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Senator Ursula Stephens
Chair
Senate Foreign Affairs, Defence and Trade Committee
Parliament House ACT 2600
By email: fadt.sen@aph.gov.au

Dear Senator Stephens

Implementation of the Defence Trade Controls Act 2012 (Cth)

Thank you for the opportunity to make a submission to the Senate Foreign Affairs, Defence and Trade Committee's scrutiny of the first six months of implementation of the provisions of the *Defence Trade Controls Act 2012 (Cth*) ('**the Act**'). After dedicating considerable time and resources engaging with the parliamentary processes that ultimately led to the passage of a significantly amended Bill in October 2012, the University of Sydney has stepped back somewhat from this next phase of legislative process. We have, however, been monitoring the Government's approach to implementation through the important early work of the Strengthened Export Controls Steering Group (**SECSG**). We have also continued to participate in domestic and international discussions about approaches to minimising national security and other risks arising from dual use research of concern ('**DURC**').

For example, in February 2013 I attended and spoke at an international conference on DURC at the invitation of the World Health Organisation ('**WHO**'). The objective of the meeting was to bring policy-makers, researchers, industry and other stakeholders from around the world together to:

- identify key issues of concern related to DURC;
- understand existing approaches to its management as well as gaps; and
- explore actions that could be taken globally and locally to better manage the inherent risks.

One of the 'take-home' messages from the gathering was that Australia's approach to managing DURC is at odds with the approaches being taken in many other developed democracies. In particular, other nations do not manage these issues primarily through a legislated permit and individual Ministerial approval regime for the public dissemination of DSGL technology. The approach we have adopted is also distinct in that the Defence Minister is solely responsible for the administration and oversight of the permit and approval regime. Moreover, control decisions are to be made based only on advice from the Department of Defence even though they will invariably involve the weighing of complex national security risks against broader public interest considerations. This includes potential Ministerial controls covering an exceptionally broad range of technologies from munitions through to life sciences and telecommunications.

Another key theme emerging from the conference was that transparency and ongoing communication between a very broad range of sectors and stakeholders (but especially between security and scientific communities) are essential if we are to establish the dynamic of shared-responsibility, cooperation and trust that will be necessary to manage DURC issues effectively. Please find **attached** the report on the outcomes of the WHO conference which I commend to the Committee.

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The critical importance of dialogue and cooperation between policy-makers, researchers and security agencies involved with DURC was also emphasised in an excellent report released jointly in November 2012 by associations of American universities and the FBI. That report, which I **attach** for the Committee's reference, concluded among other things that:

- a robust dual use review depends on scientists, research administrators, and security experts working together and openly communicating with each another;
- educating security experts and policy-makers about the process of conducting science, the many reviews associated with biological research (i.e., human and animal subjects protection and recombinant DNA review), the *benefits* and risks of the research, and measures taken to minimise the ethical, safety, and security risks of research are equally important in ensuring that dual use assessments are balanced and objective; and
- open and transparent communication among scientists and research administrators about the plausibility, possibility, and range of risks that research could pose is critically important to ensuring that dual use assessments are conducted in a balanced and objective manner.

It is encouraging that the SECSG's membership includes representatives of the university sector, the funding councils, industry and the department responsible for science, research and innovation. It is not yet evident, however, that the levels of communication and transparency from the SECSG and the Department of Defence have been sufficient to raise awareness in the research community about the need to prepare for the impending commencement of the permit requirements under Section 11 of the Act (permits for the supply of DSGL technology). Levels of awareness about the reforms and the implementation process remain low across the research sector. Among those researchers who are aware of the passage of the legislation there remains considerable confusion about what will be required of them once this section enters into force following the commencement of the U.S. and Australia *'Defense Trade Cooperation Treaty',* and when this will occur.

This is important in relation to the contractual arrangements that research organisations are entering into as the implementation process continues. While the section 14(A) offence for the publication of DSGL technologies will not come into effect until two years after the day the U.S. Treaty starts, universities and other research organisations continue to commit to research projects without certainty about whether these investments will be jeopardised through the imposition of controls at some point in the future. We acknowledge that the SECSG has provided some useful information on its website targeted at research organisations and individual researchers. Nevertheless, levels of awareness about the website and the implementation process more broadly remain low. There is much more that the SECSG and Defence could be doing to raise visibility about the implementation process through the investment of some modest resources, and by collaborating with the peak bodies representing affected sectors. The roll-out of such a communication campaign would also serve to enhance levels of compliance once the various elements of the regime take effect.

Ongoing and open communication between the SECSG and the leadership of the research community throughout the implementation phase will also be vital in terms of building awareness, and raising levels trust and confidence in the process. In this regard we note that the university sector's representatives on the SECSG have been unable to provide much information to their constituencies about the work of the SECSG because of confidentiality undertakings they have been required to sign by Defence. Moreover, we note that while a number pilots sites have been selected to test the proposed governance and processes, except for a program involving wheat rust research run by the Grains Research and Development Corporation, no specific details have been provided (to the university sector at least) about the location of the pilots, the types of research involved, or of the educational, governance and administrative processes that are being deployed for the pilots. If university participants in the pilots have also been required to sign broad confidentiality agreements, this should be of significant concern to the sector and the Committee.

We are pleased to read through the SECSG's website that consideration is being given to using the *Australian Code for the Responsible Conduct for Research* (the '**Australian Code**') as a

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vehicle for consulting with the research sector to agree best practice processes for managing DURC at the local level, including the investigation of non-legislative alternatives to managing the dissemination of controlled DSGL technology to the public. We strongly support this work, but note that if the publication offence (section 14A) is to remain in the Act, the inclusion of the 'public interest' test in that section will necessitate the establishment of coherent and appropriately funded institutional and/or national discipline/cross-disciplinary publication review processes. Such structures will be needed to ensure that when making decisions to allow or prohibit the publication of restricted DSGL technology, the Minister for Defence receives advice through a transparent process that is informed by both security and scientific perspectives and expertise about the balance of potentially competing risks and benefits.

In addition to ongoing dialogue about proposed amendments to the Australian Code and section 14A of the Act, it would be useful for the research community to understand the level of analysis that is being undertaken to assess alternative approaches to legislative controls that are being adopted internationally. For instance, what policy or other analysis has or will be undertaken of the security risks posed by controlling publication by accredited higher education providers and the corporate research industry across the full breadth of the DSGL technology? Additionally, what analysis has or will been conducted to address whether or not the amendments to the Australian Code or other non-legislative measures could reasonably meet security concerns, particularly in light of other existing Australian legislation?

The University of Sydney believes that as the implementation process progresses, Australia can learn much from the collaborative approach to the management of DURC that is being taken in the U.S. in the life sciences in particular. This has featured the adoption of a whole-of-government approach and meaningful dialogue and trust building between security agencies and the scientific community led by their national academies and the National Science Advisory Board for Biosecurity ('**NSABB**'). As the U.S. Oversight Policy on Life Sciences Dual Use Research of Concern 2012 states:

> *"Measures that mitigate the risks of DURC should be applied, where appropriate, in a manner that minimises, to the extent possible, adverse impacts on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavours to preserve and foster the benefits of research."*

We trust that these comments, along with the overview of relevant recent international developments contained in the attachments, are helpful to the Committee as it scrutinises the first six months of the Government's approach to implementing the Act.

Yours sincerely

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Appendices

A. World Health Organisation, *Report of the WHO informal consultation on Dual Use Research of Concern, Geneva, Switzerland, 26-28 February*, May 2013

B. American Association for the Advancement of Science, the Association of American Universities, the Association of Public Land-grant Universities, the Federal Bureau of Investigation, *Bridging Science and Security for Biological Research, A Discussion about Dual Use Review and Oversight at Research Institutions, Report of a meeting held 13-14 September 2014*, December 2012

Report of the WHO Informal Consultation on Dual Use Research of Concern
Geneva, Switzerland
26-28 February 2013
World Health Organization

Background

In 2011 research on the genetic basis of the transmissibility of H5N1 conducted by two groups (one in the Netherlands[1] and the other a joint Japan/USA group[2]) resulted in the creation of laboratory-modified H5N1 viruses capable of respiratory transmission between ferrets; these findings raised a number of issues. On 16–17 February 2012, WHO convened a technical consultation to address the most urgent concerns, including the scientific and public health benefit of the studies, management of the laboratory-modified viruses and public dissemination of any findings. These experiments were considered to be examples of dual use research of concern (DURC), i.e. life sciences research intended for benefit, but with results which might easily be misapplied to produce harm.

During that meeting, several issues relating to the ethical, societal, scientific, security and safety implications of DURC were noted but not explored in detail. There was general agreement that WHO should facilitate a broader discussion. In response, WHO convened a wider, informal, consultation on 26−28 February 2013.

Purpose and organization of the consultation

The purpose of the consultation was to identify key issues and concerns related to DURC; to identify existing management approaches and gaps in dealing with such concerns; and to explore possible actions and mechanisms to close the gaps.

Participants were individuals with a wide range of professional backgrounds who came from countries in all WHO Regions. Plenary sessions provided an overview of life sciences research and its associated benefits and challenges. A series of panel presentations introduced a range of perspectives on different aspects of DURC. The major work of the consultation was accomplished in eight breakout groups: research and public health; ethics; security; outreach and education; international issues; publishing and communications; biotechnology and the private sector; and societal impact.

Overview of the benefits and challenges of life sciences research

[1] Herfst S et al. Airborne transmission of influenza A/H5N1 virus between ferrets. Science 2012; 336: 1534-41.
[2] Imai M et al. Experimental adaptation of an influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets. Nature 2012; 486:420–28.

All countries benefit from life sciences research. It has generated the most important biomedical and public health advances in recent decades. The development of state-of-the-art vaccines (e.g. vaccines for hepatitis B virus and human papilloma virus); drugs (e.g. recombinant insulin and blood clotting factors); and diagnostics (e.g. tests for hepatitis C virus and human immunodeficiency virus) have been possible because of life sciences research. The accelerated pace of life sciences research is facilitated in part by widespread access to information and communication technologies, the availability of faster and higher-capacity technological tools, and the ever-decreasing cost of technology.

