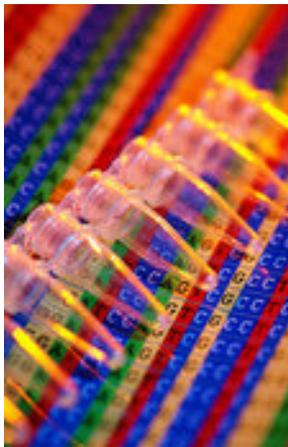


NATIONAL  
SCIENCE  
ADVISORY  
BOARD FOR  
BIOSECURITY

# **Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information**



**A Report of the National Science Advisory Board for Biosecurity (NSABB)**

June 2007

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## **ABBREVIATIONS AND ACRONYMS**

<b>DNA</b>	Deoxyribonucleic acid
<b>EMBO</b>	European Molecular Biology Organization
<b>HHS</b>	(U.S. Department of) Health and Human Services
<b>IACUC</b>	Institutional Animal Care and Use Committee
<b>IBC</b>	Institutional Biosafety Committee
<b>IRB</b>	Institutional Review Board
<b>NIH</b>	National Institutes of Health
<b>NIH Guidelines</b>	NIH Guidelines for Research Involving Recombinant DNA Molecules
<b>NRC</b>	National Research Council (of the U.S. National Academies)
<b>NSABB</b>	National Science Advisory Board for Biosecurity
<b>PI</b>	Principal Investigator
<b>Qs&amp;As</b>	Questions & Answers
<b>RAC</b>	(NIH) Recombinant DNA Advisory Committee
<b>RNA</b>	Ribonucleic acid
<b>RNAi</b>	RNA interference
<b>U.S.</b>	United States
<b>U.S.C.</b>	United States Code
<b>siRNA</b>	Small interfering RNA

## Executive Summary

Life sciences research has a critical role in understanding life at the ecosystem, organism, biological system, organ, cellular, and molecular levels. Advances in the life sciences have led to new pharmaceuticals, diagnostic procedures, preventive strategies, treatments, and cures for myriad acute and chronic diseases and conditions and has contributed to improvements in animal and plant health and the food supply.

However, the information gained from life sciences research also could be used for destructive purposes that could threaten the health and safety of life on our planet. Over the past several years, especially following the terrorist attacks of September 11 and the subsequent anthrax attacks utilizing the U.S. Postal Service, there have been increasing calls to consider the possibility that new information from life sciences research could be subverted for malevolent purposes and that new biosecurity measures should be instituted to minimize this risk.

This threat has been recognized and articulated by individuals, organizations, and governments around the world. In this country, the National Science Advisory Board for Biosecurity (NSABB) was established by the U.S. Government to advise on strategies for dealing with the generation and communication of information and new technologies from life sciences research that have the potential for both benevolent and malevolent application—referred to in this report as “dual use research”—along with the subset of dual use research with significant potential for generating information that could be misused—referred to as “dual use research of concern.”

The NSABB’s tasks include proposing an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential in consideration of protecting both national security concerns and the progress of the life sciences. The NSABB strongly promotes the free and open exchange of information in the life sciences to the maximum extent possible and believes that the best way to address concerns regarding dual use research is to raise awareness of the issue and strengthen the culture of understanding and responsibility within the scientific community and the public as well as instituting new oversight procedures to minimize the risk of misuse of research information.

The recommendations of the NSABB in the report that follows are not intended as guidelines but rather as a framework for the development—by the federal government—of a comprehensive system for the responsible identification, review, conduct, and communication of dual use research. In this report, the NSABB identifies principles that should underpin the oversight of dual use life sciences research, lists key features of such oversight (e.g., federal guidelines, awareness and education, evaluation and review of research for dual use potential, assessment and management of risk, compliance, and periodic evaluation at the local (e.g., research institution) and federal levels of the impact and effectiveness of oversight procedures) and proposes roles and responsibilities for researchers, institutions, the institutional review entity, and the NSABB and other federal government entities. The report also describes the major steps in local oversight of dual use life sciences research, including evaluation of life sciences research for its dual use potential, review of research identified as being potentially dual use of concern, conduct of dual use research of concern in accordance with risk management strategies, and responsible communication of research with dual use potential.

One of the fundamental tasks of the NSABB was to develop criteria for identifying dual use research of concern. The proposed criterion is “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.” As guidance for those assessing research for its dual use potential, the NSABB identified seven broad categories of information that might be generated by life sciences research that has a high potential for being dual use of concern.

NSABB members agreed that the principal investigator, using the criterion set forth above, should conduct the initial evaluation of his or her research for its potential as dual use research of concern. Those projects initially identified as dual use research of concern—and NSABB members anticipate that there will be very few projects that are truly dual use of concern—would undergo additional institutional review that involves interactive discussion among reviewers to assess the potential for and the ways in which information, technologies, or biological agents from the research could be misused to pose a threat; the likelihood that the information might be misused; the potential impacts of misuse; and the strategies for mitigating the risks that information from the research could be misused. To guide this review process, the NSABB developed “Points To Consider in Risk Assessment and Management of Research Information That Is Potentially Dual Use of Concern.”

The NSABB also recommends strategies and has developed tools to help ensure that research information with dual use potential is communicated responsibly, and in a manner that addresses both biosecurity concerns and the need for open sharing of research results and technologies. These tools include a set of principles for the responsible communication of research with dual use potential; points to consider for identifying and assessing the risks and benefits of communicating research information with dual use potential, including options for the communication of such research information; and considerations for the development of a communication plan for research with dual use potential.

In fulfillment of one of its specific charges, the NSABB also provides recommendations on the development of a code of conduct for scientists and all laboratory personnel that could be adopted by professional organizations and institutions engaged in the performance of life sciences research. These are articulated in “Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences,” which provides a conceptual foundation for understanding the dual use issue, describes the nature and utility of codes of conduct, articulates the fundamental principles of responsible conduct with regard to dual use research, and provides guidance on addressing the dual use issue in specific phases of the research process.

This report also addresses the importance of education and training in biosecurity issues for all life scientists and describes previous, ongoing, and future approaches to meet these goals, including the use of focus groups and roundtables, presentations at meetings of scientists and other stakeholders, exhibits at scientific meetings to educate attendees about biosecurity matters and the development of related federal policy and international dialogs. During the federal policymaking process, the NSABB recommends soliciting comment through notice in the *Federal Register*, federal government sponsorship of town-hall style regional meetings, and the

establishment of a publicly accessible docket for the collection of public comments on policy. Once requirements on the oversight of dual use research are formally agreed on by the federal government, a communications plan should be prepared for the rollout of the new federal policies as well as an intensive and ongoing campaign of workshops, presentations, print and electronic materials, exhibits, and other activities to educate all affected constituencies and promote compliance with the new requirements.

The NSABB intends to address in more detail additional aspects of oversight of dual use research issues, including outreach and education and compliance and enforcement strategies. These topics are better addressed once federal policies are more fully developed. The NSABB also strongly recommends that the U.S. Government seek broad input from the public on these and other issues presented in this report and encourage the development of education and guidance tools concerning dual use research issues by institutions, scientific associations, and professional societies. Because research is a global activity, the NSABB also recommends that the U.S. engage in dialog on these issues with other countries.

## Introduction

*Purpose of This Document.* This document sets forth recommendations of the National Science Advisory Board for Biosecurity (NSABB) for the oversight of publicly funded life sciences research as a means of minimizing the potential that information, products, or technologies resulting from this research will be misused for harmful purposes. These recommendations are not intended as comprehensive guidelines for such oversight but rather to serve as a framework or springboard for the U.S. Government to develop a comprehensive and coordinated oversight policy. The NSABB hopes and expects that there will be an iterative process of consultation with the public and the government and anticipates modifying this framework in response to this input and as it addresses additional oversight issues in the future.

*The Critical Role of Life Sciences Research.* Life sciences research encompasses a diverse array of approaches to understanding life at the level of ecosystems, organisms, biological systems, organs, cells, and molecules. Advances in molecular and cell biology, genetics, microbiology, and other life sciences disciplines have made it possible to routinely manipulate aspects of biological systems as part of an ongoing quest to better understand the health and disease states and the life cycles of humans, animals, plants, insects and microorganisms.

Advances in the life sciences have led to new pharmaceuticals, diagnostic procedures, preventive strategies, treatments, and cures for myriad acute and chronic diseases and conditions and for emerging and reemerging infectious diseases that affect humans and exact a heavy toll in terms of quality of life, medical costs, and productivity. Similar advances have contributed to improvements in animal and plant health and the food supply.

Across the globe, researchers are manipulating microorganisms to gain a deeper understanding of how they cause disease to identify new targets for the development of novel and improved treatments for the diseases these microbes cause, identify new strategies for the control of microorganisms, and develop measures to prevent infection with or illness caused by microorganisms.

Plant biologists are utilizing similar approaches to enhance crop yield and nutritional content and explore the potential for using plants to manufacture products such as vaccines, antibodies, and other biological products. Similar efforts are underway in the field of animal husbandry in an effort to produce animals for human consumption that are heartier and better sources of nutrition. In other arenas, life scientists are developing environmental remediation technologies and creating new materials and even energy sources.<sup>1</sup>

*The Dual Use Research Issue.* Information from life sciences research is clearly vital to improving public health, agriculture, and the environment and maintaining and strengthening our national security and economy. Yet the very information and tools developed to better the health, welfare, and safety of humankind also can be misused for harmful purposes. Information

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<sup>1</sup>*Globalization, Biosecurity, and the Future of the Life Sciences*, a 2006 report of the National Research Council's Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, pp. 1, 83.

from legitimate life sciences research can be misapplied to create dangerous pathogens for employment as weapons, bypass countermeasures or threaten in other ways the health and safety of humans, animals, plants, and the environment or to cause harmful consequences to materiel.<sup>2</sup>

This was recognized by the European Molecular Biology Organization (EMBO) at its 2006 meeting<sup>3</sup> and was also eloquently articulated in a statement by an august group of scientific journal editors and authors: “The process of scientific publication, through which new findings are reviewed for quality and then presented to the rest of the scientific community and the public, is a vital element in our national life. New discoveries reported in research papers have helped improve the human condition in myriad ways: protecting public health, multiplying agricultural yields, fostering technological development and economic growth, and enhancing global stability and security. But new science, as we know, may sometimes have costs as well as benefits. . . . As a result, questions have been asked by the scientists themselves and by some political leaders about the possibility that new information published in research journals might give aid to those with malevolent ends.”<sup>4</sup>

The development of new technologies and the generation of information with the potential for benevolent and malevolent purposes are referred to in this report as “dual use research.”<sup>5</sup> This dual use quality is inherent in a significant portion of life sciences research. In fact, it can be argued that virtually all life sciences research has dual use potential. Later in this report, we describe a subset of dual use research that has the highest potential for generating information that could be misused, which we call “dual use research of concern.”

The NSABB gave a great deal of thought to the issue of how much life sciences research might reasonably be considered dual use research of concern. Although it was not possible to quantify the exact amount of dual use research of concern that is generated in the U.S. or elsewhere in a given period such as a year, preliminary analyses suggested that the number of cases of true dual use research of concern will be quite small. Similarly, it was not possible to quantify the risk of misuse of information from that research, but there was a consensus among NSABB members that there is indeed the potential for misuse with severe consequences to public health and safety and other areas presented herein. Misuse of dual use research of concern is therefore a low-probability but potentially high-consequence event, and this is a significant factor in the NSABB’s formulation of oversight recommendations.

*Calls to Action.* Over the past several years, especially following the terrorist attacks of September 11, 2001 and the subsequent anthrax attacks utilizing the U.S. Postal Service over the course of several weeks beginning on September 18, 2001, there have been increasing calls to consider the possibility that new information from life sciences research could be subverted for malevolent purposes and to institute new biosecurity measures to minimize this risk.

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<sup>2</sup>Materiel includes food, water, equipment, supplies, or material of any kind.

<sup>3</sup>EMBO Reports, vol. 7, Special Issue on Science and Society (2006).

