definition. Toward that end, governments should agree on a core set of principles that reflect a global consensus on fostering international cooperation, followed by efforts to harmonize policies and practices, including those pertaining to the dissemination of dual-use research, to mitigate the potential for malevolent uses of dual-use research. The scientific community cannot afford to be bystanders in these efforts. This is not merely a matter of self-interest. Scientists have a social responsibility to inform the scientific community, the public, and policy-makers of the potential dangers of their work, as well as of the risks and lost opportunities associated with restricting the flow of scientific information. There may be good reasons for governments to control dissemination, but they should understand what the consequences may be for science and policy.

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POLICY FORUM

Implementing the New U.S. Dual-Use Policy

Carrie D. Wolinetz

After a decade of intensive policy discussions on the topic of dual-use research of concern (DURC) in the life sciences, there has been a lack of consensus on how to practically define DURC; whether it is feasible to identify and regulate DURC experiments; how to address the risks associated with DURC; and how to balance this risk with the necessity of fostering life sciences research for public health and biodefense. The publication of two avian influenza studies has brought the DURC issue back into sharp focus and has resulted in a new set of federal guidelines. However, the new DURC policy raises questions regarding whether this is the best policy solution to a complicated biosecurity concern.

Since the publication of a 2001 experiment synthesizing polio virus de novo received national attention, the research community has been engaged in a philosophical and policy debate over how to deal with the challenge of dual-use life science research. Dual-use research of concern (DURC) is roughly defined as research that is intended for legitimate, beneficial purposes but also carries a risk of being misused for malicious purposes. The ability to define DURC in a way that facilitates its identification and regulation has been an issue that the biosecurity community has struggled with for nearly a decade (*1*). Mitigating the risks associated with biological DURC has been the subject of two National Academies reports and major international fora, including meetings hosted by the InterAcademy Panel and associated with the Biological Weapons and Toxins Convention (BWTC). These led to the formation of the National Science Advisory Board for Biosecurity (NSABB), a U.S. federal government advisory committee that has produced multiple reports and workshops in the 8 years since its inception (*1*). However, there is still no consensus on how to practically define DURC; whether it is feasible to identify and regulate DURC experiments; how to address risks associated with DURC; and how to balance this risk with the necessity of fostering life sciences research for public health and biodefense.

Recent public attention on the publication of two avian (H5N1) influenza studies has brought the dual-use issue into sharp focus and has resulted in a swift response from the U.S. government in the form of the "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern" (*2*). The policy calls on federal agencies to review research involving 15 agents from the select agent list, determine whether they meet the definition of DURC, conduct a risk assessment, and then mitigate risks in collaboration with the institution and scientist conducting the research. It was issued in unusual fashion by posting on the National Institutes of Health (NIH) Office of Biotechnology Activities' Web site on 29 March 2012 and has raised questions in the research community about whether it is the best policy solution to a complicated biosecurity concern.

Does the Policy Fully Address Dual Use?

The DURC policy is limited to experiments involving 15 agents that are already on the select agent list (which includes roughly 80 agents). This list was initially generated as part of the federal Select Agent Program established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

This raises a number of questions about the redundancy of the policy. Experiments involving select agents are already stringently regulated by a system that includes background checks on all personnel involved and licensing of the facilities (*3*). In addition, the Select Agent Rule is currently under review (*4*), and the proposed changes to the regulations add even more controls to the agents addressed by the DURC policy. Many institutions that conduct a substantial amount of research involving select agents have incorporated this research into biosafety review systems that take place at the local level through Institutional Biosafety Committees (IBCs).

Moreover, many well-documented case studies of DURC that have been cited by the NSABB and many other organizations as evidence for the need for additional DURC guidance or regulation would not be covered by this policy. The de novo synthesis of polio virus, the Australian mousepox experiment, and the Penn State aerosolization study (*5*)—none of these notorious DURC cases would have been regulated under the new policy.

To the U.S. government's credit, this policy clearly tries to limit the scope to prevent the over-identification of legitimate research that does not pose much of a risk and to limit the associated burden on research institutions. However, the redundancy with the Select Agent Program and its inherent failure to capture experiments that are commonly agreed to be DURC raises the question of whether it addresses the DURC issue at all. This is the very quandary identified in a 2007 Congressional Research Service report that explored the challenges of defining DURC for the purposes of oversight (*6*).

Is the DURC Policy Feasible?