These advances, however, also present new challenges as good science can be put to bad uses. Gene cloning (i.e. copying) techniques that have led to new vaccines could be misused to produce a harmful toxin or to increase the virulence of a microorganism capable of infecting humans. Beneficial applications of synthetic biology include the development of new drugs; misapplication of this discipline could lead to the design of new or modification of existing pathogens as agents of bioterrorism.

Much of the knowledge and technologies generated by legitimate life sciences research could theoretically have *some* potential to be misused. DURC, however, comprises a limited subset of all life sciences research, i.e. research intended for beneficial purposes, but which might *easily* be misapplied to do harm. In addition to the previously noted H5N1 studies, a limited number of other research studies have raised concerns about the potential for ready misuse and subsequent consequences for public health, safety and national security.[3]

Management of DURC-related risks has been approached in several ways, including: 1) research oversight mechanisms; 2) policies for funding agencies; 3) international and national regulations and frameworks, such as the International Health Regulations (2005) and the Biological and Toxin Weapons Convention; 4) institutional and professional codes of conduct and ethics; and 5) awareness-raising and educational initiatives for a range of audiences.[4] Some of these approaches have included criteria or descriptions of the types of research that would trigger concern and further evaluation;[5,6,7,8] such as experiments that would:

- demonstrate how to render a vaccine ineffective

[3]World Health Organization. Responsible life sciences research for global health security: a guidance document. Geneva 2010. Available at: http://www.who.int/csr/bioriskreduction/lifesciences_research/en/.
[4] WHO, 2010.
[5] United States Government policy for institutional oversight of life sciences dual use research of concern. Available at: http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf.
[6] National Research Council on Research Standards and Practices to Prevent the Destructive Application of Biotechnology. Biotechnology research in an age of terrorism. Washington, DC, National Academies Press, 2004.
[7] Miller S and Selgelid MJ. Ethical and philosophical consideration of the dual-use dilemma in the biological sciences. Dordrecht NE, Springer, 2008. Report prepared by the Centre for Applied Philosophy and Public Ethics at the Australian National University for the Australian Department of Prime Minister and Cabinet, National Security Science and Technology Unit, November 2006.
[8] Steinbruner J et al. Controlling dangerous pathogens – a prototype protective oversight system. Center for International and Security Studies at Maryland (CISSM), 2007.

- confer resistance to antibiotics or antiviral agents
- enhance the harmful consequences of a pathogen or toxin or render a non-pathogen virulent
- increase the transmissibility of a pathogen
- alter the host range of a pathogen or toxin
- enable evasion of diagnostic or detection modalities
- enhance the susceptibility of a host population to a pathogen or toxin
- generate or reconstitute certain eradicated or extinct pathogens or toxins
- enable weaponization of a biological agent or toxin.

Oversight mechanisms are essential, and codes of conduct are important in ensuring awareness and building commitment to an ethically aware, legitimate research enterprise, but would likely have minimal impact on those who operate outside the system and are intent on causing harm.

Consultation

The deliberations of the breakout groups and the panel and plenary discussions identified a number of issues, concerns and gaps related to the conduct and management of DURC; possible actions to respond to these problems were also considered. These discussions are summarized in the following issue-oriented perspectives and themes.

<u>DURC is an issue for all countries and multiple stakeholders</u>

Scientific research is conducted in virtually all countries and is critical to strengthening global response to all health threats and hazards, including those posed by naturally occurring and by accidentally or intentionally released biological agents. The only way to eliminate the potential for misuse of DURC is to not perform research. Such an extreme solution, however, is neither feasible nor advisable. The global capacity to detect, monitor, counter and prevent well characterised or emerging and re-emerging infectious disease threats such as AIDS, severe acute respiratory syndrome (SARS), and pandemic influenza relies on the tools and techniques generated by life sciences research. Finding solutions to mitigate and manage the inherent risks associated with DURC, therefore, is essential to global health security.

Although a major focus of the discussion was on biological research that relates to human health, DURC is also applicable to animal and plant health and can apply as well to research in non-biological fields (such as engineering or information technology) that bears on human, plant or animal health. Participants noted the importance of strengthening links across these fields to illuminate the range of DURC origins and expressions. DURC has implications for a broad range of sectors and stakeholders, including, among others, researchers, public health professionals, the security community, funding agencies, professional societies, electronic and print publishers and media, the legal community, national governments and other oversight bodies, and civil society.

The management of DURC-related risks should take into account all stages of the research cycle

Consideration of dual use potential should start early in the research process, from the time of initial conceptualization and development of a proposal, to review and provision of funding, to conduct of the research, analysis of results, storage and potential use of material results, including modified biological agents, and dissemination of findings.

Participants noted many gaps and uncertainties in the management of DURC-related risks along this continuum. Researchers are familiar with the identification and management of laboratory biosafety[9] and biosecurity[10] issues. Regulatory approaches, including tools, training and guidance for biosafety and biosecurity, are available to assist with implementation and compliance. In contrast, there is less awareness and knowledge about "information security" issues in the scientific community. Scientists, not surprisingly, may not always recognize the potential risk for misuse of their research nor know how to reduce this risk. The expertise of the security community is more attuned to assessing and identifying research methods and findings that could be misused. In addition, information about the potential implications for DURC may not be apparent at the start of a research project, as research can sometimes lead to unanticipated results. There may be benefits, therefore, in periodic review of research projects in progress to consider if any issues, including potential for dual use, have arisen.

Representatives of funding agencies outlined their approaches to reduce potential risks for misuse of information generated by research they support. Some funding agencies have developed targeted policies and procedures for DURC, with clear requirements for assessment before approval of funding, and through the periodic reviews performed during the course of the project. Others rely on institutional requirements, national laws and/or guidelines relating to biosecurity, ethics and the like.

Efforts to limit the spread of harmful information at the point of publication are particularly difficult and may be of limited effectiveness. Review for DURC implications should begin far earlier in the research cycle. There are no standard procedures for handling manuscripts with the potential for misuse of information. Some journal editors have devised different mechanisms for papers that may require additional internal and/or external deliberation. In some instances, authors may be asked to provide clarifications and added text on the risks and benefits of research findings.

The value of redacting text in a manuscript as a means of limiting risk was a point of dissent among participants. Redaction presents difficult challenges and choices: there are no agreed guidelines on how to do this; there is a lack of clarity as to how to control information, who has the right to know it and who does not. Redaction also assumes that information can be successfully restricted. Participants noted, however, that legal mechanisms to do this may be lacking. If redaction is not used, journal editors

[9] Laboratory biosafety refers to the containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents, toxins, or their accidental release. WHO, 2010.
[10] Laboratory biosecurity refers to the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. WHO 2010.

have a limited number of options, such as adjusting the timing of publication or commissioning an accompanying paper on risks and benefits. If the decision is made not to publish, authors may submit their work to other journals or simply post it on the internet.

Journal editors emphasized the lack of guidance regarding: the type of research to be concerned about; how to screen for such papers; who to involve in discussions; and who has ultimate responsibility for identifying and resolving situations with potential DURC manuscripts. The range of stakeholders identified in publishing and communications is extensive: academic and industrial scientists, conference organizers, funding agencies, general media, amateur scientists, and scientific societies are amongst those who should be engaged.

Research oversight mechanisms are important

Some countries and institutions have developed oversight mechanisms to manage DURC-related risks. Many, however, have not done so, owing to competing demands on resources and capacity, limited awareness of the issue, or a perception that it is not relevant to their particular context or priorities. Nonetheless, oversight mechanisms that take into account both the benefits of undertaking such research as well as the risks are important.

Development of oversight mechanisms that are effective but do not compromise the conduct of legitimate research and access to research findings is very challenging. Assessing whether research methodologies and/or findings constitute DURC requires an understanding of adversaries' capabilities and intent, as well as an in-depth understanding of the experimental details. Even with training and expert input, differences may arise when assessing the potential for misuse. The near- and far-term benefits of research may not always be immediately evident. Similarly, risks can be difficult to quantify as biological systems are complex. Oversight mechanisms for DURC, nonetheless, should be commensurate with risk. The increasing aversion to risk by society and policy makers was noted with concern as it may inhibit or impede research that can lead to improvements in health and in economic and social development. The ability to perform the research required for response and control of serious health events is crucial and must be preserved.

There was wide agreement that it is in everyone's best interest to have full and open access to research methodology and results. This allows for validation or repudiation of research findings; it facilitates scientific progress by allowing researchers to build upon other findings; it fosters public trust; and it is essential for international collaborations, an increasing hallmark of contemporary research. The potential risks of full and open communication would be expected to outweigh the benefits in only the rarest circumstances. Security classification and export controls are tools that are available to many countries for use in those rare circumstances where restricted communication is necessary.

Research undertaken in the private sector poses special challenges. The private sector cuts across a wide and diverse swath of academia, industry, non-profit organizations, contract research organizations, small and medium-sized enterprises, trade associations, industry consortia, and investors, amongst

others. The decreasing cost of technological tools has encouraged the involvement of more people, including the "do-it-yourself" or home experimenter and small "start-up" companies. Technological advances make it possible for research findings to be widely disseminated. Some, but not all, entities in the private sector fall under traditional mechanisms for oversight and regulation; oversight of those that do not may be limited. Intellectual property regulations may impede the dissemination of potentially harmful information, but also hamper assessment of the full scope of research being undertaken. Outreach and education, therefore, are essential to help ensure that the private sector is aware of DURC and of the potential for misuse of research information. Inclusion of a wider range and number of participants from the biotechnology and private sector is to be encouraged in discussions about DURC.

Enhancing capacity in laboratory biosafety and laboratory biosecurity is a more immediate concern for developing countries; many countries lack capacity for managing DURC but do not currently see this as a priority, as they face other urgent health challenges. Oversight mechanisms enacted in more developed countries, however, can have substantial impacts on developing countries and limit opportunities for collaborative research, training and access to research materials.

Managing DURC at country level: a diversity of approaches

The inventory, sharing, and, where needed, development, of guiding principles, toolkits, best practices and other forms of technical assistance would help countries formulate their own policies and procedures for managing DURC. Although establishment of a legally binding global agreement or regulation is theoretically possible, such an approach would be expensive, slow, likely impractical and would not necessarily yield the desired benefits.

