that lead to misuse of scientific knowledge and tools is needed.

- Research institutions and their member organizations could encourage exchange and sharing of educational materials across institutions.
- University Offices of Sponsored Programs could provide informational resources, if available, to scientists and institutions to assist the development of international collaborations and mitigate research-related risks with foreign partners.
- Research institutions could educate scientists about the key international legal instruments that affect their research efforts, such as the BWC and United Nations Security Council Resolution 1540. This education could include the rationale and history behind the legal instruments.
- Research institutions could use case studies dealing with security issues such as dual use life sciences research, cyber security, and terrorism as educational tools.

Problem: Cross-disciplinary Research

- Some meeting participants suggested that enhanced familiarity of new types of research (i.e., emerging technologies) that might not be focused on pathogens or toxins could still elicit safety, security, and ethical concerns. One example provided was the potential vulnerability of "big data" and "cloud computing" to cyber attacks.
- Several participants indicated that very little information exists to inform identification and mitigation of risks associated with research and technologies that could be used by both life scientists and non-life scientists. One prominent example of such a field is synthetic biology, in which researchers have formal training in the engineering, computer, chemical, physical, material, or life sciences.[26]
- Despite the trend towards cross-disciplinary science, non-life scientists might not necessarily receive the same level of research oversight as life scientists.
- Meeting participants highlighted a lack of experience among research administrators in engaging non-life scientists, who work with biological materials, about regulatory and training requirements associated with biological research and biotechnology.

Approach: To address the challenges associated with cross-disciplinary science, meeting participants suggested that graduate students and postdoctoral fellows from all scientific disciplines be trained in ethics, responsible conduct of research, laboratory safety and security, and broader security issues

Problem: Temptation to Present Only "Good" Results

- One meeting participant described a situation wherein foreign scientists presented only the good results of their research.

[26] The iGEM competition and DIYBio are examples of organizations that prioritize responsible science among their competitors or members.

Approach: To remedy this problem, the meeting participant suggested that scientists should be taught the importance of communicating all experimental results. Negative results can be as informative as positive results.

Problem: Research Standards and Requirements

- U.S. institutions often have trouble facilitating international collaborations if research standards are different between partner institutions.
- Meeting participants highlighted the administrative and financial effort involved in resolving different standards of research practice, institutional requirements, and legal requirements between collaborating partners (i.e., research institutions or individual scientists) from different countries.
- Some participants stated that difficulties also stem from unwritten rules and regulations with which scientists in some countries must comply.
- Institutions may lack the infrastructure and resources needed to support and enable international collaboration.

Approach: To overcome these difficulties, meeting participants suggested the following approaches:

- Research institutions and the broader scientific community could promote the development of similar standards of research practice to facilitate international scientific collaboration.
- Research institutions could develop agreements that detail requirements, policies, procedures, and financial processes to enable collaborative research.
- Research institutions and scientists could invest the time and effort needed to resolve differences in research standards and requirements between partner countries.
- Scientists could work with trusted counterparts who are dedicated to scientific progress, well-connected, and able to navigate their research environment.
- Research institutions could request that biological materials are registered at both the U.S. and foreign partner universities.

Problem: Some Research is More Easily Conducted Overseas

- Meeting participants stated that in some cases scientists could conduct certain types of research more quickly and with less regulatory burden outside the U.S. However, all scientists are expected to comply with the legal requirements of their funding organizations, the country sponsoring the research (if funding is through a government agency), and the country in which the research is conducted.
- Several research administrators present at the meeting indicated that they believe some scientists in their institutions might be conducting research outside the U.S. to avoid or circumvent the high cost and burden of U.S. regulations or policies. A few research administrators at the meeting stated that they might not know all of the international collaborations occurring at the scientist-to-scientist level.

Approach: To address these problems, meeting participants suggested the following approaches:

- Research institutions could conduct occasional site visits to monitor and oversee overseas research. However, overseas site visits might be difficult to conduct because of limited financial and administrative resources.
- Research institutions could facilitate regular communication and oversight meetings between relevant offices within research institutions.
- The U.S. Government could re-examine burdensome regulations to better understand whether they contribute to a competitive ***disadvantage*** of U.S. research efforts or an incentive for researchers to circumvent U.S. rules. One possible forum in which burdensome regulations could be reviewed is the U.S. Government's efforts to streamline compliance requirements on research (i.e., Circular A21 discussions).

Problem: Background Checks and Vetting of Foreign Entities

- Meeting participants stated that vetting foreign scientists and institutions is extremely challenging.
- Countries use dissimilar criteria and standards to vet scientists than those used by the U.S., which could limit the feasibility of relying solely on background checks and personnel security evaluations conducted in different countries. Examples provided were different definitions for the terms, "adjudicated mental defective," and misdemeanors and felonies, all of which are qualifying terms for approval to work with harmful pathogens in the U.S. (i.e., Select Agent Program).
- Often, scientists and research administrators use trusted, personal references to assess foreign scientists, their technical expertise, and the support infrastructure for research at foreign institutions.