<sup>4</sup>Journal Editors and Authors Group, *Statement on the Consideration of Biodefense and Biosecurity*. *Nature* vol. 421, February 20, 2003.

<sup>5</sup>The NSABB Charter also describes dual use research. See Appendix 1.

Concerns about the dual use potential of biotechnology research have been articulated in reports from the National Research Council (NRC) of the U.S. National Academies, together with a number of recommendations for addressing such concerns.<sup>6,7</sup> One of the reports noted that, “[w]ith regard to oversight of research, no country has developed guidelines and practices to address all aspects of biotechnology research. . . . [E]xisting domestic and international guidelines and regulations for the conduct of basic or applied genetic engineering research may ensure the physical safety of laboratory workers and the surrounding environment from contact with or exposure to pathogenic agents or ‘novel’ organisms. However, they do not currently address the potential for misuse of the tools, technology, or knowledge base of the research enterprise for offensive military or terrorist purposes. In addition, no national or international review body currently has the legal authority or self-governance responsibility to evaluate a proposed research activity prior to its conduct to determine whether the risks associated with the proposed research, and its potential for misuses outweigh its potential benefits. . . . [T]he existing fragmentary system must be adapted, enhanced, supplemented, and linked to provide a system of oversight that will give confidence that the potential risks of misuse of dual use research are being adequately addressed while enabling vital research to go forward.”<sup>8</sup>

Similarly, the Royal Society and the Wellcome Trust noted that “[r]esearch institutions and funding agencies need to consider how to build on existing processes for reviewing research projects to ensure that risks of misuse are assessed in an appropriate and timely manner.”<sup>9</sup> Likewise, a group of distinguished journal editors and authors convened to consider biodefense and biosecurity recommended that “[s]cientists and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues.”<sup>10</sup>

*U.S. Government Response.* In acknowledgment that the threat of the misuse of research information is important and real, the U.S. Government agreed that new biosecurity measures were warranted to minimize the risk that information from life sciences research might be misused to threaten public health and safety and other aspects of national security. One of these biosecurity initiatives was the establishment of an advisory body, the NSABB. The NSABB charter states that its purpose is to recommend strategies for the efficient and effective oversight of federally conducted or supported dual use biological research (see Appendix 1 for the NSABB charter and the current roster of NSABB members.)

The NSABB is charged with a significant set of specific tasks, including proposing an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential. In doing so, the NSABB was instructed to consider both national security concerns and the needs of the life sciences research community. The latter directive acknowledges the vital role of life sciences research in public health and in national security and

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<sup>6</sup>*Biotechnology Research in an Age of Terrorism*. Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, National Research Council. National Academies Press, Washington, DC (2004).

<sup>7</sup>*Globalization, Biosecurity, and the Future of the Life Sciences*. Op. cit.

<sup>8</sup>*Biotechnology Research in an Age of Terrorism*, p.3. Op. cit.

<sup>9</sup> Report of a Royal Society-Wellcome Trust meeting. *Do no harm: Reducing the potential for the misuse of life science research*. October 7, 2004, p.1.

<sup>10</sup> *Statement on the Consideration of Biodefence and Biosecurity*. Op. cit.

the need to ensure that whatever oversight measures are put in place for dual use research do not unduly burden or slow the progress of life sciences research. Although the purview of the NSABB is life sciences research, the Board acknowledges that there is increasing overlap between biology and other disciplines and recommends that the oversight of dual use research extend beyond the traditional life sciences disciplines. The same concerns about not unduly hindering the progress of science would apply to these other fields as well.

*NSABB Considerations.* Although the potential for misuse of scientific information exists, and the consequences could be severe, one of the major concerns of the NSABB is that the response to this threat be carefully measured lest more harm than good be done in the name of biosecurity. No oversight system can bring the risk of misuse of information to zero, nor can it completely prevent those that are intent on doing harm from doing so. The goal is to implement reasonable precautions to minimize the risk of misuse while still maintaining a vibrant research enterprise. Oversight measures should not create impediments to legitimate life sciences research.

The continued rapid progress of the life sciences is paramount since findings from life sciences research directly and indirectly underpin medical progress, the safety and quality of the food supply, the quality of our environment, advances and productivity in numerous commercial sectors, and the status of public health and safety.

Indeed, in a statement on science and security in an age of terrorism that predates the formation of the NSABB, presidents of the three U.S. National Academies (National Academy of Sciences, National Academy of Engineering, and Institute of Medicine) noted that, “[i]n meeting this responsibility, the scientific, engineering, and health research community also recognizes a need to achieve an appropriate balance between scientific openness and restrictions on public information. Restrictions are clearly needed to safeguard strategic secrets; but openness also is needed to accelerate the progress of technical knowledge and enhance the nation’s understanding of potential threats.”<sup>11</sup>

Subsequently, a report from the National Academies emphasized the need to promote the free and open exchange of information in the life sciences to the maximum extent possible, noting “the many ways that biological knowledge and its associated technologies have improved and can continue to improve biosecurity, health, agriculture. . . . [C]onversely, restrictive regulations and the imposition of constraints on the flow of information are not likely to reduce the risks that advances in the life sciences will be utilized with malevolent intent in the future. In fact, they will make it more difficult for civil society to protect itself against such threats and ultimately are likely to weaken national and human security. Such regulation and constraints would also limit the tremendous potential for continuing advances in the life sciences and its related technologies to improve health, provide secure sources of food and energy, contribute to economic development in both resource-rich and resource-poor parts of the world, and enhance the overall quality of human life.” The report further recommended ensuring “that any biosecurity policies or regulations implemented are scientifically sound and are likely to reduce risks without unduly hindering progress in the biological sciences and associated technologies.”<sup>12</sup>

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<sup>11</sup> Alberts B, Wulf WA, Fineberg H. *Statement on Science and Security in an Age of Terrorism*. October 18, 2002.

<sup>12</sup> *Globalization, Biosecurity, and the Future of the Life Sciences.*, pp. 6-8. Op. cit.

Similar concerns have been voiced elsewhere. For example, a report from the Royal Society and Wellcome Trust noted that “the threat of advances in the life sciences being used for harmful purposes is a real one” and that “the challenge that the scientific community faces is to identify what measures can be taken to manage or reduce this risk without jeopardizing the enormous potential benefits from research advances. . . . Research institutions and funding agencies need to consider how to build on existing processes for reviewing research projects to ensure that risks of misuse are assessed in an appropriate and timely manner.”<sup>13</sup>

The current inability to quantify dual use research of concern and the risk of misuse of research information raises challenges for proposing an oversight framework. The NSABB recognized some parallels with recombinant deoxyribonucleic acid (DNA) research, which provides an important historical precedent for managing risk when its magnitude is unknown. The system of oversight for recombinant DNA has stood the test of time in part because it is capable of evolving with technological developments and new scientific understanding. Oversight of recombinant DNA research is not imbedded in regulation; this provides greater facility to adapt to advancing science while nonetheless establishing a standard of practice that is embraced by public and private sectors.

The NSABB has drawn from the recombinant DNA research oversight system in proposing oversight measures for dual use research of concern. The current proposals are for guidelines rather than regulations so that course corrections can be made more easily and new technological advances can be addressed as needed with relative ease. One concern that has been raised by NSABB members and also by members of the public is that the NSABB charter currently states that the scope of oversight for dual use research is federally conducted or supported biological research. The NSABB recognizes that a significant amount of life sciences research, some of which may be dual use of concern, is conducted with private funds. Regardless of whether life sciences research is publicly or privately funded, the fundamental principles regarding the responsible conduct and communication of dual use research should be followed.

*Need for Engagement of the Life Sciences Community.* The NSABB strongly believes that one of the best ways to address concerns regarding dual use research is to raise awareness of dual use research issues and strengthen the culture of responsibility within the scientific community. The stakes are high for public health, national security and the vitality of the life sciences research enterprise. Responsible scientists have a duty to be aware of the potential for misuse of their scientific findings and of their obligation to help inform and shape critical policy decisions about biosecurity in the life sciences.

As noted previously, there have been numerous calls for consideration of the security implications of life sciences research findings and for establishing processes to minimize the risk of misuse of those findings with dual use potential. This has been voiced in many different quarters: the scientific community, including journal authors and editors, researchers, academies (national and international), and professional societies; the U.S. Congress and other legislative and policymaking bodies; the federal agencies that fund and conduct life sciences research; the federal entities involved in national security; and members of the public. Thus, it is almost a

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<sup>13</sup>Report of a Royal Society-Wellcome Trust meeting. Op. cit.

certainty that new oversight procedures will be implemented in the life sciences to protect against the threat of misuse of research information.

Participating in the development of those measures is an opportunity to ensure that the open process of scientific discovery that has been so critical to the progress and achievements in life sciences research remains open. Life scientists have been and must continue to be fully committed to the free flow of scientific inquiry. It is in the life sciences community's interest to engage and demonstrate to the public and policymakers that life scientists are taking responsibility for the implications of their work.

This view has been echoed in commentaries and editorials in prestigious international scientific journals. For example, one commentator noted that “[b]iologists must begin a process of self-regulation for projects that have potential applications in developing bioweapons—or risk the imposition of restrictive controls from outside.”<sup>14</sup> Another stated that “[b]iologists should involve themselves in the debate over biological weapons—both to ensure that we have the means to counter the threats that such weapons pose and to help keep those threats in perspective. . . . By becoming more aware of the issues and engaging more vigorously in discussions on bioweapons, biologists can also help to ensure that threats are not blown out of proportion. . . . But if biologists stick their heads in the sand and pretend that their work has nothing to do with warfare, they will be doing the world a disservice.”<sup>15</sup> Yet another noted that “[t]he greatest concern is in the need for clarity. It is important to develop clear guidelines about what research is considered sensitive, what is expected of researchers whose work produces dual-use outcomes, and how the government should in practice respond without losing the priceless virtues of open scientific scrutiny. Without such clarity, officials insensitive to those virtues may institute precautionary measures that reach far beyond what is appropriate.”<sup>16</sup> Indeed, a senior official of the U.S. Government cautioned that “[t]he science community ought to come up with a process before the public demands the government do it for them, and that will be driven by the rate at which controversial papers hit the streets.”<sup>17</sup>

The NSABB recognizes that broad consultation with the scientific and security communities and with the public is essential in order for its recommendations regarding an oversight system to be useful, relevant, practicable and acceptable. As the three Presidents of the National Academies observed, “[a]chieving the purpose of scientific and technological activity—to promote the welfare of society and to strengthen national security—will require ingenuity from our science, engineering, and health community, as well as from the many agencies of the federal, state, and local governments involved in counterterrorism. The nation's safety and the continued improvement of our standard of living depend on careful, informed action on the part of both governments and the scientific, engineering, and health community. A continuing, meaningful dialogue needs to begin—one that produces a true collaboration for the many decisions that need to be made.”<sup>18</sup> Similar thoughts were articulated in a report of the Royal Society and the Wellcome Trust: “The challenge is to think beyond the obvious and identify those avenues of

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<sup>14</sup> Aldous P. *Biologists urged to address risk of data aiding bioweapon design*. *Nature* 2001. 414(6861):237-8.

<sup>15</sup> *A call to arms*. *Nature* 2001. 411(6835):223.

<sup>16</sup> *Risks and benefits of dual-use research*. *Nature* 2005. 435(7044):855.

<sup>17</sup> Check E. *US officials urge biologists to vet publications for bioterror risk*. *Nature* 2003. 421(6920):197.

<sup>18</sup> Alberts B. et al. *Op. cit.*

research and technologies that present risks of being misused for harmful purposes that are quite distinct from the original aims of the work. This needs imaginative thinking as the vast majority of work falls into the grey area of having some potential for misuse.”<sup>19</sup>

It is the NSABB’s expectation that its recommendations will be a useful springboard for the U.S. Government in the development and implementation of a comprehensive system for the responsible identification, review, conduct, and communication of dual use research. To this end, the NSABB emphasizes that comments are welcome on any and all aspects of this report. Specific questions are posed in Appendix 2, but input need not be limited to these questions. In addition, the NSABB notes that, in keeping with its charge, as the oversight system is further developed by the U.S. Government, the Board will address certain issues in more detail in the near future, including compliance and enforcement and education and outreach.