The lengthy and complex review of the two H5N1 experiments underscored the need for 1) clarity on the types of research that should trigger further examination for issues of biosafety, biosecurity and DURC and 2) criteria and practical tools for weighing the relevant interests of all stakeholders involved at all stages of the research process.

There was a diversity of views on how to meet these needs. Many countries and institutions have chosen to emphasize the role of self-governance by the scientific community and the need to embed dual use management measures into existing research oversight mechanisms. International regulations, frameworks, initiatives and prototypes, such as the International Health Regulations (2005), the Biological and Toxin Weapons Convention (BWTC), the Center for International Security Studies' Biological Research Security System, and institutional and professional codes of conduct could serve as potential resources for countries when developing policies and procedures for DURC. It was observed, however, that these approaches are unevenly implemented across countries, they are not coordinated or harmonized and none of them sufficiently addresses DURC. While some participants expressed support for global harmonization of standards, others advocated for adaptation of a set of fundamental principles to design locally appropriate approaches.

The lack of global guidance or a framework for management of DURC that bridges the many stakeholder communities was repeatedly noted as a critical gap. Suggested elements for global guidance/framework

included overarching principles, categories of experiments of potential concern, and strategies for risk/benefit assessment and mitigation of risk. Development of such a framework would require a forum where key stakeholders, governments and international organizations can come together. Participants emphasized that WHO could play a vital role in convening in this regard. International organizations such as the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE) can play a similar role for agriculture and animal life sciences research.

Communication across a broad range of sectors and stakeholders is essential

Communication and continuing dialogue across a broad range of sectors and stakeholders are essential to create a culture of responsibility, cooperation and trust. In particular, improving mutual understanding of the various approaches to risk identification and assessment among stakeholders will be critical to establishing that dialogue.

It was acknowledged that at times a certain amount of tension or distrust has characterized the relationship between the security and scientific communities. The inability of security experts to share specific information about the likelihood of misuse and harm from research findings creates a level of asymmetry in the relationship between the two groups. The two groups, however, are reliant upon each other: researchers need the expertise and advice of security experts to assess potential security risks associated with DURC, and the security community depends on scientists for technical information and perspectives on non-security contexts to help inform their assessment. Security experts noted the complexities in assessing and quantifying risk for what may be unpredictable and/or low probability events, but which entail a high impact should they occur. It was observed that a very similar challenge was faced by public health scientists working on severe emerging diseases, and that there might be ways to develop a common language and compatible methodologies for describing risk. An optimally functioning relationship between scientists and security experts requires mutual engagement to bridge gaps in communication, collaboration and culture.

The public is an essential stakeholder in DURC. Openness and transparency about DURC can help to ameliorate public fears, counter rumours and misinformation, and increase public confidence. Participants allowed that efforts to increase the public's understanding of DURC, including both the benefits and risks of such research, and the role of biosafety and biosecurity measures have been limited. Inequity of access to technology and the benefits of life science research, including DURC, can feed public mistrust.

The audiences for education and training are diverse

Awareness-raising, education and training on biosafety, biosecurity and DURC are essential not only for researchers but also for all sectors and stakeholders. It needs to occur at all levels—global, national, institutional, and the individual investigator—and incorporate diverse perspectives, including those of foreign ministers, policymakers and regulators. Training researchers and students who will become researchers was particularly emphasized.

Education and training must be practical and suitable for a wide range of audiences; it can include guidance, toolkits, best practices, and case studies. Incorporation of DURC into existing curricula and educational programs may be efficient and economical. Codes of Conduct are another way to increase awareness of biosafety, biosecurity and the potential for misuse of life sciences research. It is important that all forms of outreach and educational training provide information about both the benefits as well as the risks of DURC.

Education and communication activities have been hampered by significant challenges. The lack of standardized definitions and terminology that are universally accepted across sectors and stakeholders leads to confusion and misunderstanding as does the lack of harmonization among existing guidelines, regulations, codes of conduct and the like. Guidance and tools to identify and manage risks require significant development and must include the entire spectrum of the research process from inception to publication. Training for DURC can be integrated with other capacity development activities for developing countries. Many countries will require financial as well as technical support to undertake culturally and contextually appropriate education and training.

Ethical considerations are fundamental to management of DURC

Questions about the governance of dual use life science research of concern are inherently ethical in nature: what are the responsibilities of various actors; how can the benefits of research, including DURC, be promoted while avoiding harm or minimizing risk; and how can conflicting or divergent priorities be reconciled, i.e. the importance of scientific freedom and progress versus the importance of security.

DURC raises ethical questions for a broad range of sectors and stakeholders at different hierarchical levels of the governance of science:

- individual scientists who must decide what research to conduct and to publish
- research institutions, which must decide, among other considerations, how to regulate research within their confines; how to educate their researchers; and which laboratory security measures should be in place
- funding organizations, which must decide how considerations of DURC are incorporated in the application and review processes
- professional societies, which must make decisions about the development, promulgation and/ or enforcement of codes of conduct and education
- editors and publishers, who must make decisions regarding the review and publication of potentially dangerous papers
- national governments, which must decide the extent to which important considerations such as review of research and the relevant education of scientists will be mandated, how to bring in the essential stakeholders to formulate sound policies, if/which DURC can be funded, and the extent to which controls should be placed on access to potentially dangerous material
- international organizations, which must make decisions concerning relevant global policy.

As in other areas of ethics, absolutist or polarizing approaches to governance of DURC should be avoided. The diversity of actors demands a multi-pronged approach to governance of DURC. Diverse kinds of measures working in concert (a “web of prevention”) offer the best chance of achieving a successful balance between benefit and risk. The global consequences of DURC are such that no single national approach can fit the needs and concerns of all countries.

Some participants noted that the degree to which research ethics are prioritized varies across the world. Different levels of resourcing in comparison to acute needs, cultural differences, the way some ethical guidelines are developed and disseminated, and misconceptions about their application all contribute to this. Enlightened leadership, which values ethics, along with vision, safety, responsibility and accountability, as essential components of high-quality research should be embraced and promoted.

Next steps

This informal consultation provided an opportunity to explore a wide range of the complexities and interdependencies posed by consideration of DURC. Robust and beneficial life sciences research must be balanced with measures to reduce potential misuse or misapplication of knowledge. WHO will engage with Member States and others to assess how best to encourage effective approaches.

Prepared by the American Association for the Advancement of Science
in conjunction with the Association of American Universities,
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Bridging Science and Security for Biological Research:

A Discussion about Dual Use Review and Oversight at Research Institutions

Report of a Meeting September 13-14, 2012

AAAS
ADVANCING SCIENCE, SERVING SOCIETY

ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES

BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH: A DISCUSSION ABOUT DUAL USE REVIEW AND OVERSIGHT AT RESEARCH INSTITUTIONS

Meeting Report
September 13-14, 2012
Washington, DC

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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 59 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 its relationship with that community, 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 American Association of 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 preventing 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 administrators from small, medium, and large research institutions to share best practices and lessons learned about the review and oversight of dual use research with each other and with the security and policy-making communities. Participants described existing oversight programs that were developed to minimize the risk of dual use research with adverse potential and the challenges they faced in implementing those programs. The information shared at this meeting will have particular relevance to current policy discussions and proposed policies, guidance, and regulations that seek to address the dual use dilemma.

Background

> *I am not an advocate for frequent changes in laws and constitutions. But laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions change, with the change of circumstances, institutions must advance also to keep pace with the times.*
>
> - Thomas Jefferson

The concern that knowledge, technologies, and techniques could be misused to cause harm is not new. In fact, concerns about the possibility that basic, fundamental research could pose national security risks have surfaced time and again during the past several decades. In the physical and mathematical sciences, scientists and security experts worked together to develop mutually acceptable policies, regulations, and programs that resulted in an environment that promoted basic research while minimizing potential national security risks. Until relatively recently, similar security concerns were not raised for life sciences research and consequently, similar interactions and levels of cooperation did not occur in the life sciences or biotechnology sector. Without adequate input from each sector about the security or scientific context within which the research is conducted, scientists, security experts, and policy-makers run the risk of inadvertently under- or overestimating scientific and/or security considerations involved in identifying possible national security risks of biological research. This situation could lead to the development of measures that might not be commensurate with the actual risk or are inappropriately restrictive (e.g., classification of research), either of which could affect the degree and type of actions taken to minimize possible risks and jeopardize transparency of U.S. infectious disease research.

The emergence of recombinant DNA technology in the early 1970s,[1] development of new encryption schemes,[2] open communication of university-based scientific and technological advancements,[3] and greater investment in research on harmful infectious diseases[4] are among the issues that have raised concerns within the national security community. Scientists were able to address the safety concerns of recombinant DNA by

[1] Petro, J. B. Intelligence (2007) Support to the Life Science Community. Mitigating the Threats from Bioterrorism. Available at https://www.cia.gov/library/center-for-the-study-of-intelligence/csi-publications/csi-studies/studies/vol48no3/article06.html. Accessed: September 28, 2012.
[2] National Research Council. (1982) *Scientific Communication and National Security.* National Academies Press (Washington, DC), p. 120-125. Available at: http://books.nap.edu/catalog.php?record_id=253. Accessed: September 28, 2012.
[3] National Research Council. (1982) *Scientific Communication and National Security.* National Academies Press (Washington, DC). Available at: http://books.nap.edu/catalog.php?record_id=253. Accessed: September 28, 2012.
[4] National Research Council. (2004) *Biotechnology Research in an Age of Terrorism.* National Academies Press (Washington, DC). Available at: http://www.nap.edu/catalog.php?record_id=10827. Accessed: September 28, 2012.

self-regulating,[5] whereas the U.S. Government issued high-level policy to address concerns about the open communication of basic research.[6] In addition, addressing the risks of sharing information about research on encryption methods and devices resulted in the implementation of unclassified research programs at an intelligence agency to clarify the boundary between unclassified and classified cryptography research.[7]

Two significant events occurred during the early 1970s that influenced the current legal environment within which biological research is conducted in the United States. Approximately 40 years ago, the emergence of recombinant DNA technology raised concerns about laboratory safety.[8] These concerns lead to a voluntary moratorium on the use of the technology until the risks and mitigation strategies were adequately addressed. This lead to the 1974 Asilomar Conference on recombinant DNA where members of the scientific community, lawyers, members of the press, and government officials discussed the potential risks of recombinant DNA and developed possible guidelines for the safe use of the technology. These guidelines were subsequently promulgated to the entire biological sciences community by the National Institutes of Health.[9]

The adoption of the Biological and Toxin Weapons Convention (BWC) in 1972 was the other significant event influencing life sciences research in the United States and internationally. The BWC is an international treaty that both prohibits the development, production, and stockpiling of biological weapons and promotes the conduct and international collaboration on "peaceful and prophylactic" research.[10] The United States has implemented the provision of the BWC that prohibits the development of biological weapons by passing the Biological Weapons Anti-Terrorism Act of 1989 and related statues, policies, and guidance.[11] The U.S. also supports research and international collaboration on pathogens, toxins, and emerging technologies for legitimate, beneficial purposes, including for health, agriculture, environmental remediation, and infectious disease preparedness.