Approach: To address the problems for vetting foreign entities, meeting participants suggested the following approaches:

- Research administrators and scientists could ask their trusted colleagues about foreign scientists and institutions, or develop trusted partnerships with foreign institutions to aid in vetting foreign researchers.
- Research institutions could require a probationary period under mentorship in the laboratory to aid in the assessment of scientists' technical competency and ability to follow safety and security requirements. Although several participants supported the use of a probationary period, at least one participant stated that this approach is problematic because it involves non-reimbursable costs and unknown consequences if a student researcher does not demonstrate technical expertise and safe laboratory practices.
- The FBI could help scientists and research administrators understand the concepts of elicitation and targeting, conduct background checks, assess the legitimacy of conferences, and determine the legitimacy of unsolicited requests, such as surveys on foreign policy or transfer of laboratory materials.
- Research institutions could use in-country U.S. government resources to assist in vetting foreign scientists and institutions.

Problem: Trust between Peers and Unrealistic Expectations

- Meeting participants described the importance of trust between peers to ensure a safe, secure, and ethical research environment or collaborative effort.
- Several participants described complaints about a lack of respect between U.S. scientists and their international colleagues.
- Some meeting participants cautioned that many foreign students have unrealistic expectations about the research and education environment, availability of funding or resources, or research opportunities in the U.S. These students are often shocked and disappointed when the reality of studying and working in the U.S. does not meet their expectations.

Approach: To promote trust between peers and manage unrealistic expectations, meeting participants suggested the following approaches:

- Scientists could learn about the culture of their peers or collaborating partners to break down any mistrust.
- Scientists could treat their foreign counterparts honorably, respectfully, and ethically.
- Collaborating scientists could share all benefits of their research.
- Collaborating scientists could maintain their partnerships after the completion of research projects.
- Research institutions could highlight the shared and common responsibility to safeguard research.

Other Problems: Meeting participants articulated additional difficulties about which matching approaches were not discussed.

- Several meeting participants stated that foreign scientists in the U.S. who are unable to communicate well in English often have difficulties understanding the rules governing research and their responsibilities to conduct safe, secure, and ethical research.
- Some participants described examples in which scientists have trouble admitting that they do not understand questions, concepts, laboratory experiments, or requests.
- Some meeting participants suggested that foreign scientists in the U.S. might be more vulnerable than U.S. scientists to negative consequences if they are caught acting unsafely or unethically. Some participants indicated that the fear of deportation from the U.S. contributes to such vulnerabilities.
- Several meeting participants indicated that scientists from some countries are reluctant to respond to female authority figures.
- In some cases, scientists might not feel as though they have the authority to withdraw from a research activity or choose options that run counter to their supervisors.
- A few meeting participants described a practice in which U.S. scientists have accepted money from foreign institutions to attribute already published articles to the foreign institution as well as their U.S. employer. The purpose of such

solicitations is purportedly to improve the international ranking of the foreign research institution, not to subvert security protocols. However, research administrators were not pleased that their investments in their scientists were being exploited. This situation also raised concerns about personnel reliability and scientists' vulnerabilities to elicitation by groups or individuals with malicious intent.
    - Although a few research administrators were aware that their scientists were solicited, most other institutional officials at the meeting began to question whether their scientists also were being solicited by foreign research institutions.
- Meeting participants discussed examples in which scientists have been asked to publish their data in scientific journals without listing the senior project researcher. Many scientific journals have policies in place requesting authors to describe and/or certify their contributions to the submitted article.

Suggested Action Items

The challenges of supporting research that involves scientists and research institutions from different countries are complex and require strong communication and coordination among all parties involved. Participants identified gaps in current knowledge and/or available resources to adequately address several of the problems presented in the previous section. They suggested specific action items to build the knowledge base and institutional resources needed to address current challenges in ensuring safe, ethical, and secure research practices with their research staff and international partners. **These suggestions, which are listed below, do not indicate source of funding, ease of implementation, or support for carrying out the action items.**

Safety, Security, and Ethics

1. The scientific community should develop community norms that clearly define acceptable and unacceptable research conduct and practices.

2. The U.S. Government or research institutions should develop guidance for research administrators and scientists to resolve differences in safety and security regulations between collaborating countries.

3. Member associations should establish a forum wherein research administrators can share their experiences and concerns with their peers to identify possible ethical violations, share practices that address those violations, and discuss lessons learned from actions taken to address violations. The AAU, APLU, and Council on Government Relations have established forums that might provide a venue for such information sharing.

4. The U.S. Government should catalog relevant laws and regulations from around the world to anticipate differences in risk perception and risk mitigation between scientists trained in the U.S. and those trained or working in other countries.

5. Research institutions should train scientists from all disciplines and at all levels of experience in responsible conduct of research (RCR) and broader security issues. Implementation of comprehensive training programs would require additional funds to support administrative and educational investments, which are often shouldered by the research institution.

6. Research institutions should educate scientists about responsible communication of research results to ensure that information sharing maximizes the benefits and minimizes the risks of the research.