### **Guiding Principles for Oversight of Dual Use Life Sciences Research**

As a first step in proposing a framework for oversight, the NSABB identified a number of principles that should underpin any oversight of dual use life sciences research:

- Life sciences research underpins advances in public health, agriculture, the environment, and other pertinent areas and contributes significantly to a strong national security and economy. The life sciences are a global enterprise and becoming ever more so. The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise; thus the “default” position should be the unfettered progress and communication of science. Any decision to do otherwise should be undertaken very carefully.
- However, life sciences research has the potential to produce information or technology that can be misused to pose a threat to public health and safety, and therefore it is appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.
- Effective oversight will help maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of dual use research and is acting responsibly to protect public welfare and security. The federal agencies that fund life sciences research, the institutions that are the recipients of those public funds, and the individuals who conduct this research share this oversight responsibility.
- Any oversight system must balance the need for security with the need for research progress. The degree of oversight should be consistent with the likelihood and possible consequences of misuse.
- The foundation of oversight of dual use research includes investigator awareness, peer review, and local institutional responsibility. Such oversight allows input directly from

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<sup>19</sup>Report of a Royal Society-Wellcome Trust meeting, p.1. Op. cit.

the investigators, facilitates timely review, offers appropriate opportunities for public input, and demonstrates to the public that scientists are taking responsibility for their research.

- The responsible conduct and communication of dual use research of concern depend largely on the individual conducting such activities. No criterion or guidance document can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key to the responsible evaluation of research for dual use potential. It is incumbent on the institution and the investigator to adhere to the intent of such guidance as well as to the specifics.
- Life sciences research is by nature dynamic and can produce unanticipated results and therefore must be periodically evaluated for dual use potential.
- For the oversight system to be effective, it is essential that the various federal government agencies involved pursue a harmonized approach to the oversight of dual use research.
- The effectiveness of an oversight framework depends on awareness by the scientific community and the public of the dual use potential of research.
- An efficient and effective oversight system also requires ongoing dialogs among the scientific communities, governmental agencies, and the public.
- The responsible communication of dual use research of concern is essential to maintain public confidence in the scientific community.
- The oversight process for dual use research must be periodically evaluated both for effectiveness and impact on the research enterprise.

Below are the key features and roles and responsibilities proposed by the NSABB for the oversight of life sciences research with dual use potential.

### **Key Features of the Proposed Oversight System**

Following are descriptions of seven key features of the proposed oversight system:

*Federal Guidelines.* Federal guidelines for oversight of dual use life sciences research should be developed by the relevant federal agencies with a role or interest in life sciences research. The guidelines should take into consideration the recommendations of the NSABB, including the considerations for a code of conduct and the specific tools/guidances developed for identifying dual use research of concern, for assessing and managing risk, and for communicating dual use research responsibly—as well as public comments on the NSABB recommendations.

The guidelines will assist scientists, institutions, other entities, and the federal government in determining and implementing safeguards regarding dual use research. The guidelines should address at a minimum:

- Scope and applicability of the guidelines

- Definitions
- Research covered by the guidelines, including criteria for identifying dual use research of concern and points to consider in applying the criteria
- Guidance for the review of research that is potentially dual use of concern, including points to consider in risk assessment and strategies for risk management
- Roles and responsibilities of entities and individuals engaged in life sciences research
- Criteria for referring issues from the local level to the federal level
- Processes and procedures for addressing dual use research issues at the federal level
- Compliance and penalties for noncompliance

The guidelines should be clearly written, well organized, and understandable to both the scientific community and the general public. The guidelines should also be periodically updated to keep pace with developments in the life sciences.

*Awareness.* Researchers, research personnel, and research administrators should be fully aware of dual use research concerns, issues, and policies. An enhanced culture of awareness is essential to an effective system of oversight and is a critical step in scientists taking responsibility for the dual use potential of their work.

*Education.* Awareness will be enhanced through ongoing, mandatory education about dual use research issues and policies. This will ensure that all individuals engaged in life sciences research are aware of the concerns and issues regarding dual use research and their roles and responsibilities in the oversight of such research.

The federal government should develop training and guidance materials on federal requirements that can be used as educational resources at the local level. Furthermore, scientific societies, professional associations, and others in the private sector have an important contribution to make in promoting a culture of awareness and responsibility by educating broadly about dual use research, the associated tenets of responsible research, and the best practices in identifying and overseeing dual use research. The federal government can foster the development of such private sector training and education initiatives by providing appropriate resources for their development. Research institutions and associations should utilize these materials, tailoring them as needed to different audiences as part of promoting an awareness of dual use research issues among those involved in life sciences research.

*Local Evaluation and Review of Research for Dual Use Potential.* The initial evaluation of the dual use potential of life sciences research should be conducted by the investigator, after appropriate training. Additional review by others at the research institution may also be appropriate to ensure an unbiased and comprehensive evaluation and application of the criteria for identifying dual use research of concern. Local evaluation and review ensure that those with the appropriate expertise and the best understanding of local personnel, facilities, and ethos are assessing research for dual use potential. Local evaluation and review also demonstrate to the public that scientists and their institutions are attending to the biosecurity implications of dual use research and facilitates the timeliness of the oversight process.

*Risk Assessment and Risk Management.* The degree of oversight should be commensurate with the degree of risk and the potential impact of any misuse of research information. Risk assessment and management should be the foundation for local oversight of dual use research of concern. This will help minimize the potential for misuse of dual use research information while minimizing any negative impact on the conduct of science and will facilitate the responsible conduct of life sciences research.

*Periodic Evaluation.* There is a need for periodic evaluation, at the local and federal levels, of the need for oversight of dual use life sciences research, of the effectiveness of the oversight system, and of the administrative burden of the oversight system. Assessing the need for and effectiveness of the oversight system in minimizing the risks associated with dual use research of concern, while allowing important research to go forward, will promote the conduct of life sciences research and its efficient and effective governance and will facilitate the implementation of course corrections as appropriate.

*Compliance.* As the oversight framework is formalized into policy and guidelines by the U.S. Government, mechanisms at both the federal and local level for ensuring compliance will be an important consideration and will need to be addressed in detail. The NSABB will advise on this topic as necessary in the future. Thus, the NSABB recommends that federal agencies develop consistent mechanisms for enforcement, including penalties for noncompliance, perhaps by making compliance a term and condition of funding.

It is also understood that the applicability of the federal policy for oversight of dual use research, at least initially, will be to federally conducted or funded dual use life sciences research. The NSABB recommends that the applicability of federal policy for dual use research be as wide as possible. For example, the applicability of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* goes beyond research that is funded by the National Institutes of Health (NIH); it extends to all research that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from the NIH, including research that is privately funded. Such a mechanism should be considered for dual use life sciences research as well. The NSABB recognizes that this still will not cover all entities engaged in dual use life sciences research. Nonetheless, the NSABB anticipates that the dual use research issue will be appreciated by those entities engaged in life sciences research that are not subject to the federal policy and that these entities will voluntarily comply with dual use research oversight guidelines. The effectiveness of voluntary compliance by noncovered entities should be evaluated at a designated time after Federal policies are implemented to inform decisions as to whether other federal enforcement mechanisms should be contemplated.

The NSABB also notes that lines between biology and other disciplines are increasingly blurred as multidisciplinary approaches are employed for addressing complex biological problems. For example, mathematical modeling and chemical engineering approaches are often combined with more traditional biologic techniques to solve a problem. Consequently, disciplines not ordinarily considered to fall within the life sciences may yield dual use biological information. Therefore, the NSABB recommends that the U.S. Government consider the need to apply dual use research oversight measures beyond what is usually thought of as the traditional life sciences disciplines.

## **Roles and Responsibilities in Oversight of Life Sciences Research With Dual Use Potential**

*Researchers.* Researchers are the most critical element in the oversight of dual use life sciences research. They know the work best and are in the best position to anticipate the types of knowledge, products, or technologies that might be generated, the potential for misuse, and the degree of immediacy of that threat. However, to fulfill this responsibility, the principal investigator (PI) must be cognizant of the concept of dual use research of concern and aware of the risk that technologies or information produced by life sciences research may be misused. Researchers thus have a professional responsibility to be aware of dual use research issues and concerns, to be aware of the implications of their work and the various ways in which information from their work could be misused, and to take steps to minimize misuse of their work. This includes being knowledgeable about and complying with all local and federal policies for oversight of dual use research, ensuring that their own dual use research training and that of their staff is current, assessing their own work and that of their research personnel for dual use potential on an ongoing basis, and communicating dual use research in a responsible manner.

Researchers should carry out their work in an ethical and responsible manner, adhering to the standards of conduct described in the NSABB document “Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences” (see Appendix 3).

On an annual basis, researchers should also provide formal assurance to their institutions that they are assessing their work for potential dual use of concern. The NSABB also recommends that there be a mechanism, such as a check box, on new grant applications and competing renewals, indicating that the dual use potential of the proposed work has been evaluated and whether there is such potential. The NSABB recognizes that these mechanisms will need to be implemented by science funding entities.

*Research Institutions.* Institutions have a number of general responsibilities regarding the oversight of life sciences dual use research:

- Ensuring that life sciences research is conducted in conformance with applicable federal, state, local (e.g., municipal), and institutional policies.
- Establishing and implementing internal policies and practices that provide for the effective and efficient oversight of dual use research of concern. The degree of oversight should be consonant with the degree of risk of misuse and the potential impact of misuse of research information. Policies and practices for oversight of dual use research should minimize any negative impact on the conduct of life sciences research.
- Establishing mechanism(s) for advising on dual use research issues and assisting investigators in complying with dual use research policies. This should include the designation of a point of contact within the institution for questions regarding dual use research.

- Providing appropriate education on dual use research for individuals involved in life sciences research. This can utilize educational and training materials developed by the federal government.
- As necessary, assisting the PI in deciding whether her or his research meets the criterion for dual use research of concern and thus requires further review or oversight. In the great majority of cases, it is anticipated that the institution will rely on the judgment of the researcher. In some cases, however, the researcher may request additional review by an individual with sufficient knowledge and/or expertise to assist in these determinations. Such an independent evaluation of the dual use potential of the research may bring to bear additional objectivity, perspective, and knowledge and may assist in considering the ways in which the information from the research could be misused.
- Establishing an internal mechanism for investigators to appeal local decisions regarding dual use research.
- Addressing internal requests for referral of dual use research issues to the federal level.
- Upon request and as appropriate and consistent with applicable laws, making available to the public information pertaining to institutional oversight of dual use research.
- Periodically assessing the effectiveness of internal policies for oversight of dual use research, including feedback from investigators and other stakeholders.
- Reporting significant violations of federal dual use research policies as specified by an institution or by federal policy.

Institutions also have specific responsibilities regarding the evaluation of research for dual use potential and the review of research that has been identified as dual use of concern:

- Establishing an institutional mechanism for expert committee review (including risk assessment and risk management) of research that has been identified as dual use of concern.
  - This local committee should be constituted in a manner so as to have the necessary expertise to consider the dual use implications of research and to recommend and oversee risk management strategies.
  - When institutions already have an Institutional Biosafety Committee (IBC) in place, they should consider using this existing mechanism for the review of dual use research of concern. Many of the kinds of experiments raising dual use considerations entail recombinant DNA and would otherwise be subject to IBC review, helping minimize any additional burdens. Dual use expertise could be brought to the IBC through the use of ad hoc members.
  - Alternative approaches should also be acceptable—such as establishing a committee exclusively for dual use review or utilizing an externally administered committee (e.g., an IBC at a neighboring institution or a commercial IBC)—as long as the committee is competent to conduct dual use review.

- Institutions should strive to develop review processes that do not encumber the conduct of life sciences research that is not dual use of concern.