The recent review and re-review of the H5N1 avian influenza publications by the NSABB illustrates the difficulty in making decisions about

Association of American Universities, 1200 New York Avenue NW, Washington, DC 20005, USA. E-mail: carrie_wolinetz@aau.edu

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how to mitigate the risk of DURC, even as it underscores the need for a workable system to help address the real risks associated with some biological research. The decision-making process ultimately took nearly 5 months and an international summit of experts (*7*), and the group failed to reach consensus in its final decision to recommend publication (*8*). Given that this review process dealt with only two publications documenting similar experiments, it is difficult to imagine an analogous review and risk mitigation system applied to a larger body of research not causing delays and disagreements or resulting in an onerous burden for both the agency and the institution.

There are a number of questions raised by both this example and the ambiguities in the policy itself. Who at the federal departments and agencies conducts "a review to identify all current or proposed" research for DURC potential (*2*)? What expertise must they have? While a timeline for reporting these findings to the U.S. government has clearly been stated in the policy, what is the timeline for reporting to the researcher and institution, so they might move to the next step, to "in collaboration with the institution or researcher, develop a risk mitigation plan" (*2*)? How does the timing of this review fit into the scheme of NIH study section review, funding deadlines, or other regulatory reviews?

What if there is disagreement over the elements of the risk mitigation plan or the identification of a research project as DURC? The H5N1 case illustrates how legitimate disputes about the science among experts can make true risk assessment extraordinarily difficult (*9*). As Bouvier stated in a recent commentary, "Where to draw the line between acceptable and unacceptable risk is a subjective assessment, made by individuals with vastly different opinions, values, backgrounds, and beliefs. We simply have no objective measure." (*10*). There is no appeals process identified in the policy, nor even any point of contact at any research agency. Furthermore, elements of the risk mitigation plan, as described by the policy, such as ongoing review at the institutional level, are ill defined. For example, how often is "ongoing"? What entity or individual at the university should be tasked with "ongoing" review, and will this lead to a substantial unfunded regulatory burden at the institutional level? If this is a task given to IBCs, what additional resources will be available to support these activities? To what federal body do the IBCs report and consult? Will IBCs be establishing a relationship with the NSABB similar to that currently shared with the Recombinant DNA Advisory Committee?

Research universities are already struggling to sustain research programs while facing increasing compliance requirements and underrecovery of indirect costs associated with federally funded research (*11*). Clearly, researchers or institutions are under no obligation to receive federal funding if the terms or conditions of a grant or contract are not acceptable, but this seems contrary to the nation's public health and biodefense needs. As the Federal Experts Security Advisory Panel recently stated in its final report, "work with biological select agents and toxins (BSAT) is critical to national security, appreciating that this work is important in the development and manufacturing of medical countermeasures, the ability to perform diagnostic tests, and the ability to securely transport specimens, among other activities" (*12*). Discouraging researchers or institutions from federally funded research with select agents or delaying research with additional layers of review can only hurt national security, the antithesis of the intent of the DURC policy.

> *"Discouraging researchers or institutions from federally funded research with select agents or delaying research with additional layers of review can only hurt national security."*

Is the DURC Policy Inconsistent with NSDD-189 and National Security?

Originating in the Reagan Administration and reaffirmed by every subsequent administration, including that of President Obama, National Security Decision Directive (NSDD) 189 is a federal policy expressing the principle that openness is essential to scientific progress and should be preserved whenever possible (*13*). Although the DURC policy cites NSDD-189 specifically, the policy itself seems to fly in the face of this directive. The risk mitigation options described in the policy include modifying research protocols, determining communications modes and venues, or requesting redaction, all of which run directly counter to NSDD-189: "No restrictions may be placed upon the conduct or reporting of federally-funded fundamental research that has not received national security classification." Perhaps more alarming is the idea that through ongoing review, federal agencies might classify fundamental research midstream. Although technically this is an authority allowable under NSDD-189, doing so would violate the spirit of this policy, which unequivocally states, "The strength of American science requires a research environment conducive to creativity, an environment in which the free exchange of ideas is a vital component.… It is the policy of this Administration that, to the maximum extent possible, the products of fundamental research remain unrestricted." At the very least, dual-use research has an inherent beneficial, and in the case of the life sciences often life-saving, potential: Restricting access to research results and methodology will deny researchers and the public the ability to use that research for positive societal benefit.