7. Whenever possible, the FBI should communicate with research administrators, who have contacted FBI WMD Coordinators about potential security concerns at

their institutions. The FBI should continue to link research institutions and state and local law enforcement agencies if the situation requires.

Need for Applied Research

8. The U.S. Government, research institutions, and relevant trade associations should cooperate to develop laboratory safety measures and laboratory security practices based on applied research.

9. The U.S. Government, research institutions, and relevant trade associations should cooperate to develop research ethics training programs based on applied research.

10. The U.S. Government, research institutions, and relevant trade associations should cooperate to better understand the psychological and behavioral characteristics that lead to misuse.

11. Research institutions and scientists should develop quantitative approaches to measure the effectiveness of training programs. These approaches should involve equivalent comparisons to evaluate the impact of safety, security, and research ethics training programs.

Enabling International Partnerships

12. Research institutions should develop guidance and financial support systems to help scientists build international dimensions of their research activities.

13. The U.S. Government and research institutions should cooperate to catalog regulations, needs for scientific infrastructure, and costs involved in building the international dimensions of research efforts in an easily accessible format.

14. Research institutions should develop a clear set of minimum criteria that could help support international scientific collaboration with U.S. research institutions. The criteria would include information about the basic research infrastructure and educational components needed to support collaborative efforts.

15. Member associations should collect information about scientists' and research administrators' experiences when working with foreign colleagues, including specific challenges faced, surprises encountered, and processes that were easy to navigate. This information could be compiled into a best practices guide for institutions, a how-to guide for scientists, and a mentorship program for scientists to facilitate the development of international scientific partnerships.

16. Scientists should define intellectual property rights and develop a technology control plan whenever entering an international collaboration. Technology control plans include plans for physical, information, and personnel security.

Oversight of Research

17. Research institutions should increase communication and develop partnerships with relevant offices within their university to identify instances when: a) scientists are inappropriately approached by foreign institutions or entities; and b) scientists do not comply with institutional policies or national regulations by working abroad.

18. Research administrators should establish "brown-bag" sessions at research institutions to help identify and address problems associated with the process of international scientific collaboration.

19. Research institutions should develop a system for initial and ongoing psychological evaluations and encourage reporting of questionable behavior.

Appendix 1:
Meeting Agenda

BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH: INTERNATIONAL BIOLOGICAL SCIENCE AND BIOSECURITY

February 4-5, 2013
Washington, DC

Agenda

Day 1 (February 4, 2013)
Location: Zentan, Donovan House, 1155 14th Street, N.W. Washington, D.C.20005

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

Speaker: *M. Peter McPherson, J.D.,* Association of Public and Land-grant Universities

Day 2 (February 5, 2013)
Location: AAU, 5th Floor, 1200 New York Ave, NW, Washington, DC 20005

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

8:30 – 9:45 **Setting the Stage: Biological Research in Today's Global Research Environment**

Speaker: *Samuel Stanley, M.D.,* Stony Brook University

9:45 – 11:15 **Intersection between Science and Security Globally**

Moderator: *Piers Millett, Ph.D.,* United Nations

Scientific: *Randall Rettberg,* International Genetically Engineered Machine (iGEM) Competition

Larry V. McIntire, Ph.D., The Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University

Security: *Stacey Mantha, MSc,* Public Health Agency Canada
Robbin Weyant, Ph.D., Centers for Disease Control and Prevention

11:15 – 11:45 **Break**

11:45 – 12:45 **Working Lunch: Current Challenges Associated with Biological Research with Foreign Students, Faculty, Staff, and Collaborative Partners**

Moderator: *F. Gray Handley, M.S.P.H.,* National Institute of Allergy and Infectious Diseases

Panelists: *Bertram Jacobs, Ph.D.,* Arizona State University
Special Agent Janel Lobur, Ft. Detrick FBI Field Office

12:45 – 1:45 **Education and Workforce Development for Promoting Shared Understanding and Best Mitigation Practices of Security Risks**

Moderator: *Judi Sture, Ph.D.,* University of Bradford, UK

Panelists: *James LeDuc, Ph.D.,* University of Texas, Medical Branch
Elizabeth Heitman, Ph.D., Vanderbilt University

1:45 – 2:15 **Break**

2:15– 3:15 **Creating an Enabling Scientific Environment for Promoting International Scientific Partnerships between Biological Scientists**

Moderator: *DeAndra Beck, Ph.D.,* National Science Foundation

Panelists: *Scott Steele, Ph.D.,* University of Rochester
Tom Arrison, National Academy of Sciences

Discussant: *Caroline Whitacre, Ph.D.,* The Ohio State University

3:15 – 3:30 **Break**

3:30 – 5:00 **Suggestions for Jointly Addressing Current Concerns and Challenges with the FBI**

	Moderators:	*Carrie Wolinetz, Ph.D.*, Association of American Universities
		Kavita M. Berger, Ph.D., American Association for the Advancement of Science
		Supervisory Special Agent Edward You, Federal Bureau of Investigation
		Kari McCarron, Association of Public and Land-grant Universities
5:00	**Adjourn**	

Appendix 2:
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