Since 2001, the United States has found itself in a difficult situation. On the one hand, the U.S. Government increased funding for biodefense research, such as vaccine and drug

[5] Berg, P., Baltimore, D., Brenner, S., Roblin, R. O., Singer, M. F. (1975) Summary Statement of the Asilomar Conference on Recombinant DNA Molecules. *PNAS*, 72(6), 1981-1984; Berg, P. (2004) Asilomar and Recombinant DNA. Nobelprize.org. Available at: http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1980/berg-article.html. Accessed: September 28, 2012.; Berg, P. (2012) The Dual-Use Conundrum. *Science*. 337(6100), 1273.
[6] President Ronald Reagan. (1985) National Security Decision Directive 189: National Policy on the Transfer of Scientific, Technical and Engineering Information. Available at: http://www.fas.org/irp/offdocs/nsdd/nsdd-189.htm. Accessed: September 24, 2012.
[7] National Research Council. (1892) *Scientific Communication and National Security*. National Academies Press (Washington, DC), p. 120-125. Available at: http://books.nap.edu/catalog.php?record_id=253. Accessed: September 28, 2012.
[8] Berg, P. (2004) Asilomar and Recombinant DNA. Nobelprize.org. Available at: http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1980/berg-article.html. Accessed: October 18, 2012.
[9] The *NIH Guidelines* for recombinant DNA research is available at: http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm. Accessed: October 18, 2012.
[10] United Nations Office for Disarmament Affair. (1972). Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. Available at: http://disarmament.un.org/treaties/t/bwc/text. Accessed: October 18, 2012.
[11] The relevant laws, regulations, policies, and guidelines are available at: http://www.phe.gov/s3/legal/Pages/default.aspx. Accessed: October 18, 2012.

development to prevent or treat natural, accidental, or deliberate infectious disease infections and biosurveillance tools to identify unusual infectious disease outbreaks. Simultaneously, the U.S. Government developed and implemented several more stringent security requirements to minimize the risk of theft, loss, accidental release, and/or misuse[12] of research with Select Agents, which comprise the majority of biodefense research efforts. It has also established a process for seeking advice, recommendations, and guidance on minimizing the risks of misuse of information, products, and methods from biological research.[13]

After the intentional release of anthrax through the postal system in 2001, security experts began identifying published scientific articles and research activities that they believed could be intentionally misapplied to pose significant risks to national security. Most of the research, technologies, and published results that led to these concerns involved routine genetic modification or chemical synthesis[14] of certain infectious diseases for a legitimate purpose (e.g., pest control[15] or scientific basis for infection control in people[16]). However, the concern that individuals or groups could use the results, products, or methods from legitimate biological research to inflict harm prompted several policy proposals from the scientific and security communities, ranging from the self-governance of scientists[17] and journal editors[18] to multilayered oversight systems to identify and modify research with the potential for misuse.[19] In 2004, the National Research Council published a report on the potential threats posed by the misuse of legitimate life sciences research. The committee responsible for this report adopted the term "the dual use dilemma" to describe the situation that the same knowledge, tools, and techniques involved in legitimate, beneficial research could be used to develop biological weapons.[20] It listed seven categories of experiments that could have dual use potential and recommended the establishment of a federal advisory body to "provide advice, guidance, and leadership for the system of review and oversight" of dual use research.[21]

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[12] Within the context of this report, "misuse" refers to the intentional use of legitimate, beneficial biological research results, methods, products, and technologies to cause harm.

[13] The primary vehicles for scientific input about the intentional misuse of research results and tools are the National Science Advisory Board for Biosecurity and federal register notices seeking public input.

[14] Cello, J., Paul, A.V., Wimmer, E. (2002) Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template. *Science*. 297(5583), 1016-1018.

[15] Jackson, R. J., Ramsay, A. J., Christensen, C. D., Beaton, S. Hall, D. F., Ramshaw, I. A. (2001) Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Resistance to Mousepox. *J Virol*. 75(3), 1205-1210.

[16] Rosengard, A. M., Liu, Y., Nie, Y. Z., and Jimenez, R. (2002) Variola Virus Immune Evasion Design: Expression of a Highly Efficient Inhibitor of Human Complement. *PNAS*. 99, 8808-8813.

[17] Kwik, G., Fitzgerald, J., Inglesby, T., and O'Toole, T. (2003) Biosecurity: Responsible Stewardship of Bioscience in an Age of Catastrophic Terrorism. *Biosec Bioterr*. 1(1), 27-35.

[18] Journal Editors and Authors Group. (2003) Statement on Scientific Publication and Security. *Science*. 299(5610), 1149.

[19] Steinbruner, J. and Okutani, S. (2004) The Protective Oversight of Biotechnology. *Biosec Bioterr*. 2(4), 273-80.

[20] National Research Council. (2004) *Biotechnology Research in an Age of Terrorism.* National Academies Press (Washington, DC). p. 19. Available at: http://www.nap.edu/catalog.php?record_id=10827. Accessed: September 28, 2012.

[21] National Research Council. (2004) *Biotechnology Research in an Age of Terrorism.* National Academies Press (Washington, DC). p. 118-121. Available at: http://www.nap.edu/catalog.php?record_id=10827. Accessed: September 28, 2012.

In 2004, the U.S. Government created the National Science Advisory Board for Biosecurity (NSABB). Its charter defined "dual use research" as "research with legitimate scientific purpose that may be misused to pose a threat to public health and/or national security."[22] The NSABB was charged to develop criteria for identifying dual use research; develop guidelines for the oversight of dual use research; provide recommendations on a code of conduct, and education and training programs for researchers; advise on national policies related to dual use research, including the communication and review of such research; review and provide guidance on addressing research with dual use potential; and recommend approaches for the international oversight of dual use research.[23] Since its inception, the NSABB has proposed criteria for defining dual use research, oversight approaches, a code of conduct toolkit, and communication strategies, and developed an education video and outreach strategies for dual use research. Because most life sciences research could pose potential dual use risks, however indirectly, the NSABB identified a subset of life sciences research that could be directly misused to cause harm, which they termed, "dual use research of concern." Building on the NSABB's proposed definition of "dual use research of concern," the U.S. Government has defined the term as:

> Research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.[24]

The NSABB also has provided recommendations on the minimization of biosecurity risks associated with synthesis of Select Agents, personnel reliability, and education of amateur biologists.[25] In addition, the NSABB has reviewed unpublished scientific papers, including the recent H5N1 influenza virus papers, for their potential "dual use research of concern."

The H5N1 Papers

For nearly 15 years, the threat of the highly pathogenic avian influenza H5N1 virus naturally acquiring mutations that would increase person-to-person spread of the virus has driven billions of dollars of

"It's not a possibility but a certainty that we will be facing this issue again."

[22] National Science Advisory Board for Biosecurity. 2008 Charter. Available at: http://oba.od.nih.gov/biosecurity/PDF/NSABB_Charter_508_accessible.pdf. Accessed: October 14, 2012.
[23] Shea, D. (2007) *Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity.* Congressional Research Service (Report Number RL33342). Available at: http://www.fas.org/sgp/crs/natsec/RL33342.pdf. Accessed: September 28, 2012.
[24] U.S. Government. (2012). United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. Available at: http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf. Accessed on October 15, 2012.
[25] The NSABB Recommendations are available at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html. Accessed: October 17, 2012.

investments in pandemic preparedness planning and research efforts in the United States and internationally. In 2006, the National Institute of Allergy and Infectious Diseases (NIAID) issued a request for proposals identifying the ways in which H5N1 influenza virus spreads within and between human and animal populations.[26] The rationale for this research was to provide public health officials with specific genetic or protein information that could be used to identify H5N1 viruses posing significant public health risks (i.e., influenza surveillance capability) and to develop vaccines and drugs to prevent or treat infection with viruses containing these mutations. A number of U.S. and international expert review panels set forth similar priorities and recommendations.[27]

In mid-2011, two independent research groups funded under the 2006 NIAID initiative – one in the United States and the other in the Netherlands – submitted papers to *Nature* and *Science*, respectively, that described the elements of the H5N1 virus that enabled rapid spread between ferrets[28] in the laboratory. Both groups considered the potential safety and security risks associated with the studies and conducted their research under appropriate biosafety and biosecurity conditions (biosafety level 3 enhanced laboratories).[29] In addition, the group from the United States used a 2009 H1N1 virus that contained the H5 protein, which is associated with a lower degree of risk than the H5N1 virus because current antiviral drugs are known to treat infection with the 2009 H1N1 virus. The Dutch group worked with a naturally-occurring H5N1 influenza virus.[30]

Both groups discussed their research and results at scientific conferences prior to submitting their papers to the journals. However, concerns about the potential dual use risks of the research results were raised only after these papers were submitted to *Science* and *Nature* in 2011. In January 2012, the top researchers from around the world who work with H5N1 influenza viruses voluntarily agreed to stop conducting transmission research studies until they clearly understood how to proceed with and communicate the research safely and securely. This self-imposed moratorium, which was initially intended to last 60 days,[31] is still in effect ten months after it began; U.S. policy-makers are currently developing the criteria that will allow the moratorium to be lifted.