Institutions also have some administrative responsibilities regarding the oversight of dual use life sciences research:

- As may be required by federal policy, registering their review mechanism and updating that registration annually
- Designating an institutional point of contact on dual use research issues
- Collecting and maintaining records of personnel training on dual use research and of investigator assurances, provided on an annual basis, that the researchers are assessing their research for dual use potential

*Institutional Review Entity.* The review entity utilized to fulfill the institution's responsibility to review work that has been identified as dual use research of concern should have, or be able to provide on an ad hoc basis, sufficient breadth of scientific expertise to assess the dual use potential of the range of research conducted at a given research facility. The review entity must have knowledge of dual use issues, concerns, and policies and understand risk assessment and risk management considerations. Risk assessment and management considerations should include, but not necessarily be limited to, those in the guidance developed by the NSABB and described below.

At institutions subject to the *NIH Guidelines*, the most suitable review entity will likely be the IBC, supplemented as appropriate with expertise pertinent to dual use research. Alternatively, institutions may wish to establish a committee exclusively dedicated to the review of dual use research. However this review function is established, the review entity should be sufficiently empowered by the institution to be able to ensure compliance with dual use research policies.

*NSABB.* The NSABB should continue to carry out the functions specified in its charter. This includes recommending strategies for the efficient and effective oversight of dual use life sciences research, taking into consideration both national security concerns and the needs of the research community. This includes, but is not limited to, advising on federal and local oversight of dual use research, contributing to the development of federal guidelines for dual use research, recommending procedures and practices for communicating dual use research results and methodologies, advising on interpretation and application of federal guidelines for dual use research, and recommending strategies for outreach and education at national and international levels.

In addition, the NSABB should also periodically evaluate the oversight system for dual use research, both for effectiveness and impact on the research enterprise.

As requested and appropriate, the NSABB should also serve as a resource to the research community, including the scientific publishing community, on dual use research issues.

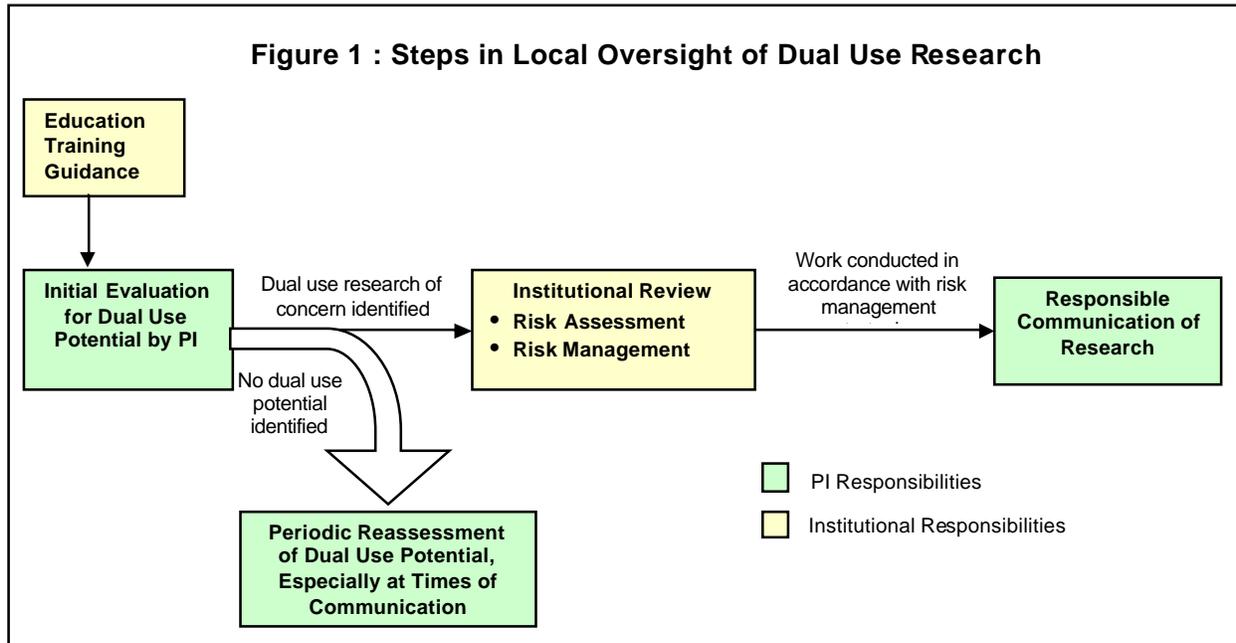
*U.S. Federal Government.* The government is responsible for ensuring that any oversight system is efficient and effective and should also ensure that any negative impact on life sciences research is minimized. This includes ensuring a harmonized governmental approach to the oversight of dual use research. Thus, those federal entities with a role or interest in dual use research should work together on the development of policy that aligns with their agency mission and organizational function for the effective oversight of dual use research, including compliance mechanisms, penalties for noncompliance, and processes for adjudication. There will also need to be harmonized interpretations of policy in the future. A related and key responsibility is periodic federal government evaluation of the oversight system, for both effectiveness and impact on the research enterprise.

Proper oversight of dual use research should not be an unfunded mandate. Thus, the federal government should ensure that sufficient resources are provided to institutions in the fulfillment of this responsibility. The provision of resources for oversight should not be at the expense of existing research programs.

Additional roles and responsibilities include education and outreach to affected entities about dual use issues, policies, and applicable regulations and the development and encouragement of the development of training tools and materials for use at the local level to educate employees about dual use issues and their responsibilities.

The federal government is also responsible for the support and administration of the NSABB and should conduct expert consultations and solicit public comment as appropriate on dual use research and biosecurity issues.

## Major Steps in Local Oversight of Dual Use Life Sciences Research



The critical underpinnings of the oversight system will be education about dual use issues and all applicable policies as well as the provision of guidance and tools that facilitate compliance with the policies.

With that as a backdrop, the major steps or stages of local oversight are as follows (see also Figure 1 above):

- Evaluation of life sciences research for its dual use potential. This should be done at the inception of any research and periodically throughout the research process.
- Review of research identified as being potentially dual use of concern.
  - Assessment of any biosecurity risk(s) associated with the findings, technologies, or biological agents<sup>20</sup> that might be generated from the research. This includes:
    - Identification of the ways in which the information, technologies, or biological agents could be misused
    - Consideration of the potential consequences if the research information, technologies, or biological agents are misused
  - Recommendation of strategies for mitigating or managing the risk of misuse.
- Conduct of dual use research of concern in accordance with risk management strategies.

<sup>20</sup>As is consistent with 18 U.S.C. § 178, a biological agent is “any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing - (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment; . . .”

- Responsible communication of research with dual use potential. This should be done throughout the research process.

Each of these steps will be further elaborated in the text that follows.

### Criterion and Considerations for Identifying Dual Use Research of Concern

The biosecurity concerns that the NSABB is tasked with addressing pertain to the misapplication of information, technologies, or biological agents resulting from legitimate dual use research, not the conduct of the research itself. The goal of identifying dual use research of concern is to initiate a process aimed at reducing the potential that knowledge, products, or technology derived from certain life sciences research could be misapplied to threaten public health and safety or other aspects of national security. To facilitate consistent determinations of the dual use potential of research, the NSABB developed a criterion as a tool for those involved in any aspect of life sciences research.

During the process of developing the criterion, the NSABB identified a number of considerations and key concepts that are discussed below and are reflected in the final criterion:

- Because arguably most life sciences research has some potential for dual use, the NSABB strove to delineate a threshold that would identify that subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security. This subset of research is referred to herein as “dual use research of concern.”
- It is important to emphasize that evaluation of the dual use potential of research should be based on a *current understanding* of the implications of the research results and whether it is reasonable to anticipate that such information could be misapplied to pose a threat. The results of research are of concern when they can be directly misapplied to pose a threat.
- In addition, the NSABB focused on the *scope* of a potential threat as a key consideration in evaluating research for dual use potential. Thus, the criterion captures threats with *broad* potential consequences to public health or other aspects of national security (e.g., that threaten populations rather than individuals).
- It cannot be overemphasized that characterization of research as dual use research of concern should not be viewed pejoratively. Such a characterization does not automatically mean that this type of research should not be conducted or communicated, rather that the conduct and communication of that research should be carefully considered from the outset and throughout the research process. The oversight process is about the responsible conduct and communication of research, not the restriction of research.

- The concern regarding dual use research is that the information, technologies, or products developed from it could be misused to threaten national security. The NSABB found that there are many different understandings of the term “national security,” so it identified the relevant aspects and used the collective terms. Thus, the criterion refers to the potential for threats to public health and safety, agricultural crops and other plants, animals, the environment, and/or materiel. This would include threats to farming, livestock, aquaculture, terrestrial and marine wildlife, companion animals, domestic and wild plants and trees, ecological systems, and other natural resources, as well as manmade resources.
- An evaluation of research for its dual use potential will require scientific expertise and logical, sound judgment about the probability or foreseeability that others could misapply/misuse research results. It is important to acknowledge, however, that any such evaluation is subjective and will be influenced by the individual’s knowledge, experience, and judgment.
- Life sciences research is an extraordinarily dynamic field that encompasses many diverse disciplines; therefore, it will be important to periodically review the criterion and modify it as necessary to ensure its relevance in the face of new advances and technologies.

With these concepts in mind, the NSABB proposes the following criterion for identifying dual use research of concern:

**Criterion for Identifying Dual Use Research of Concern**

Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.

Determining the applicability of this criterion is a subjective and sometimes challenging task. To assist those who need to make a determination as to whether research is potentially dual use of concern, the NSABB also delineated some categories of information, products, or technologies that might be especially likely to meet the threshold within the criterion for dual use research of concern, and thus deserve careful consideration with regard to the applicability of the criterion. It is important to emphasize that not all research that fits the categories below is necessarily dual use research of concern; rather, it is research for which the criterion needs to be especially carefully considered. Moreover, it is also the case that research that does *not* fall into the categories below might also meet the criterion for being dual use research of concern.

Finally, it is important to acknowledge that the starting point for the categories below was the seven “experiments of concern” from the NRC report referenced in footnote 1. However, the

NSABB categories have a different purpose and meaning from those of the NRC report. In the NRC report, the seven experiments of concern are classes of experiments that the NRC Committee believed illustrated the types of endeavors or discoveries that would require review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail. The NSABB categories below, which in some cases are modifications of the NRC categories, are descriptors of information, products, or technologies that, if produced from life sciences research, might define that research as meeting the criterion for being dual use research of concern. Therefore, such research should be especially carefully assessed for meeting the criterion for dual use research of concern.

The NSABB categories are knowledge, products, or technologies that could enable any of the following:

1. ***Enhance the harmful consequences<sup>21</sup> of a biological agent<sup>22</sup> or toxin.<sup>23</sup>*** The rationale for this category is that enhancing the pathogenic consequences of an agent or toxin could increase the likelihood of disease and compromise the ability to treat the disease(s) they cause if extant therapeutics are no longer effective. Of note, enhancing the pathogenic consequences of an agent includes rendering a nonpathogenic microbe pathogenic. Information that would fall into this category and would likely be considered dual use of concern would be how to make a seasonal strain of the influenza virus as deadly as the 1918 pandemic strain.

An example of information that would fall under this category, but is unlikely to be dual use of concern, includes routine techniques for restoring the virulence of viral stocks by back-passaging in animal hosts, identification of virulence factors through genome-wide screening or gene knockout techniques, and standard genetic manipulation to study the virulence of an organism.

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<sup>21</sup>*Harmful consequences:* The ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

<sup>22</sup>*Biological agent:* As is consistent with 18 U.S.C. § 178, “any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing - (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment; . . .”

<sup>23</sup>*Toxin:* As is consistent with 18 U.S.C. § 178, “the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever the origin and method of production, and includes - (A) any poisonous substance or biological product that may be engineered as a result of biotechnology that is produced by a living organism; or (B) any poisonous isomer or biological product, homolog, or derivative of such a substance; . . .”