The feasibility of risk mitigation options related to security classification and redaction also presents challenges. The ability to retroactively or selectively control information in an extramural funding environment is, for a variety of reasons, quite limited. It was the complexity of this issue that caused the World Health Organization (WHO) panel of experts reviewing the H5N1 papers to call for full publication of the studies, in opposition to the original NSABB recommendation (*14*). Public universities are subject to state open records laws that make many documents freely available to the public; research proposals, reports, and publications go through multiple reviews by many individuals and entities before publication; and much of the life sciences research covered by the policy has been going on for decades. Is it truly possible to retroactively classify research-related information that has been extraordinarily accessible for some period of time? How can you ensure that "bona fide" researchers have access to the important details of redacted publications necessary to develop medical countermeasures, without slowing research progress? Even if a system of researcher verification is established, who controls access to databases and materials? Journal publishers are private entities, and although many have acted responsibly in setting up their own

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systems of DURC review short of classification, by what authority can the government or institutions prevent publication of research results?

Finally, the specter of classifying or controlling life sciences research raises larger security issues. The post-2001 expansion of biodefense research in the United States has raised questions as to whether the U.S. effort was in violation of the international BWTC (*15*). One of our strongest arguments against this perception is the openness of the university environment in which much of this research takes place, a transparent system that helps dispel concerns of a "secret" U.S. bioweapons program. Classifying the research, redacting research results, or driving select agent research out of universities to national or defense laboratories will only exacerbate this negative perception of the U.S. life science research program, which could cause greater national security or diplomatic issues. We have already seen this concern play out in the H5N1 publications case, as NSABB Acting Chair Paul Keim recently testified at a Senate Homeland Security and Government Affairs Committee hearing (*16*).

Is There a Better Path Forward?

The life sciences and security communities represent two perspectives with one common goal of working for the public good. It is unfortunate that the controversy over the H5N1 publications has in some cases polarized what has been an evolving and productive discussion, nationally and internationally, on how to work together to foster the highest-quality, appropriately regulated biological research (*1*).

Reaching that goal will require balance, which in this context can perhaps be best defined as the understanding that the most stringent security measures do not necessarily translate to a commensurate increase in security, nor does scientific freedom equate to abrogation of responsibility. It has already been demonstrated that scientists, once made aware of the potential risks associated with their research, are willing to modify their research methodologies or communications to minimize the risk (*17*).

The proposed modification to the Select Agent Rule adds additional requirements for biosafety and biosecurity training for those personnel with any access to these dangerous pathogens (*4*). Although institutions conducting research with select agents or in biocontainment laboratories already typically conduct extensive training of personnel, it does not seem unreasonable to add a discussion of the risks of dual-use research as a component of that required training. There are already a number of excellent resources for DURC education available, including modules developed by the NSABB (*18*) and the Federation of American Scientists (*5*), both at the local and national level.

Finally, responsible communication of research should start with the principles set forth by the NSABB. These include consideration of "the need for the inclusion of contextual and explanatory information that might minimize" concerns about the dangers posed by the research; an examination of the protective and oversight measures currently in place; and a full understanding and analysis of the positive benefit of the study (*19*).

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PERSPECTIVE

Securing Medical Research: A Cybersecurity Point of View

Bruce Schneier

The problem of securing biological research data is a difficult and complicated one. Our ability to secure data on computers is not robust enough to ensure the security of existing data sets. Lessons from cryptography illustrate that neither secrecy measures, such as deleting technical details, nor national solutions, such as export controls, will work.

Science and *Nature* have each published papers on the H5N1 virus in humans after considerable debate about whether the research results in those papers could help terrorists create a bioweapon (*1*, *2*). This notion of "dual use" research is an important one for the community, and one that will sooner or later become critical. Perhaps these two papers are not dangerous in the wrong hands, but eventually there will be research results that are.

My background is in cryptography and computer security. I cannot comment on the potential value or harm from any particular piece of biological research, but I can discuss what works and what does not to keep research data secure. The cryptography and computer security communities have been wrestling for decades now with dual-use research: for example, whether to publish new Windows (Microsoft Corporation) vulnerabilities that can be immediately used to attack computers but whose publication helps us make the operating system more secure in the long run. From this experience, I offer five points to the virology community.

First, security based on secrecy is inherently fragile. The more secrets a system has, the less secure it is. A door lock that has a secret but unchangeable locking mechanism is less secure than a commercially purchased door lock with an easily changeable key. In cryptography, this is known as Kerckhoffs' principle: Put all your secrecy into the key and none into the cryptographic algorithm (*3*, *4*). The key is unique and easily changeable; the algorithm is system-wide and much more likely to become public. In fact,

Minneapolis, MN 55410, USA. E-mail: schneier@schneier.com

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Carrie D. Wolinetz

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