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[26] National Institutes of Allergy and Infectious Diseases. (2009) *NIAID Influenza Report: 2009 Progress Report, Appendix A*. Available at: http://www.niaid.nih.gov/topics/Flu/Documents/fluresearch09.pdf. Accessed: October 17, 2012.

[27] National Institute of Allergy and Infectious Diseases. (2006) *Report of the Blue Ribbon Panel on Influenza Research, September 11-12, 2006*. Available at: http://www.niaid.nih.gov/topics/flu/documents/influenzablueribbonpanel2006.pdf. Accessed October 5, 2012; World Health Organization. (2009) WHO *Public Health Research Agenda for Influenza, Version 1*. Available at: http://www.who.int/influenza/resources/research/2010_04_29_global_influenza_research_agenda_version_01_en.pdf. Accessed October 5, 2012.

[28] The ferret is an established animal model for human respiratory anatomy and physiology.

[29] Kawaoka, Y. (2012) *Transmission of an Influenza Virus Possessing and H5 Hemagglutinin via Respiratory Droplets in Ferrets*. Royal Society meeting on H5N1 Research: Biosafety, Biosecurity, and Bioethics. Available at: http://www.voiceprompt.co.uk/royalsociety/030412/. Accessed: September 28, 2012; Roos, R. (2012) Research on Contagious H5N1 Viruses: Space Suites Needed? *CIDRAP*. Available at: http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/mar0612biosafety.html. Accessed: October 18, 2012.

[30] Fouchier, R. (2012) *Aerosol Transmission of Influenza A/H5N1 Virus in Ferrets*. Royal Society meeting on H5N1 Research: Biosafety, Biosecurity, and Bioethics. Available at: http://www.voiceprompt.co.uk/royalsociety/030412/. Accessed: September 28, 2012.

[31] Malakoff, D. (2012) Flu Controversy Spurs Research Moratorium. *Science*. 335(6067), 387-389.

In December 2011, the NSABB was asked to review the dual use implications of the research results communicated in the unpublished papers.[32] The NSABB concluded that both unpublished papers contained information that could be misused by possible terrorist entities and recommended that both papers be published only after the researchers removed key information about experimental methods.

In February 2012, the World Health Organization (WHO) convened a meeting to evaluate the risks and benefits of the research.[33] The participants of the WHO meeting concluded that the papers provide valuable information for global health and pandemic influenza planning and response efforts, and recommended that the papers be published in full at a later date rather than in partial form immediately.[34] Their assessment was based in part on additional scientific data presented by the Dutch group at the meeting. The WHO participants also expressed doubts about the feasibility of redacting parts of the paper, which was suggested by the NSABB. Based on the recommendations of the NSABB and the WHO participants, the researchers revised their papers. In March 2012, the revised papers were reviewed by the NSABB; the NSABB recommended approval of one paper unanimously and it recommended approval of the other by a majority of NSABB members.[35] The paper from the group from the United States was published in *Nature* in May 2012; after journal editors and researchers secured the appropriate export licenses, the paper from the Dutch researchers was published in *Science* in July 2012.

In addition to publication issues, the H5N1 papers presented the issue of controlled access to information. Following the NSABB's initial review, the researchers and journal editors agreed to redact some methodological information from the unpublished papers prior to publication only if "responsible" scientists could have access to that missing information.[36] The recommendation to limit publication of certain research methods provoked the U.S. and Dutch governments to place export controls on the information contained in the papers,[37] because the fundamental research exemption for export controls is only in effect if research results are shared freely and openly. The United States and many other countries regulate the transfer of controlled items – including

[32] National Institutes of Health. (2011) *Press Statement on the NSABB Review of H5N1 Research*. Available a: http://www.nih.gov/news/health/dec2011/od-20.htm. Accessed: September 27, 2012; 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. (2012) Adaptations of avian flu virus are a cause for concern. *Science*, 335(6069), 660-1.
[33] Cohen, J. (2012) WHO Group: H5N1 Papers Should Be Published In Full. *Science*, 35(6071), 899-900.
[34] World Health Organization. (2012) *Public Health, Influenza Experts Agree H5N1 Research Critical, but Extend Delay*. Available at: http://www.who.int/mediacentre/news/releases/2012/h5n1_research_20120217/en/index.html. Accessed: September 27, 2012.
[35] National Science Advisory Board for Biosecurity. (2012) *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*. Available at:
http://oba.od.nih.gov/oba/biosecurity/PDF/NSABB_Statement_March_2012_Meeting.pdf. Accessed: September 27, 2012.
[36] Enserink, M. and Malakoff, D. (2012) Will Flu Papers Lead to New Research Oversight? *Science*. 335(6064), 20-22.
[37] Enserink, M. (2012) Will Dutch Allow 'Export' of Controversial Flu Study? *Science*. 336(6079), 285; Roos, R. (2012) Export Controls Still Blocking Publication of Fouchier's H5N1 Study. *CIDRAP*. Available at: http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/apr1012h5n1.html. Accessed: October 17, 2012.

information, technologies, software, and services – to foreign nationals.[38] Basic research conducted at accredited universities generally is exempt from these export control regulations because the research results are ordinarily published in open literature and shared broadly among the scientific community. If a researcher accepts restrictions on the open communication of research results or the federal funding agency imposes access controls on the research results, the research no longer qualifies for the fundamental research exemption; the researcher and institution must apply for an export license to share information if the exception does not apply.[39] Noncompliance with these regulations could limit research opportunities to scientists and impose severe penalties (e.g., loss of research funding, or monetary or criminal penalties).[40]

Scientists and journal editors had to get export licenses to share information about the papers at the February WHO meeting, and NSABB members had to have export licenses to review the revised manuscripts. In April 2012, the Dutch group was issued an export license to publish its paper in *Science*.

U.S. Government Policy on Dual Use Research

> *"If we knew the answers before we did the science, then there's no sense in doing the science."*

Following more than a decade of policy, security, and scientific debate and catalyzed by the recent H5N1 papers, the U.S. Government issued a federal policy on the oversight of dual use research on March 29, 2012.[41] This policy is the first of a proposed multi-step procedure to develop a formalized process of regular national review of federally funded or conducted research to facilitate the safe and secure conduct of life sciences research.

The March 2012 policy provides a basic framework for funding agencies and scientists to identify current, federally funded research that might qualify as "dual use research of concern" and requires the development of risk mitigation and communication plans, as appropriate. The policy enhances scrutiny of research with 15 Select Agents,[42] which are highly regulated pathogens and toxins in the United States, and with one or more of the

[38] The Ohio State University. Export Control. Available at: http://orc.osu.edu/regulations-policies/exportcontrol/. Accessed: October 15, 2012.
[39] MIT. Exclusions and Exemptions. Available at: http://osp.mit.edu/compliance/export-controls/research/exclusions-and-exemptions. Accessed: October 15, 2012.
[40] The Ohio State University. Export Control. Available at: http://orc.osu.edu/regulations-policies/exportcontrol/. Accessed: October 15, 2012
[41] U.S. Government. (2012) *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*. Available at: http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf. Accessed on October 15, 2012.
[42] The fifteen Select Agents and Toxins included in the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern: Highly pathogenic avian influenza virus, *Bacillus anthracis*, Botulinum neurotoxin, *Burkholderia mallei*, *Burkholderia pseudomallei*, Ebola virus, Foot-and-mouth disease virus, *Francisella tularensis*, Marburg virus, Reconstructed 1918 Influenza virus, Rinderpest virus, Toxin-producing strains of Clostridium botulinum, Variola major virus, Variola minor virus, and *Yersinia pestis*.

seven categories of experiments similar to those listed by the National Research Council in 2004 and the NSABB in 2007. Under this policy, funding agencies are required to assess the research they support for "dual use research of concern." If research raises these concerns, funding agencies must work with researchers and their institutions to mitigate those risks by modifying the research, enhancing biosafety and biosecurity, and/or developing communication strategies to address concerns about the potential misuse of the proposed research, information, and knowledge. An additional policy describing the roles and responsibilities of researchers and institutions to identify and manage potential dual use risks of biological research is expected to be issued by the U.S. government.

University Programs

Several research institutions, namely those supporting Select Agent research, have responded to the decade-long calls for minimizing dual use risks of research by voluntarily implementing education, review, and/or oversight programs to increase awareness of, identify, and address potential security risks associated with their research. The size and scope of the programs vary based on the type of organization (e.g., university, private research institution, or government research institution), the amount of research that might be identified as "dual use research of concern," and available resources. Many of these programs have emerged because of concerned members of their institutions, the National Institutes of Health's outreach efforts, the Federal Bureau of Investigation's biosecurity outreach program, and/or the policy debate on the dual use dilemma in the life sciences.

Most, if not all, review and oversight programs rely on the Institutional Biosafety Committees (IBCs) to identify and address dual use risks, and base their assessments on the seven categories of experiments of concern listed by the National Research Council in 2004 and the NSABB in 2007. IBCs were implemented as part of the *NIH Guidelines* for research involving recombinant DNA; all research institutions receiving federal funds must have an IBC that reviews the safety of research that involves recombinant DNA. The composition of IBCs varies by institution and might not cover all of the scientific and/or security expertise needed to assess all research proposals.

In a recently published study compiling data from three separate surveys of IBC members from public and private research institutions, hospitals, and clinics, over 50% of the respondents indicated that their IBC reviews research for potential dual use risks.[43] Another 15% of respondents stated that their IBC was considering whether to include dual use risks as part of their IBC reviews. In addition, the survey indicated that only 37% of IBC members, 19% of principal investigators, and 14% of laboratory staff were being trained on dual use risks. (Training of these groups on the *NIH Guidelines* for recombinant DNA research, which is what IBCs are required to review, was significantly higher.)

[43] Hackney, R.W., Myatt, T.A., Gilbert, K.M., Caruso, R.R., and Simon, S.L. (2012) Current Trends in Institutional Biosafety Committee Practices. *Applied Biosafety*, 17(1), 11-18.