2. ***Disrupt immunity<sup>24</sup> or the effectiveness of an immunization<sup>25</sup> without clinical and/or agricultural justification.*** The rationale for this category is that immunity is a key component in a host's defense against pathogens and toxins, thus rendering an immunization ineffective or disrupting immunity could have harmful consequences for public health, agricultural crops and other plants, and animals. For instance, rendering an immunization ineffective could make a host population vulnerable to the pathogenic consequences of a microbe from which the host population would have otherwise been protected or for which protection, such as a vaccine, was available.

An example of information that fits this category and might qualify as dual use of concern is the insertion of an immunosuppressive cytokine into a viral genome to render the antiviral immune response less effective. Information about the immunosuppressive properties of chemotherapeutic drugs for cancer or autoimmune disorders could also fit this category, although it is unlikely to be dual use of concern.

3. ***Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions<sup>26</sup> against that agent or toxin or facilitate their ability to evade detection methodologies.*** The main concept is that anything that might compromise the ability to detect, treat, or prevent disease or illness (human or agricultural) caused by biological agents or toxins could result in a significant public health and/or economic burden.

Examples of information that might fit this category and be considered dual use of concern include conferring doxycycline resistance to *Vibrio vulnificus* or conferring antibiotic resistance to agriculturally relevant microbes, such as rendering *Ralstonia solanacearum* (a bacterium on the U.S. Department of Agriculture list of high-consequence organisms) resistant to rifampin. Examples of research that might fit this category, but are unlikely to be dual use of concern, include the use of standard laboratory selection procedures with antibiotics using host-vector systems that do not present a significant risk to health or the environment (e.g., transforming a nonpathogenic/nontoxic *Escherichia coli* strain with a construct for the expression of a nontoxin protein or conferring rifampin resistance to *Pseudomonas fluorescens*).

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<sup>24</sup>*Immunity*: Encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators).

<sup>25</sup>*Immunization*: Refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids.

<sup>26</sup>*Clinically and/or agriculturally useful prophylactic or therapeutic interventions*: Includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algacides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algacides, insecticides, rodenticides, etc.

4. ***Increase the stability,<sup>27</sup> transmissibility,<sup>28</sup> or the ability to disseminate<sup>29</sup> a biological agent or toxin.*** The rationale for this category is that increasing an agent's stability, transmissibility, or ability to disseminate could facilitate the purposeful malevolent use of a biological agent or toxin and increase the rate or ease by which an agent could spread, impeding attempts to contain disease outbreak. Uncontained outbreaks could lead to a large infected host population, which may not receive adequate care and treatment due to limited resources, allowing the disease to spread. Effective dissemination of a pathogenic agent or toxin could result in large-scale exposure and the inability to prevent or treat ensuing disease and/or damage in a host population. The inability to prevent or treat the disease or toxicity due to the lack of resources or therapeutics could result in a significant threat to the health of the host population(s). Of note, this category includes transmission between hosts of the same species or between hosts of differing species. The use of the term "weaponization" was carefully considered for this category, but since the term is not uniformly understood within the life sciences community, the concept of dissemination, which is a key component of weaponization, seems more appropriate.

Examples of research that falls within this category and that might be considered dual use of concern include changing genetic factors to increase transmissibility and altering the route of transmission or vector to increase the ease and effectiveness by which an agent may be transmitted. With regard to increasing the capability of an agent or toxin to be disseminated, there are inherent challenges in deciding whether information that falls into this category is dual use of concern. Some of the challenge relates to issues of scale and intent. For example, work on vectors to increase their activity for gene therapy may also enable the wide-scale dissemination of a pathogenic agent or toxin. Research on adjuvants, methods, and tools for the increased efficacy of biocontrol agents in agriculture may also encompass work with equipment such as agricultural sprayers that may need to be examined for their dual use potential.

5. ***Alter the host range<sup>30</sup> or tropism<sup>31</sup> of a biological agent or toxin.*** The rationale for this category is that altering the host range or tropism of a pathogenic agent or toxin could endanger a host population that normally would not be susceptible. Prevention and therapy measures for the newly vulnerable host population may be lacking, possibly allowing for the uncontrolled spread of disease. An example of research information that would fall under this category and that may be dual use of concern

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<sup>27</sup>*Stability:* The ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host.

<sup>28</sup>*Transmissibility:* The ease with which an agent spreads from host to host or from vector to host, e.g., via arthropod vectors.

<sup>29</sup>*Dissemination:* The process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

<sup>30</sup>*Host range:* The number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier.

<sup>31</sup>*Tropism:* The specificity of a biological agent or toxin for a particular host tissue or cell.

includes converting nonzoonotic agents into zoonotic agents, altering the tropism of viruses, and expanding the varieties of the same plant that a pathogenic agent could infect. Certain vaccine research and the development of animal models for infectious disease, which may involve alterations of the host range or tropism, are unlikely to constitute dual use research of concern. Specifically, the attenuation of viruses for vaccine development, whereby the attenuation procedure relies on a change in host range to reduce human virulence, is unlikely to constitute dual use research of concern.

- 6. *Enhance the susceptibility of a host population.***<sup>32</sup> Information about rendering host populations more susceptible to the pathogenic consequences of an agent or toxin could be used to compromise immune responses and enable the acquisition and spread of disease on an epidemic scale. Of note, the distinction should be made that research applicable to this category would not alter the susceptibility of an individual host or research cohort but rather that of a host population.

Thus, examples of research information that would fall under this category and might be considered dual use of concern include creation of a stable recombinant *Lactobacillus casei* that could effectively block the host's ability to synthesize an important immune signal, such as tumor necrosis factor alpha, which may directly facilitate the evasion of normal host defenses. Examples of research that generates information unlikely to be considered dual use of concern are research on the systemic exposure to immunostimulatory and immunosuppressive DNA and their effect on host susceptibility to local inflammatory challenge, studies to develop immunosuppressive drugs for cancer or transplantation, and delivery of a small interfering ribonucleic acid (RNA) (siRNA)<sup>33</sup> to a mouse that makes it hypersensitive to ionizing radiation, an infectious agent, or a toxin.

- 7. *Generate a novel pathogenic agent***<sup>34</sup> **or *toxin or reconstitute an eradicated***<sup>35</sup> **or *extinct***<sup>36</sup> **biological agent.** The rationale for this category is that host populations may not be immune to novel agents and reconstituted eradicated agents and there may not

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<sup>32</sup>*Host population:* A collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the criteria, this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

<sup>33</sup>*Small interfering RNA (siRNA):* Known as “short interfering RNA” or “silencing RNA”; a class of RNA molecules that play a variety of roles in biology, most notably, siRNA is involved in the RNA interference (RNAi) pathway where the siRNA interferes with the expression of a specific gene.

<sup>34</sup>*Novel agent:* An agent that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype). Novel agents of concern are those for which there is no known or widely available prophylactic or therapeutic interventions, those that could evade detection, or those for which there is no known immunity.

<sup>35</sup>*Eradicated agent:* A biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. Note: Reconstituted eradicated agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade diagnostics, or those for which there is no known immunity.

<sup>36</sup>*Extinct agent:* These agents are thought to no longer exist in nature or in the laboratory.

be existing diagnostics or known or widely available prophylaxes or therapeutics for such agents.

Examples that would fall into this category and that might be considered dual use of concern include the de novo construction of a microbial pathogen using wholly unique gene sequences or combinations of sequences that do not exist in nature and reconstitution of a pathogen that no longer exists in nature, such as the reconstruction of the 1918 pandemic influenza virus. Research that is not likely to be dual use of concern includes standard experimentation that generates knockouts, mutants, reassortants, complement strains, or infectious molecular clones of viruses that are similar to naturally occurring agents.

### **Evaluation of Life Sciences Research for Dual Use Potential**

The NSABB members agreed that the PI should conduct the initial evaluation of his or her research for its potential as dual use research of concern, using the criterion set forth above as guidance for decision-making. This observation notwithstanding, an independent assessment can be valuable. It is important to emphasize, however, that there may be significant variation in the assessment of the dual use potential of any particular research project when it is considered by two or more different, equally expert reviewers. In many cases, there may be no clearly right or wrong answer. During the NSABB discussions of the oversight process and how the criterion would be applied in the initial evaluation for dual use of concern potential, the Board found significant differences in assessments made by individual NSABB members. In such cases, interactive discussion among multiple evaluators helped in the development of consensus regarding the dual use potential. Given the difficulties inherent in explicitly defining the point at which the magnitude and/or immediacy of the threat of misuse makes dual use research “of concern,” there should be an emphasis at the institutional level on education and enhanced PI awareness of the dual use issue. In the long term, an enhanced awareness and understanding of the risks of dual use research is likely to be the greatest benefit of the oversight system.

The NSABB also recommends a formal, annual attestation by researchers that they have been evaluating their work on an ongoing basis for its potential as dual use research of concern.

### **Review of Research That Is Potentially Dual Use of Concern: Risk Assessment and Risk Management**

After life sciences research is initially evaluated for its potential as dual use research of concern, the subset that may be considered dual use of concern should undergo more thorough review to determine whether the research in question does indeed constitute dual use research of concern and, if so, how the potential for misuse should be managed. The review should address:

- The potential for, and the ways in which, information, technologies, or biological agents from the research could be misused to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel

- The likelihood that the information might be misused
- The potential impacts of misuse
- Strategies for mitigating the risks that information from the research could be misused

The NSABB developed a tool for guiding this review process, “Points To Consider in Risk Assessment and Management of Research That Is Potentially Dual Use of Concern,” which can be found in Appendix 4 for consideration and comment.

### **Responsible Communication of Life Sciences Research With Dual Use Potential**

One of the major charges to the NSABB is to recommend strategies to help ensure that research information with dual use potential is communicated responsibly, in a manner that addresses both biosecurity concerns and the need for open sharing of research results and technologies so that the research can be validated and used for further research. Toward this end, the NSABB developed a set of tools to facilitate consistent decisionmaking about the responsible communication of research information with dual use potential.

These tools consist of:

- A set of principles for the responsible communication of research with dual use potential
- Points to consider for identifying and assessing the risks and benefits of communicating research information with dual use potential, including options for the communication of such research information
- Considerations for the development of a communication plan for research with dual use potential

It is important to note that it is *not* the intent of the NSABB that every potential communication of research—be it an abstract, poster, seminar, or manuscript—be assessed using the communication tools. Rather, the tools may be utilized for the subset of life sciences research or research information determined to be dual use research of concern.

Because research findings are communicated at many points along the research continuum (e.g., during project concept and design, in funding applications, in seminars, and in publication of manuscripts), it is important to be aware of the potential for misuse of information at every point. The communication tools are designed to help individuals identify and assess the risks and benefits of communicating information with dual use potential. The tools can be employed by a variety of users in a number of settings. These include researchers who are developing research proposals; investigators engaged in dual use research who are preparing abstracts, posters, seminars, and manuscripts about their work; and individuals involved in the prepublication review of such information, such as research supervisors and administrators, peers, and dual use

research review entities. The tools might also be useful to the scientific publishing community and for science ethics courses.

The variety of potential uses and users of these communication tools makes it likely that not all aspects of the tools will be applicable at all times. Thus, users are encouraged to tailor and format the tools for their specific purpose(s). For example, students in an ethics course might use the “Points To Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential” (see Appendix 5) to analyze actual manuscripts, and so would need to provide detailed answers to the questions posed. Alternatively, an institution might want a researcher developing a manuscript or poster about research with dual use potential to attest to having considered the risks and benefits of communicating that research; thus, it might be helpful to format the assessment framework with checkboxes to indicate that the points had been considered and perhaps to add a signature line. Scientific journals might find this “Points To Consider” tool most useful as a hyperlink in whatever system the journal employs for instructing authors and manuscript reviewers, especially those reviewing for biosecurity concerns.

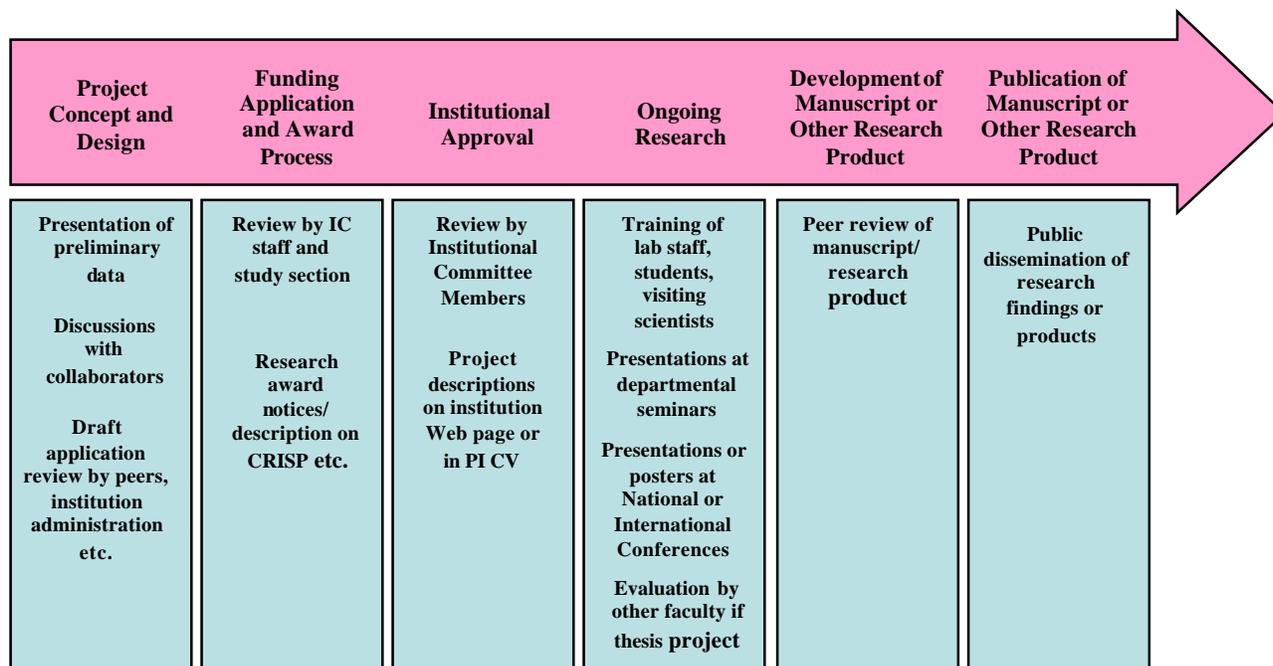
#### *Principles for the Responsible Communication of Research With Dual Use Potential.*

1. The open and unfettered sharing of information and technologies has been a hallmark of the life sciences and has fostered a steady stream of scientific advances that underpin public health and safety, a strong and safe food supply, a healthy environment, and a vigorous economy.
2. Progress in the life sciences relies heavily on the communication of research findings so that the findings can be both validated and used for further research.
3. Life sciences research should be communicated to the fullest extent possible to ensure the continued advancement of human, animal, plant, and environmental health. Consequently, any restriction of scientific communication should be the rare exception rather than the rule.
4. There is a need for reasonable balance in decisions about the communication of research with dual use potential. It is important to recognize the potential for the deliberate and malevolent misuse of dual use research findings and to consider whether the disclosure of certain information might reasonably pose a threat to national security (i.e., public health and safety, agricultural crops and other plants, animals, the environment, or materiel). If the communication of dual use research *does* pose potential security risks, the logical next step is a risk-benefit analysis of communicating the information.
5. After weighing the risks and benefits of communicating dual use research findings, the decision regarding communication is not necessarily a binary (yes/no) one. Rather, a range of options for communication should be identified and considered. The options available will depend on the research setting (e.g., academia, government, or private). They could range from full and immediate communication, to delayed and/or modified communication, to restricted/no communication, and could be recommended singly or in appropriate

combinations on a case-by-case basis, depending on the nature of the dual use finding and the potential risks associated with its communication.

6. Paradigms for the responsible communication of research with dual use potential should also take into consideration that the communication of dual use research can occur at multiple points throughout the research process, that is, at points well upstream of the publication stage (see Figure 2 below). Thus, it is important to apply principles and practices of responsible communication at these early stages as well.
7. It is important to consider not only *what* is communicated but also the *way* in which it is communicated. Investigators and sponsors of research with dual use potential should recognize that the communication of certain dual use information is likely to raise biosecurity concerns, not only within the scientific community but also within the general public. Consideration should be given to the potential for public concern and misunderstanding and for sensationalism. Thought should be given to the need for the inclusion of contextual and explanatory information that might minimize such concerns and misunderstanding.
8. Public trust is essential to the vitality of the life sciences research enterprise. It has always been important for life scientists to participate in activities that enhance public understanding of their research. However, because of the potential for public misunderstanding of and concerns about dual use research, it is especially important that life scientists conducting research with dual use potential engage in outreach on a regular basis to increase awareness of the importance of the research and to reassure the public that the research is being conducted and communicated responsibly.

**Figure 2. Examples of Points of Communication of Dual Use Research During the Research Process**



*Points To Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential.* The NSABB developed a tool to guide researchers, manuscript reviewers, and others in identifying and assessing the risks and benefits of communicating research information that may be dual use of concern. This tool includes a series of questions that can be considered as well as options for the communication of research information judged to be dual use of concern; this tool is found at Appendix 5 for consideration and comment.

*Considerations in the Development of a Communication Plan.* Because of the potential for misuse of dual use research results, concerns on the part of the public, including members of the scientific community, about the sharing of such information can be anticipated. In addition, the public is increasingly sensitive to issues pertaining to research involving dangerous microbes and the risk of accidental or intentional release of such agents. A lack of public understanding and appreciation for the reason for conducting and communicating dual use research, sensationalism of dual use research findings, and concerns about public safety and national security all serve to undermine public trust in the life sciences research enterprise. Therefore, it is the responsibility of the scientific community to ensure that dual use research results and technologies are communicated responsibly.

Depending on the nature of the dual use research result/technology being communicated and the potential impact of communicating the information, it may be prudent to consider steps to maximize public understanding of, and appreciation for, the research effort and the decision to communicate the information. This can be achieved through the development of a plan for the responsible communication of dual use research information. For example, it may be important

to address the following issues, both in the content of the work product and in the activities associated with dissemination of the work product:

- The significance of the research findings for public health and/or safety, agriculture, the environment, or materiel
- How the new information or technology will be useful to the scientific community
- The biosafety measures in place during the conduct of the research
- The dual use aspects of the information and the careful consideration given to biosecurity concerns in the decision to publish

In addition to including this type of information in the content of the work product, the following are some additional means for conveying the types of contextual information listed above. These means can be employed either singly or in any combination as deemed appropriate:

- Editorials are useful tools for providing contextual information, messages, and opinions. Editorials may be in the journal that publishes the dual use research manuscript. This type of editorial could be written by an individual who is not directly involved with the work, perhaps is not even in the same field, but who is nevertheless held in high regard by the scientific community. The editorial might speak to the significance of the research findings for public health, agriculture, the environment, or materiel; how the new information or technology will be useful to the scientific community; and the biosafety measures in place as the research was carried out and might acknowledge the dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to publish.

Editorials may also be in the popular press and issued at the same time as the manuscript or shortly afterwards. This type of editorial would be geared toward the general public and should be written in nontechnical language to the greatest extent possible. Nevertheless, it should address the same issues as described above (i.e., the nature and importance of the scientific discovery/technology; the significance of the research findings for public health, agriculture, the environment, or materiel; the safety precautions in place as the work was conducted; the dual use aspects of the information; and the consideration that was given to the biosecurity concerns in the decision to publish). Ideally, the author would be an individual who is known to and trusted by the general public.

- Press releases are commonly used by research institutions to highlight significant scientific advances for the media. They also provide an opportunity to provide contextual information (regarding issues that may be of concern to the public) and scientific perspectives on the findings (via quotes from other scientists). If the project involves investigators from multiple institutions, it will be important to coordinate the preparation and release of the announcement. In addition to including a description of the findings and their scientific significance, a press release might also address the significance of the research findings for public health, agriculture, the environment, or materiel; the biosafety and biocontainment measures in place as the work was conducted; the dual use

aspects of the information; and the consideration that was given to the biosecurity concerns in the decision to publish.

- A press conference is usually reserved for highlighting the most significant and/or sensitive advances and provides an opportunity for direct interaction with the media. The investigator(s) and institutional representatives are usually present, but press conference organizers also should consider having other experts on hand who can address questions about the potential for misuse of the dual use information, biosafety, etc. A press release is usually provided to the media at a press conference (see above), but additional relevant materials can also be made available, such as backgrounders and fact sheets.
- Questions and Answers (Qs &As) are useful tools for preparing to respond to queries from the press, the general public, or others. They might address:
  - The nature of the dual use advance
  - Reasons for conducting the work
  - Whether the public is/was at risk from the work
  - The potential for misuse of the research findings
  - Safety procedures utilized during experimentation
  - The review process prior to publication
- Talking Points are developed and employed for responding to questions from the press, the general public, or others. Talking points might include:
  - An explanation of the biosafety and biocontainment conditions that were employed to safeguard laboratory workers and the public (if applicable)
  - Acknowledgment that, along with significant benefits (to public health, agriculture, the environment, or materiel) of sharing the information widely, there are also some potential risks to publicly disseminating the information
  - Assurances that the national security implications of making such information publicly available was thoroughly considered
  - A description of how the information contained within the research findings is critical for developing public health countermeasures

## **Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences**

One of the charges to the NSABB is to provide recommendations on the development of a code of conduct for scientists and laboratory workers that could be adopted by professional organizations and institutions engaged in the performance of life sciences research. The NSABB has taken this charge to heart, recognizing that the process of developing, adopting, and adhering to a code of conduct can serve a critically important educational role in raising the awareness of the scientific community to the dual use issue and in sustaining a culture of responsibility.

In fulfillment of its charge, the NSABB developed *Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences* as a resource for scientific societies,

professional associations, and research institutions to use in the development of codes on this topic. This document:

- Provides a conceptual foundation for understanding the dual use issue
- Describes the nature and utility of codes of conduct
- Articulates the fundamental principles of responsible conduct with regard to dual use research
- Provides guidance on addressing the dual use issue in specific phases of the research process

Organizations can adopt portions of the document verbatim in developing their own codes, or modify the content as appropriate to the research activities of their members and employees. Either way, the concepts presented in the NSABB's resource document should be considered and discussed broadly as part of the process of educating scientists and laboratory staff about their responsibilities in this arena.

*“Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences”* is presented in Appendix 3 for consideration and comment.

## **Outreach and Education**

One of the charges to the NSABB is to advise on mandatory programs of education and training in biosecurity issues for all life scientists at federally funded institutions. The educational content of these training programs will derive in part from specific federal policy and requirements, which are still under development.

In the meantime, the NSABB has conducted outreach with two key purposes in mind: (1) to hone the development of its recommendations by taking into account the concerns and perspectives of diverse stakeholders and (2) to promote broader awareness of the dual use issue and to sensitize life scientists to its importance. Indeed, the NSABB has observed throughout this document that creating awareness about the dual use issue is of fundamental importance and critical to the success of an effective oversight system.

Toward these ends, NSABB members and staff have been engaged in the efforts described below:

- The development of all of the NSABB work products and recommendations entailed stakeholder consultation solicited through such means as focus groups and roundtables. This process helped the NSABB better understand the concerns of these groups and led to the development of recommendations that were meant to be reflective of the diverse perspectives of the various communities within the life sciences. These activities had the collateral benefit of raising awareness of the issue with key thought leaders and promoting dialog within the organizations they represent.