Beyond the IBC, some institutions convene a separate committee to review research involving Select Agents with dual use potential. These separate committees include scientific, medical, security, and safety experts to ensure that risk assessments conducted by the institution reflect the appropriate balance of security, safety, and science.

Several existing, voluntary dual use review programs were discussed at the meeting. Lessons learned from these programs are described in the *Emerging Themes* section of this report.

Two examples of institutional processes for dual use review and oversight are described in the text boxes below. Both involve separate committees.

Boston University's Dual Use Research Review Process

The formal review process starts with the researchers responding to eight specific questions, which are based on the recommendations of the National Research Council report "Biotechnology Research in An Age of Terrorism: Confronting the Dual Use Dilemma," during the IBC application process. The eight questions, which investigators must consider when evaluating the dual use potential of their research, are:

1. Enhance the harmful consequences of a biological agent or toxin.
2. Disrupt immunity or effectiveness of an immunization without clinical and/or agricultural justification.
3. Confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against agent or toxin.
4. Facilitate their ability to evade detection methodologies.
5. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
6. Alter the host range or tropism of a biological agent or toxin.
7. Enhance the susceptibility of a host population.
8. Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

If the answer to any of these questions is "*Yes"*, then the research falls under the category of dual use research and the IBC forwards the application materials, including the research proposal, to the University's Dual Use Research Review Committee (DURRC). This committee reviews the application and determines whether the research may be "dual use research of concern".

If the preliminary assessment identifies the research as "dual use research of concern," the DURRC begins a dialogue with the researcher to determine whether the research should proceed as planned. During this consultation, the security aspects of the research are reviewed with the appropriate officials (e.g., deans, provosts, Associate Vice President for Research Compliance). Internal experts (e.g., other researchers, security experts) and external experts (e.g., NSABB) may also be consulted for advice on potential management plans. Risk-management strategies might include limiting access to the research information, limiting information that will be publicly disclosed (e.g., in publications and presentations at scientific forums), and potentially curtailing certain aspects of the research.

The initial screening of research proposals and determination of dual use potential are based on the best information available at the time of the assessments. Because information gained during the course of the research might raise new questions or concerns regarding the nature of the research, the open exchange of information between the researchers, the DURRC, and the IBC is very important.

Publication of research results categorized as "dual use research of concern" may raise security issues that are not encountered routinely. The decision about whether to publish such research results requires thoughtful consideration by University officials, researchers, and publishers to ensure that valuable scientific data is made available and that security concerns about the potential for malevolent use of the published data are addressed adequately. If required, the University consults with external experts, such as the NSABB, during the risk-assessment and analysis process for publication of research results with dual use potential.

The decision concerning whether to publish may include an assessment about the feasibility or appropriateness of publishing the results without any changes, publishing with redacted information, or not publishing at all. If the results are to be published, appropriate commentary is included in the manuscript describing the process that lead to the decision to publish.

The University of Wisconsin-Madison's Dual Use Review with Select Agent Research

The University of Wisconsin's general approach for dual use review involves education of principal investigators (PI), Select Agent and Toxins researchers and Responsible Officials (including the Responsible Official and Alternate Responsible Official), Institutional Biosafety Committee (IBC) members, and the Biosecurity Task Force members to identify and appropriately address research possessing potential dual use risks.

Identification of "dual use research of concern" involving Select Agent and Toxins research by PIs, internal university committees, and/or an external funding agency initiates a formal review and oversight process at the University.

1. The PI and his/her selected laboratory personnel meet with the University's Select Agent and Toxins Responsible Officials to discuss the relevant issues of "dual use research of concern" based on the seven categories of experiments established by NSABB. The information gathered during this process is used as the basis for gathering relevant information for the assessment, including the research protocols, grant aims, progress reports, and any other information needed assist in the University's review of the research for its dual use potential.

2. These documents are forwarded to the chair of the IBC, who designates a subcommittee consisting of approximately three IBC members to interview the PI and assess the potential "dual use research of concern." Based on their evaluation of the documents and discussions with the PI, the IBC subcommittee writes a report that reviews the grant and its aims, describes the documents provided by the PI for review, assesses whether the research grant aims contain potential "dual use research of concern" based on the NSABB's seven categories of experiments, and makes a formal recommendation about whether and how to proceed.

3. The IBC subcommittee report is presented to the full IBC for discussion and vote.

4. The full IBC vote and the report are forwarded to a separate committee, the Biosafety Task Force, for further discussion and vote. In some instances, the Biosafety Task Forces sends recommendations or questions back to the IBC for consideration. The process continues until the members of both the IBC and Biosafety Task Force agree on the conclusions of the review and provide the PI their final response. This process involves input from the PI.

5. The Select Agent Responsible Official provides the federal funding agency a letter explaining the its review process, the final decision of whether the research is "dual use research of concern," and the IBC subcommittee report.

FBI Biosecurity Outreach and the Dual Use Dilemma

The FBI contributes to the U.S. Government's implementation of the BWC by enforcing the federal statues to prohibit development, production, or stockpiling of biological weapons and by preventing the misuse and exploitation of biological research. To accomplish these functions, the Biological Countermeasures Unit of the FBI's WMD Directorate has implemented a successful biosecurity outreach program.[44] Through this

[44] FBI Academic Biosecurity Workshops. Available at: http://academicbiosecurityworkshop.org/; Edward Lempinen. (2011) *FBI, AAAS Collaborate on Ambitious Outreach to Biotech Researchers and DIY Biologists.* Available at:

program, the FBI and its WMD Coordinators from each of its 56 field offices in the U.S. are reaching out to members of the scientific community to build trust and relationships with and among these organizations. The WMD Coordinators provide local support, resources, and security expertise that help scientific institutions identify and minimize real and perceived threats to prevent an incident from occurring and assist in responding to an incident that has taken place. Since its inception in 2006, the program has grown from strictly FBI-initiated activities to university-invited activities and from threat-focused to science-focused outreach stressing scientific progress in a safe and secure manner.

The goal of the FBI outreach program is to establish strong, sustainable relationships between the local WMD Coordinators and officials from research institutions to prevent and mitigate potential threats, including theft, loss, and/or misuse of biological agents; cyber-security; animal-rights extremism; theft of intellectual property; and the "insider threat." FBI WMD Coordinators have initiated a series of dialogues and outreach activities to build trust, open lines of communication, and increase awareness of biosecurity issues with universities, the private sector, and amateur biologists. 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.

Research institutions have recognized the utility of this biosecurity outreach program and the benefit of developing productive working relationships with the FBI. During the past year alone, the FBI has conducted more than thirty biosecurity outreach workshops at research institutions, many of which have a significant Select Agent research programs.

The H5N1 papers and subsequent policy proposals, discussions, and actions have increased the priority of providing information about the dual use dilemma in the FBI's biosecurity outreach activities and highlighted the need to include a security perspective in assessments of research for its dual use potential. The meeting, reported here is the FBI's first formal outreach event that has focused solely on dual use review and oversight with scientists and research administrators from academic and private research institutions. Active engagement between the FBI and members of the scientific community complements the research goals for biodefense and emerging infectious diseases[45] by drawing on both the scientific and security perspectives to identify and mitigate potential dual use risks, share best practices for the review and oversight of dual use research, and promote the development of dual use policies in a manner consistent with local resources, needs, and best practices.[46]

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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.

[45] The research goals for biodefense and emerging infections are to understand better the host-pathogen responses of harmful infectious diseases, including Select Agents, and to develop medical countermeasures (vaccines, drugs, and devices) to identify, prevent, and/or treat intentional, accidental, or natural infectious disease outbreaks.

[46] The FBI recognizes the differences among institutions that are large and small, and privately or publicly funded. It understands that these differences might affect their available resources and expertise to address and minimize security risks of dual use research.

The Meeting

In September 2012, 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 existing programs for review, oversight, and communication of dual use research. Experts were chosen based on their familiarity with biosecurity policy issues, dual use review and oversight, and/or biodefense research.

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

- Share best practices from voluntarily-implemented review and oversight programs;
- Identify and discuss lessons learned about the review, mitigation, and communication of research with dual use potential using the recent H5N1 papers as a case study; and
- Inform current national-level policy debates on dual use life sciences research.

Meeting participants were asked to consider the following questions:

- What dual use oversight strategies have institutions voluntarily implemented?
- What challenges did institutions face when implementing dual use review and oversight programs?
- What aspects of dual use review and oversight worked well?
- What is the current state of the regulatory burden on research institutions?

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* and *Policy and Programmatic Suggestions* sections are followed by two appendices that include the meeting agenda and list of participants.

Emerging Themes

Dual use research is a challenge that has resurfaced several times throughout the past half-century. Scientists, policy-makers, and security experts have addressed the problem in different ways, from self-regulation to national policy. Working together, physical and mathematical scientists and security experts created research and policy contexts to allow scientific progress while reducing the risk of illicit use of openly communicated research results or information. Until relatively recently, similar concerns were not raised for life sciences research. For over a decade, policy-makers and security experts have raised many of the same concerns about the potential national security risks of intentional misuse of emerging biotechnology and infectious disease research. Cooperation among biological scientists, research administrators, security experts, and policy-makers can facilitate the development of policies and programs at the local and national levels to enable science to progress and minimize risk without inappropriate classification or inordinate restriction of biodefense and infectious disease research. Striking this balance between science and security is important for building and maintaining public trust and promoting public safety through beneficial science and social responsibility, which encompasses ethics, safety, and security.

> *"If we don't have a science and security dialogue, we can't achieve real security. If we don't do this right, both science and security will pay the price."*

The public plays a critical role in both supporting scientific endeavors and expressing concerns about what and how research is conducted and communicated. The public reaps the medical, agricultural, energy, environmental, safety, and security benefits of biological and biotechnological research. However, public trust in and support for research depends on scientists acting responsibly and not conducting research that could cause harm to individuals or society. Of relevance to biodefense, members of the general public have expressed serious concerns about biodefense research and high-containment laboratories that house and/or accommodate laboratory work with Select Agents. Gaining and continually maintaining the public's trust in the scientific enterprise is indispensible to ensure government support of research activities. Active engagement and communication with the public and demonstration that scientists hear and address many of the public's concerns, including addressing biosecurity concerns, are key components of building public trust.