- The NSABB members and staff<sup>37</sup> regularly deliver presentations on the dual use issue and the NSABB's activities at meetings of scientists, biosafety officers, IBC members, research compliance staff, the public and other stakeholders. These presentations are an essential means of sensitizing the research community to this issue and keeping it apprised of evolving federal policymaking activities. These interactions also provide opportunities for feedback from stakeholder groups as the NSABB develops recommendations in this area. There should be continued efforts to identify key stakeholder groups and find opportunities to present to their memberships.
- The NIH staff has developed and staffed at major scientific and professional society meetings an exhibit about dual use research issues to educate attendees about dual use research and biosecurity matters and the development of related federal policy. Exhibits represent an opportunity to educate at the individual level and enhance the visibility of the issue with key constituencies. These activities should continue to highlight educational materials and specific federal requirements as they are developed.
- Under the aegis of the NSABB's Working Group on International Collaboration, the Board hosted a successful international roundtable with individuals from 20 countries and international organizations. The purpose of the meeting was to share perspectives on the dual use issue and to inform participants about the NSABB's activities. This effort was an important first step in awareness building and information sharing at the international level, and the momentum created by this event will be sustained through continuing activities of this Working Group.

As NSABB recommendations are transformed into federal policy, additional types of outreach and education will become appropriate, initially to ensure public input into the policymaking process and subsequently to educate about emerging federal requirements. Thus, the NSABB believes that a vigorous program of outreach to the research community and education of those involved in life sciences research is a logical and essential follow-on to the formal transmittal of its oversight recommendations to the U.S. Government.

With those considerations in mind, the NSABB makes the following observations and recommendations about public outreach during the federal policymaking process:

- By definition, "outreach" means going out into the community, and thus the federal government should sponsor town-hall style regional meetings orchestrated in conjunction with nongovernmental partners (such as universities) as a means of heightening awareness locally and creating more locally accessible forums for scientists and others to have input into the federal policymaking process.

As formal federal policy is developed, it will be key to solicit public comment through formal channels. This includes notice in the *Federal Register* and the establishment of a publicly accessible docket for the collection of public comments on policy that the government is considering or proposing, as well as formal analysis by federal agencies.

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<sup>37</sup>The NSABB is funded by the U.S. Government and is staffed by the NIH, an agency of the U.S. Department of Health and Human Services.

Other outreach efforts described here would supplement these important and federally required modes of informing and soliciting input from the public.

Finally, when requirements on the oversight of dual use research are formally adopted by the U.S. Government, a communications plan will be needed for the rollout of the new federal policies, as well as an intensive and ongoing campaign of workshops, presentations, print and electronic materials, exhibits, and other activities to educate about and promote compliance with new requirements. These materials and venues will be used by the federal government to educate institutions and their staffs, as well as by institutions in training their own investigators.

The NSABB also makes the following observations and recommendations regarding ongoing educational and awareness-building strategies:

- The NSABB should play a continuing advisory role in outreach and education strategies, consulting as appropriate with representatives of professional societies and government who are knowledgeable and involved in education and public relations. Specifically, the NSABB should advise on the (1) identification of key stakeholder groups, (2) formulation of message points and educational content to promote awareness of the dual use issue, (3) development of training curricula mapped to federal policy when it emerges, and (4) development of tools to convey educational content effectively to the research community. The NSABB would also advise as appropriate on the development and implementation of specific efforts, such as those described below.
- Educational programs help foster a culture of responsibility, which is important to cultivate early in the development of future scientific talent. Consequently, educational efforts on dual use research should have a broad reach. Although instruction in the responsible conduct of research is an essential ingredient of collegiate and graduate education, instructional materials and resources should be developed for incorporation into high school and even junior high school science programs. Programs should also be developed for U.S. commercial research entities and international audiences.
- The NIH currently requires formal training in the responsible conduct of research for all recipients of NIH-funded training grants and fellowships. The NIH outlines various topics that these training programs may include, and institutions should routinely incorporate the topic of dual use research into the content of NIH-mandated training programs.
- Although the federal government has a responsibility and is best poised to educate about federal policies and requirements, domestic and international nongovernmental organizations—particularly scientific associations and professional societies—have special contributions to make with respect to promoting responsible research conduct generally, including best practices, and a number of important and impressive efforts are already underway. The federal government should stimulate educational initiatives on the part of nongovernmental organizations, including the development of case studies, course curricula, and multimedia educational tools.

## **APPENDICES**

- 1. NSABB Charter and Roster**
- 2. Questions for Comment**
- 3. Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences**
- 4. Points To Consider in Risk Assessment and Management of Research Information That Is Potentially Dual Use of Concern**
- 5. Points To Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential**

## APPENDIX 1. NSABB Charter and Roster



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

### CHARTER

#### NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

##### PURPOSE

The purpose of the National Science Advisory Board for Biosecurity (NSABB) is to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. The NSABB will advise the Secretary of the Department of Health and Human Services (HHS), the Director of the National Institutes of Health (NIH), and the heads of all federal departments and agencies that conduct or support life sciences research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community. The NIH shall manage and provide support services for the NSABB.

##### AUTHORITY

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The NSABB is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

##### FUNCTION

The NSABB will advise the Secretary of HHS, the Director of NIH, and the heads of all federal departments and agencies that conduct or support life sciences research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community.

The NSABB will be composed of nongovernmental subject matter experts as well as ex officio members from the federal departments and agencies listed below and will perform the following activities:

- Develop criteria for identifying dual use research and research results.
- Develop guidelines for the oversight of dual use research, including guidelines for the risk-benefit analysis of dual use biological research and research results.
- Provide recommendations on the development of a code of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in the performance of life sciences research.

- Provide recommendations on the development of mandatory programs for education and training in biosecurity issues for all scientists and laboratory workers at federally funded institutions.
- Advise on national policies regarding the conduct of dual use biological research. This includes strategies for addressing national security concerns while at the same time fostering continued rapid progress in public health research and food and agriculture research (e.g., new diagnostics, treatments, vaccines and other prophylactic measures, and detection methods).
- Advise on national policies governing the publication, public communication, and dissemination of dual use research methodologies and results.
- Advise on national policies governing local review and approval processes for dual use biological research, including the development of guidelines for the case-by-case review and approval by Institutional Biosafety Committees (IBCs).
- Advise on criteria and processes for referral of classes of research or specific experiments by IBCs to the NSABB for guidance.
- Review and provide guidance on specific experiments insofar as they exemplify a significant or particularly complex permutation of an existing category of dual use research or represent a novel category of dual use research that requires additional guidance from the NSABB.
- Respond to requests submitted by research institutions for the interpretation and application of the guidelines to specific research proposals in instances where a proposal has been denied by an IBC and the institution seeks additional advice.
- Recommend strategies for fostering international collaboration for the effective oversight of dual use biological research.
- Address any other issues as directed by the Secretary of HHS.

As necessary, subcommittees may be established to perform functions within the Board's jurisdiction. The advice/recommendations of that subcommittee must be deliberated by the parent advisory committee. A subcommittee may not report directly to a federal official unless there is statutory authority to so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count toward the quorum for a subcommittee meeting. Ad hoc consultants do not count toward the quorum and may not vote. Subcommittee members who are not members of the parent committee may attend closed sessions of the parent committee meeting, but they may not count toward the quorum of the parent committee, and they cannot vote on committee actions. The NSABB may call upon special consultants; assemble ad hoc working groups; and convene conferences, workshops, and other activities necessary to the fulfillment of the NSABB's responsibilities.

## STRUCTURE

The NSABB shall consist of not more than 25 voting members, including the Chair. Members will be appointed by the Secretary of HHS in consultation with the heads of federal departments and agencies that conduct or support life sciences research. The Secretary will designate the Chair. All members will hold security clearances at the level of Secret or higher. A member of the NIH Recombinant DNA Advisory Committee (RAC) will serve as a voting member of the NSABB.

Areas of expertise/perspectives to be represented on the NSABB, include inter alia:

- Molecular Biology/Genomics
- Microbiology (Bacteriology)

- Microbiology (Virology)
- Clinical Infectious Diseases/Diagnostics
- Laboratory Biosafety and Biosecurity
- Public Health/Epidemiology
- Health Physicist/Radiation Safety
- Pharmaceutical Production
- Veterinary Medicine
- Plant Health
- Food Production
- Bioethics
- National Security
- Military Biodefense Programs and Military Medicine
- Intelligence
- Biodefense
- Law
- Law Enforcement
- Academia
- Scientific Publishing
- Industry Perspective
- NIH RAC Experience/Perspective
- Public Perspective
- IBC Perspective
- Export Controls

There may be nonvoting ex officio members from each of the following departments and agencies:

- Executive Office of the President
- Department of Health and Human Services
- Department of Energy
- Department of Homeland Security
- Department of Veterans Affairs
- Department of Defense
- Department of the Interior
- Environmental Protection Agency
- Department of Agriculture
- National Science Foundation
- Department of Justice
- Department of State
- Department of Commerce
- Intelligence Community
- National Aeronautics and Space Administration
- Others as appropriate

Members shall be invited to serve for overlapping terms of two to four years; terms of more than two years are contingent upon the renewal of the NSABB's Charter by appropriate action prior to its expiration. A member may serve after the expiration of the member's term until a successor has been appointed.

Management and support services for the NSABB shall be provided by the Office of Biotechnology Activities, the Office of Science Policy, and the Office of the Director, NIH. HHS and NIH staff will hold security clearances at the level of Secret or higher, as needed, to provide support to the NSABB.

### MEETINGS

Meetings shall be held at least twice a year and may be convened on an as-needed basis, at the call of the HHS Designated Federal Official who shall also approve the agenda. The Designated Federal Official shall be present at all meetings.

Meetings of the NSABB will be open to the public except as determined otherwise by the Secretary of HHS, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act. Notice of all meetings will be given to the public. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and Departmental policies.

### QUORUM

A quorum for the NSABB and each of its subcommittees shall consist of a majority of the appointed members eligible to vote. The nonvoting agency representatives shall not be counted in calculating a quorum. Of the voting members, any who are disqualified from participating in an action on a particular issue (e.g., due of a conflict of interest) shall not be counted in calculating the quorum. All votes relating to any review of a recommendation by the NSABB shall be open to the public unless the meeting has been closed to the public in accordance with the Government in the Sunshine Act and the Federal Advisory Committee Act.

### COMPENSATION

Members shall be paid at the rate of \$200 per day for each meeting day, plus per diem and travel expenses as authorized by Section 5703, Title 5 U.S.C., as amended, for persons in Government service employed intermittently. Members who are officers or employees of the U.S. Government shall not receive compensation for service on the NSABB.

### ANNUAL COST ESTIMATE

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is \$449,527. The estimated annual person-years of staff support are 4.5, at an estimated cost of \$650,073.

### REPORTS

Annual reviews and reports will be prepared, filed, and retained as required by applicable laws and Departmental policies. In the event a portion of a meeting is closed to the public, an annual report shall be prepared that shall contain, at a minimum, a list of the members and their business addresses; the NSABB's functions, dates, and places of meetings; and a summary of the NSABB's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

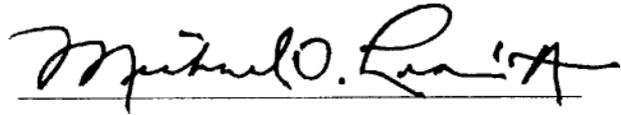
TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the National Science Advisory Board for Biosecurity shall expire April 7, 2008.

APPROVED

MAR 16 **2006**

\_\_\_\_\_  
Date

A handwritten signature in black ink, appearing to read "Michael O. Lanza", written over a horizontal line.