The promise that research can address national security, health, agricultural, environmental, and safety challenges comes with significant financial and administrative costs that are involved in ensuring that institutions and scientists are fully compliant with the many policies, rules, and regulations that govern biological research. Research universities currently are facing financial difficulties because of decreases in state funding to higher education institutions and federal funding for research grants. This situation is forcing scientists to compete for increasingly limited research funding. In

addition to financial pressures, research institutions and scientists must comply with requirements to address a number of concerns about research integrity, environmental risks, safety, and security as they carry out their missions to educate students and conduct research. During the past few years, research institutions have reported a two-to-four fold increase in the cost of compliance of regulatory requirements of research.[47] This scientific environment is driving many research institutions towards a tipping point where conducting research might be prohibitive both financially and administratively, resulting in abandonment of entire research programs. Several universities already have begun to refuse certain types of research because of the associated regulatory and cost burdens. Not only does this affect the pace at which research, including biodefense research, progresses, but it also affects the size and experience level of the available workforce to conduct the research (now and in the future), which might affect the quality of research.

These overarching issues provide the broader context within which dual use life sciences research of concern exists. The following points highlight key issues raised by meeting participants about the review and oversight of dual use research and the U.S. Government policy on dual use research that was released on March 29, 2012.[48]

Specific solutions to the concerns and challenges provided by meeting participants are presented in the *Policy and Programmatic Suggestions* section.

Existing Institutional Review and Oversight of Dual Use Research

- In response to concerns about the dual use potential of research, several institutions have implemented formal programs, processes, or procedures for reviewing and overseeing research with dual use potential.

> *"You can't measure intent. But we have to show due diligence within our community and to our customers to make reasonable attempts to do that."*

- A single process or procedure for all research institutions to review and oversee dual use research is not feasible or appropriate. Research institutions differ by size, sector, funding sources, and scientific expertise and interests. These differences influence the types of review and oversight processes implemented at public and private research institutions.

- Universities that have experience with biosecurity concerns (directly or through interactions with policy-makers, the NIH, and/or the FBI) tend to have extensive dual use review programs that include experts who are aware of dual use or other

[47] AAU, APLU, COGR. (2011) *Regulatory and Financial Reform of Federal Research Policy. Recommendations to the NRC Committee on Research Universities.* Available at: http://www.aau.edu/policy/nrc_study_universities.aspx?id=11954. Accessed: October 17, 2012.
[48] Collins, F. (2012) Statement by NIH Director Francis Collins, M.D., Ph.D. on the NSABB Review of Revised H5N1 Manuscripts. Available at: http://www.nih.gov/about/director/04202012_NSABB.htm. Accessed: October 5, 2012.

security concerns, whereas many other institutions base their assessments on the NSABB's seven categories of experiments of concern as part of their IBC review.

- Some institutions review only research with Select Agents for its dual use potential while others review all research proposed by and conducted at the institution for associated dual use risks. Many of these reviews are done by the IBC and often without security experts familiar with biosecurity concerns. In addition, the Select Agent Program prohibits certain types of research.

- Periodic review of all research could enable researchers to identify the dual use potential, if any, of their research proactively.

- At least two institutions have established a separate biosecurity risk-assessment group to review Select Agent research for its potential for misuse. These groups are convened only when needed and include experts from the scientific, medical (both human and veterinary), safety, and security fields to help the evaluation and decision-making process. While participants liked the idea of having a separate institutional group to review research for biosecurity risks, several stressed the lack of resources (funding, security expertise, and staff time) to establish and support such groups.

- A few institutions raised concerns about potential legal liability associated with deciding whether a research activity has dual use potential and recommending strategies for minimizing risks of dual use research. They wanted to defer the decision to another body, such as the NSABB or another federal entity.

- Despite the presence of several voluntary review systems, many academic research institutions have not implemented programs for reviewing research for its dual use potential for the following reasons: the institution does not conduct Select Agent research, which is where much of the dual use discussion has focused; the institution does not possess the appropriate expertise needed to conduct a review; or dual use review has not been mandated by the federal government.

- Institutional commitment and broad involvement is critical to implementing long-term, sustainable, and effective dual use review and oversight programs. Even with a strong institutional commitment to biosecurity, institutions may find that some of their researchers remain unconvinced of the need for dual use oversight and distrust interactions with the security community. Continued education of and outreach to researchers by institutional officials work to counter this view.

- Safety and security concerns are different but complementary and both can be addressed through transparent and open communication among scientists, administrators, and safety and security experts.

Cooperation between Scientists and Security Experts for Dual Use Review

- A robust dual use review depends on scientists, research administrators, and security experts working together and openly communicating with each another.

- Education of security experts and policy-makers about the process of conducting science, the many reviews associated with biological research (i.e., human and animal subjects protection and recombinant DNA review), the *benefits* and risks of the research, and measures taken to minimize the ethical, safety, and security risks of research are equally important in ensuring that dual use assessments are balanced and objective.

- Open and transparent communication among scientists and research administrators about the plausibility, possibility, and range of risks biological and biotechnological research could pose is critically important to ensuring that dual use assessments are conducted in a balanced and objective manner.

- Education of scientists and security experts about the history of exploitation and/or misuse of biology to inflict harm and the legal underpinnings to prevent such actions might raise the level of awareness that security and the life sciences are interconnected. This awareness might enable a more positive and productive working relationship between the security and scientific communities.

Governance of Dual Use Review

- The March 29 policy on the oversight of dual use research requires funding agencies to review certain research for its dual use potential and work with institutions to minimize the risks. However, this might lead to inconsistent evaluations and demands, and pose significant security and compliance challenges for institutions receiving funding from more than one government agency. Different agencies impose different degrees and types of restrictions on research and its dissemination, which also could present concerns about academic freedom. Although this concern is not unique to dual use research, any differences among government agencies could increase the burdens of an already stressed system.[49]

- Reviews conducted by federal agencies might lead to conflicts if those organizations do not want to identify dual use risks in the research they choose to support. Independent review of research might alleviate some of the concerns, but the March 29 policy does not include a mechanism for independent review of research.

[49] AAAS, AAU, and APLU. (2010) *Competing Responsibilities?: Addressing the Security Risks of Biological Research in Academia.* Available at: http://cstsp.aaas.org/content.html?contentid=2331. Accessed: October 24, 2012.

- The March 29 dual use policy involves review of research conducted with 15 Select Agents and with seven specific categories of experiments. This policy might duplicate and/or confuse existing Select Agents and Toxins Regulations,[50] and it does not sufficiently broaden the dual use review to research with other pathogens or emerging biotechnologies.

- The intent to misuse research results, information, materials, or methods to cause harm deliberately is at the heart of the dual use dilemma. The March 29 dual use policy does not provide agencies and research institutions with sufficient guidance on how to identify and minimize the risk that the results, methods, or information generated by the research could be misused once communicated. The policy also does not provide guidance on how scientists, research administrators, or reviewers should minimize the risk that some unknown person with malicious intent will misuse the research.

- Enabling the scientific community to assess and balance the risks and benefits of research through greater education of IBC members about dual use risks, inclusion of security experts with relevant expertise on review panels, and interaction with the security community could contribute to effective self-regulation. This self-regulation and open communication between the scientific and security communities could help ensure that biodefense, health, and agricultural research progresses safely and securely.

- The procedures and policies of some existing review and oversight programs might have to be modified to conform to any federal mandate for institutional review, particularly if current best practices are not included in the development of those mandates.

- Overly restrictive policies could increase the risk that scientists and institutions will abandon research with Select Agents. This has occurred to some degree already.[51] Further abandonment of biodefense and infectious disease research activities, and the associated laboratory workforce, could negatively affect the productivity of the researchers and quality of the research. This could have negative repercussions on biodefense preparedness, health, and agriculture, and possibly result in increased vulnerability to biological threats.[52]

- Adding another federal requirement to the current list of unfunded mandates with which research institutions must comply would increase the financial, administrative, and regulatory burden at already-stressed research institutions. A possible consequence of this situation might be the refusal by institutions to

[50] Restricted Experiments in Select Agents and Toxins Regulations. 7 CFR § 331.13, 9 CFR § 121.13, and 42 C.F.R. § 73.13;. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. Law 107-188.
[51] AAAS, AAU, and APLU. (2010) *Competing Responsibilities?: Addressing the Security Risks of Biological Research in Academia.* Available at: http://cstsp.aaas.org/content.html?contentid=2331. Accessed: October 24, 2012.
[52] These concerns are not restricted to the dual use policy but also to the broader Select Agents and Toxins Regulations.

accept and support Select Agent research, which would ultimately negatively impact national and health security.

- Redacting parts or full methods sections of posters, presentations, and publications might raise concerns about the quality and reproducibility of the research in question, and possible infringements on academic freedom.

- Research results and methods are communicated to different audiences and in different venues throughout the lifetime of a research project. With the internet and social media joining the list of venues in which research could be communicated (and often without advanced review), participants raised concerns about online publication of research results and methods from scientists throughout the world.

- Some policy-makers have indicated that, rarely, research results might pose significant risks to national security. They have suggested, as a possible remedy, that this research could be *classified* from the start of the project.
    - Classification of research might increase public concern over biodefense research.
    - The March 29 policy does not provide standards or criteria for classification of research.
    - The United States has made significant efforts to be transparent about its biodefense research activities to other countries.[53] Classifying research with dual use potential might harm these efforts significantly.
    - Classification of research could discourage scientists from other countries from sharing the results of their research.
    - Classification might not be a feasible solution for cases when dual use potential of unexpected results is identified during the course of the research. Retroactively classifying information conducted in a public setting is extremely difficult.
    - Classification of research might prevent scientists from publishing their research results and demonstrating their knowledge and research progress. This is a big problem for scientists seeking tenure, funding, and/or graduate degrees or faculty positions. In fact, many top research institutions have policies against conducting classified research.

Outstanding Challenges

- Currently, no national-level body is responsible for reviewing research for its dual use potential. Although a significant majority of research can be reviewed by institutions, some research might be difficult to assess at the local level and might require a higher-level review by outside experts (e.g., NSABB).

[53] Ambassador Laura Kennedy. (2012) *Advancing the Biological and Toxin Weapons Convention with Bio-Transparency and Openness Initiative*. DipNote, Department of State Official Blog. Available at: http://blogs.state.gov/index.php/site/entry/biological_toxin_weapons_convention. Accessed: October 15, 2012.

- Dual use potential might not be identified at the start of a project because research results are not known at the research design stage. Currently, no guidance is available for research administrators, IBC members, and scientists on how to address potential dual use risks that arise during the course or after completion of the research. However, review of research during the course of the project and expansion of the review to include research beyond Select Agents present significant logistical challenges.

- Through Freedom of Information Act (FOIA) requests and state open-records laws, the public can request information about the deliberations and reviews of biological research. Public access to the deliberations and risk assessments of research that might have dual use potential itself presents a security risk. These risks might include knowledge of the researcher, facility and/or laboratory in which research with dual use potential is being conducted; this information could present a security risk to individual researchers (both the Principal Investigator and laboratory staff), institutions, and the country. However, IBC minutes and documents must be made freely available to the public under the *NIH Guidelines*. While some institutions that conduct dual use reviews have found legal means to prevent the disclosure of deliberations about the dual use nature of certain research, the prospect of unlimited public access to such information remains a significant concern.

- The potential for dual use research to emerge from non-Select Agent and non-microbiological research has been demonstrated several times in the recent past. Examples of technologies about which national security concerns have been raised include neuroscience[54] and synthetic genomics.[55] Limiting dual use review and policy to only Select Agents and biological research might focus risk assessment efforts away from emerging science. Identifying ways in which institutions and the federal government could assess the dual use potential of rapidly advancing technologies without inappropriately reviewing *all* life science and related (e.g., bioengineering) research is a major challenge that the scientific, security, and policy-making communities face. However, some workshop participants suggested that expanding the review beyond the 15 Select Agents listed in the March 2012 federal guidance on dual use review would not be difficult.

- Implementing local dual use review and oversight programs requires research administrators, IBC members, and individual scientists to develop the necessary expertise to identify and mitigate potential dual use risks of research.

[54] Tennison, M. N. and Moreno, J. (2012) Neuroscience, Ethics, and National Security: The State of the Art. *PLoS Biol.* 10(3); Moreno, J. (2006) *Mind Wars: Brain Research and National Defense*. Dana Press (New York, NY).
[55] Bansak, K and Tucker, J. (2012) *Innovation, Dual Use, and Security: Managing the Risks of Emerging Biological and Chemical Technologies*. MIT Press. (Boston, MA).

- Measuring the success of dual use review and oversight programs is challenging because neither the scientific community nor the security community can accurately quantify the number of times dual use review and subsequent mitigation measures prevented “dual use research of concern” from being intentionally misused for harmful purposes.

- Because research is highly collaborative and involves scientists within the United States and throughout the world, review and oversight of research for its dual use potential might require additional expertise and processes to ensure consistency in the identification, communication, and mitigation of those risks among research partners and their institutions.

Policy and Programmatic Suggestions

The following are a list of suggestions made by meeting participants to ensure science can progress while minimizing the risk that research results and information could be misused or otherwise exploited. With one exception, the suggestions are categorized into three groups – Cooperation between the Scientific, Public Health, and Security Communities; Dual use Review, Oversight, and Communication; and Public Outreach. These suggestions are not consensus recommendations and do not imply ease of implementation.

1. The U.S. Government should encourage open and transparent research, and communication of research results to enable and support scientific progress to address the U.S. biodefense, health, agricultural, and environmental missions.

Cooperation between the Scientific, Public Health, and Security Communities

2. The scientific, public health, and security communities should continue to work together to identify and minimize risks, and share information about biosecurity and related security risks.

3. Within the cooperative environment, the public health and security communities should inform scientists about instances in which an intent to misuse legitimate research has been identified. This input could help scientists understand the broader security context within which they work.

4. Researchers should educate public health and security experts about the science and research environment within which they work to help the relevant subject matter experts assess security risks more effectively and provide appropriate mitigation and protection, if necessary.

5. Those at higher education institutions should educate security experts about the traditions and long-standing principles of academic freedom and the open exchange of information. Because the priorities of academic institutions are different from those at government laboratories or at research institutions without a predominant education mission, security experts should learn about the unique challenges, priorities, research environments, and missions of different types of research institutions.

Dual use Review, Oversight, and Communication

6. The U.S. Government should develop a guidance document that outlines how the research community could navigate the dual use review process and include outside experts in that process.

7. The U.S. Government should provide guidance on how to address unexpected research results that might pose dual use risks.

8. Research administrators, scientists, and security experts should share best practices for the review and oversight of biological research for possible dual use potential, and for educating reviewers to identify potential dual use risks. The research community, together with the U.S. Government, should create a mechanism to facilitate this sharing of best practices.

9. The U.S. Government should be acutely aware of the risks, perceived benefits, and non-reimbursable institutional costs of imposing restrictive regulations on members of the scientific community that contribute to the U.S. biodefense and preparedness missions.

10. The U.S. Government should work closely with the scientific community (including those working in public and private research institutions) when developing policies on dual use research to ensure that current best practices are incorporated and increase acceptance and participation by the regulated community.

11. The U.S. Government might designate or create a single, national-level body composed of independent experts and at least one member of the public to review research that local institutions cannot adequately assess themselves or for which the institutions want additional guidance and to recommend risk-mitigation measures to address those risks. Such a review body should not impose additional pressures or burdens on the research community.

12. The U.S. Government should encourage information sharing between the research and security communities about scientific advances and actual security risks.

13. Scientists should base their dual use discussions with their international partners on core ethical principles of autonomy, mutual responsibility, respect for persons, beneficence, and non-maleficence and on common risk-identification and mitigation practices.

14. Scientists and research administrators should communicate research with potential dual use implications responsibly, while ensuring that the research can be reproduced and is high quality.

Public Outreach

15. Scientists should be aware of their role in society and how scientific responsibility contributes to gaining and maintaining public trust. Scientific responsibility historically has addressed research integrity, but it should also include security because of the persistent concerns about issues, such as the theft or loss of Select Agents and misuse of biological research.

16. Scientists should actively engage in public outreach and building of public trust. Scientists should work with other scientists and with members of the public on outreach and use language without technical jargon when interacting with diverse members of the public.

17. Scientists should encourage and participate in the development of education programs in schools and other venues wherein members of the public can become familiar with the process of science and scientific research.

18. Scientists should develop education, review, and oversight programs that instill social responsibility and the importance of public trust in future generations of scientists as part of the currently mandated ethics training. Education programs should include information about international norms banning the illicit use of biological materials and information (e.g., the Biological Weapons Convention and United Nations Security Council Resolution 1540), and measures implemented in the United States (e.g., Biological Weapons Anti-Terrorism Criminal Statutes, Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and Select Agents and Toxins Regulations).

Appendix 1:
Meeting Agenda

The American Association for the Advancement of Science (AAAS)
Association of American Universities (AAU)
Association of Public and Land-grant Universities (APLU)
and the Federal Bureau of Investigation (FBI)

Workshop on Dual Use Research of Concern (DURC)

Washington, DC
September 13-14, 2012

Day 1

Location: Bobby Van's Grill, 1201 New York Avenue NW

6:15 – 9:00 **Reception and Dinner**

7:00 – 8:00 **Dinner Speaker**
Welcome: Norman Neureiter, Ph.D., American Association for the Advancement of Science

Speakers: Alan Leshner, Ph.D., American Association for the Advancement of Science
Acting Deputy Assistant Director Barbara Walls, Federal Bureau of Investigation, WMD Directorate

Day 2
Location: Association of American Universities, Conference Room

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

8:30-9:30 **Overview comments: Life sciences in an era of biosecurity**

Panelists: Susan Ehrlich, NSABB
Ed You, FBI

9:30-10:45 **Case study: H5N1 and Dual Use**
Moderator: Barbara Jasny, AAAS

Panelists: Bill Mellon, University of Wisconsin - Madison
Kenneth Berns, University of Florida, NSABB

10:45-11:15 Break

11:15-12:30 **Models for Minimizing Risk of Dual Use Biological Research**
Moderator: Henry Metzger, NIH

Panelists: Ara Tahmassian, Boston University
Wayne Thomann, Duke University
Carolyn Keierleber, Scripps Research Institute

12:30-1:30 Lunch – Amy Patterson, NIH Director of Science Policy

1:30-2:45 **Models for Minimizing Risk of Dual Use Biological Research (Cont.)**
Moderator: Steve Geary, University of Connecticut

Panelists: Jerry Jaax, Kansas State University
Robert Ellis, Colorado State University

2:45-3:00 Break

3:00 - 4:30 **Case Study/Table Top Exercise**

- Walk through of dual use review with participants playing (presumably their own) roles of funders, VPR, IBC/IRB/IACUC members, FBI WMD coordinators.
- Purpose: To identify useful steps, policy/institutional barriers, other issues

4:30-5:30 **Meeting recap/policy suggestions**

Appendix 2: Meeting Participants

Alan Barbour, M.D.
Professor of Medicine, Microbiology & Molecular Genetics, and Ecology & Evolutionary Biology
University of California, Irvine
Director, Pacific Southwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases

Ralph Baric, Ph.D.
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Pam Bounelis, Ph.D.
Assistant Dean for Biomedical Research
The University of Alabama at Birmingham

Donald H. Bouyer, Ph.D.
Director, Galveston National Laboratory-Keiller BSL3 Research Core
Associate Professor, Department of Pathology
The University of Texas Medical Branch at Galveston

Susan A. Ehrlich, J.D., LL.M. (biotechnology & genomics)
Judge (ret.), Arizona Court of Appeals

Robert Ellis, Ph.D., CBSP
Biosafety Director and Professor
Colorado State University

Andrea R. Ferrero
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Julie E. Fischer, Ph.D.
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Associate Vice President for Research Compliance
Kansas State University

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