Secretary

**Roster**  
**National Science Advisory Board for Biosecurity**

Chair

**Dennis L. Kasper, M.D.**

William Ellery Channing Professor of Medicine and  
Professor of Microbiology and Molecular Genetics  
Harvard Medical School  
Director  
Channing Laboratory  
Department of Medicine  
Brigham and Women's Hospital  
Boston, MA

Other Voting Members

**Arturo Casadevall, M.D., Ph.D.**

Professor and Chairman  
Department of Microbiology and Immunology  
Division of Infectious Diseases  
Albert Einstein School of Medicine  
Bronx, NY

**Murray L. Cohen, Ph.D., M.P.H., C.I.H.**

President and Chairman  
Frontline Healthcare Workers®  
Safety Foundation, Ltd.  
Atlanta, GA

**Susan A. Ehrlich, J.D.**

Judge  
Arizona Court of Appeals  
Phoenix, AZ

**Lynn W. Enquist, Ph.D.**

Professor and Chair  
Department of Molecular Biology  
Princeton University  
Editor and Chief  
*Journal of Virology*  
Princeton, NJ

**Barry J. Erlick, Ph.D.**

President  
BJE Associates, Inc.  
Affiliate Professor  
Auburn University  
Adjunct Professor  
Kansas State University  
Alexandria, VA

**David R. Franz, D.V.M., Ph.D.**

Vice President and Chief Biological Scientist  
Midwest Research Institute  
Director  
National Agricultural Biosecurity Center  
Kansas State University  
Frederick, MD

**Claire M. Fraser-Liggett, Ph.D.**

Director  
Institute of Genome Sciences  
University of Maryland School of Medicine  
Baltimore, MD

**General John A. Gordon (Ret.)**

General, USAF (Retired)  
Alexandria, VA

**Michael J. Imperiale, Ph.D.**

Professor  
Department of Microbiology and Immunology  
University of Michigan Medical School  
Ann Arbor, MI

**Paul S. Keim, Ph.D.**

Division Director, Pathogen Genomics  
Translational Genomics Research Institute  
Cowden Endowed Chair in Microbiology  
Northern Arizona University  
Flagstaff, AZ

**Stanley M. Lemon, M.D.**

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## APPENDIX 2. Questions for Comment

1. The proposed institutional responsibility for expert review of research that has been identified by the principal investigator (PI) as dual use of concern may have significant implications for institutions in terms of cost, administrative burden, and workload. We are especially interested in feedback regarding these concerns and estimates of the number of projects conducted at a given institution that might meet the criterion for dual use research of concern and therefore warrant specific local review for dual use risk assessment and management.
  - What is the most appropriate entity for conducting risk assessment of research that has been identified as potential dual use research of concern? For example, should it be the Institutional Biosafety Committee (IBC), augmented with additional expertise, or should it be a separate committee?
  - If the IBC, what additional expertise would be needed to facilitate the review of dual use research of concern?
  - Is a single institution likely to have the necessary in-house expertise for this review?
  - Depending on how many projects an institution anticipates will require dual use review, would it be more efficient and effective to have the option to utilize a regional or central review entity? Would it be helpful to have the option of utilizing a commercial review entity or the review entity at another institution?
2. We anticipate that true instances of dual use research of concern will be fairly rare and so tried to design a criterion and guidance that would result in the identification of only those few cases. At the same time, we wanted to make the criterion sufficiently inclusive that it would indeed capture those instances of genuine dual use research of concern.
  - Is the criterion sufficiently specific and understandable so that research personnel can apply it consistently?
  - Will the criterion capture research that is not appropriately considered as being dual use of concern?
  - Does the criterion need to capture additional types of information?
3. Is the guidance (considerations) that follows the criterion for identifying dual use research of concern helpful and sufficient? Is it clear and understandable?
  - Should additional categories of research that may yield dual use findings of concern be included in the guidance (e.g., bioinformatics, synthetic biology, development of bioregulators, psychological/psychosocial studies of terrorists, etc.)?

- How much research at your institution would be captured with this criterion for dual use research of concern?
- 4. Is it sufficient to have the PI make the initial determination as to whether his or her research might be considered dual use of concern in a supportive environment, or should the initial evaluation always be made with input from others? If the latter, who else should participate in the initial evaluation?
- 5. Is additional guidance needed for any aspect of the proposed oversight process?
- 6. The NSABB is very concerned that the oversight system put in place achieves a reasonable balance between protecting against the misuse of information from life sciences and maintaining the free and open communication of life sciences research. We are especially mindful of the potential burden imposed by the proposed requirement for specific, additional review of that subset of research identified by investigators as possibly being dual use research of concern. We are aware that there are concerns that all institutions do not have the expertise for this and that additional resources would be required, in addition to the increased workload.
  - How much of a burden would this proposed oversight system pose to your institution? Please keep in mind that while it is a (proposed) institutional responsibility to ensure review of research that is potentially dual use of concern, it may not be necessary to conduct the review “in house” (i.e., it may be possible to conduct the reviews at a regional or central locus and/or to use commercial review entities).

## **APPENDIX 3. Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences**

### **INTRODUCTION**

Important benefits to society have been achieved in no small measure by scientists who have strived to conduct their work conscientiously and with integrity. This commitment forms the basis of a culture of responsibility in which scientists consider the risks and implications of their research and take appropriate measures to ensure that they carry out their work safely, ethically, and in a manner that warrants continued public trust and support. To achieve this aim, scientists should consider the relevant standards and guideposts for ethical and responsible research conduct as well as the potential impact their research may have on society. The importance of thoughtful consideration of ethics and research is amplified when scientists engaged in well-intended research are confronted with its potential for misuse.

In recent years, increased attention has been directed to the possibility that the knowledge, products, or technologies derived from some life sciences research may be misapplied to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as “dual use research of concern.” All those involved in life sciences research have a responsibility to avoid or minimize the foreseeable risks and harm that could result from malevolent use of research outcomes.

The National Science Advisory Board for Biosecurity (NSABB) has given extensive consideration to the characteristics that define dual use research of concern. Following its charge, the NSABB is proposing a series of recommendations and tools to help the scientific community identify and manage the risks associated with this type of research. The NSABB has observed that there is a need not only to raise life scientists’ awareness of the dual use potential of their research but also to provide and promote principles of research conduct that will sustain a culture of responsibility within the scientific community.

One useful tool for raising awareness of the potential for dual use research and promoting responsible research behavior is a code of conduct. Typically developed by societies, associations, and institutions, a code of conduct articulates shared values and standards of conduct. Codes also can be used to educate people regarding their ethical responsibilities. The value of a code is reinforced when it is discussed in training sessions, at meetings, and during the course of routine activities.

### ***Using This Document***

The following document lays a foundation for a code of conduct that explicitly addresses dual use research of concern by:

- Describing the general utility and potential applications of such a code
- Articulating a core set of responsibilities related to dual use research that can serve as a foundation for a code

- Delineating additional responsibilities related to specific phases of the research process and research-related activities

The core set of responsibilities and the additional specific responsibilities outlined below provide a template that users of this document can adopt verbatim, modify, or use as the basis for developing more specific guidance on ethical behavior. This document is intended to be used in tandem with other elements of the framework of policy and guidance pertinent to this issue that are now under development.

### *Audiences for This Document*

Every individual associated with the life sciences should be aware of the potential dual use of scientific knowledge, products, or technology and be knowledgeable of the ethical obligations that ensue in regard to research that can be considered “dual use of concern.” Specifically, the considerations in this document are intended to apply to the following audiences:

**Life sciences societies and associations.** Life sciences societies and associations are important sources of guidance for scientists on the ethical standards that apply to their disciplines. These organizations are encouraged to enhance their bylaws or codes of conduct to address the considerations within this document. They may choose to adopt any portion of this document into an existing code or to modify its contents in order to adapt them to a specific discipline and context. Alternatively, organizations may choose to adopt or create a stand-alone document to give it particular salience. In either case, organizations generally adopt or modify their codes through a governance process involving broad discussion with the membership; therefore, the process of considering the ethical standards applicable to dual use research of concern is a valuable exercise in its own right. Whatever the manner in which a society chooses to develop and adopt a code on dual use research of concern, the code should be widely disseminated to members (for example, by publishing it in society newsletters and journals). It should be revisited frequently at annual membership meetings and other events in order to refresh and reinforce its impact and to address evolving issues.

**Research institutions.** Whether public or private, academic or industrial, research institutions are responsible for the integrity of their research programs. Institutions that oversee a body of research typically have rules, guidelines, and standard operating procedures to guide staff on how to conduct research in an ethical and legal manner, as well how to conform to institution-specific policies and requirements. Institutions should consider the adoption and dissemination of specific guidance on dual use research in faculty handbooks, procedures manuals, institutional Web sites, training and education of students and staff, and other appropriate venues. Many such institutions also offer formalized employee orientation programs and courses of instruction in the responsible conduct of research. It would be appropriate and helpful to incorporate the topic of dual use research, along with related guidance on ethical and legal responsibilities, in such courses and programs.

**Industry.** Life scientists who are engaged in research for commercial purposes share the same responsibilities for safeguarding the public welfare as their colleagues in the academic or public

sectors. Each commercial organization will have its own mechanisms for raising awareness of dual use research of concern and for developing policies to address related issues.

**Research leadership.** Scientists who have risen to leadership positions (for example, society presidents, medical school deans, and department chairs in universities) serve as role models for other scientists. In particular, those who are responsible for oversight of research programs should consider how their institutions are addressing the responsibilities outlined in this document. For example, it is important to ensure that issues related to dual use research of concern are well understood by life scientists, that dual use research of concern is reported in accordance with institutional policies, and that life scientists are aware of and compliant with other applicable requirements. All those who have gained the respect of other scientists through their work can play a critical role in assuring that the issues associated with dual use research of concern are thoughtfully addressed.

**Individual life scientists.** Scientists bear the primary responsibility for the integrity of their own research. By their actions and explicit guidance, they can foster a sense of ethical responsibility in the research team and an awareness of applicable laws and guidelines. This document may aid in increasing their awareness of their responsibilities in the area of dual use research of concern and help them mentor students, trainees, and technical staff. Mentors are encouraged to involve these individuals in laboratory discussions of dual use research of concern, the ethical responsibilities that are outlined in this document, and the relevance of these responsibilities to their work.

**Technicians, trainees, and others involved in the research process.** Technical staff, postdoctoral fellows, students, and others who contribute to research activities bear their own measure of responsibility for the integrity of these projects. These individuals are also encouraged to review this document carefully, consider how it may apply to current work, and engage their instructors and mentors in addressing any questions they may have regarding its relevance.

**Funding agencies/institutions.** Institutions and agencies that fund research establish the framework for decisions about the research considered eligible for funding and provide oversight to ensure responsible stewardship of funds. In order to avoid endangering public health, agriculture, plants, animals, the environment, or materiel, they are responsible for ensuring that projects that could be considered dual use research of concern are identified prior to funding. When a project meets the criteria for this type of research, the funders should ensure that a process is in place to manage risks through a thoughtful and informed consideration of options that could mitigate or manage them.

**Journal editors, reviewers, and publishers.** Those who play decisionmaking roles in the process of communicating scientific information have an ethical responsibility to consider whether the information being considered for publication could be used to endanger public health, agriculture, plants, animals, the environment, or materiel. Depending on their analysis of the risks and benefits of communications regarding information or technology that meet criteria for dual use research of concern, they may choose to proceed in a way that mitigates or manages the risks associated with communication, for example, by adding contextual information not

found in the original article or delaying communication until a time at which the risks would be reduced.

### **CORE RESPONSIBILITIES OF LIFE SCIENTISTS IN REGARD TO DUAL USE RESEARCH OF CONCERN**

The following page identifies the fundamental responsibilities of all life scientists with regard to dual use research of concern. These obligations flow from the underlying principle of concern for the public good and should lie at the heart of any code of conduct that addresses this topic.

## **LIFE SCIENTISTS: CORE RESPONSIBILITIES REGARDING DUAL USE RESEARCH OF CONCERN**

Life sciences research is a critically important endeavor that has benefited society by advancing our understanding of living systems. Critical to the future of scientific progress and freedom is the preservation of public trust and support, which scientists have earned through their attention to responsible research practice. Despite a scientist's conscientious approach to research conduct, the knowledge, products, or technologies derived from some life sciences research may be misused by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as "dual use research of concern."

**Individuals involved in any stage of life sciences research have an ethical obligation to avoid or minimize the risks and harm that could result from malevolent use of research outcomes.**

Toward that end, scientists should:

- Assess their own research efforts for dual use potential and report as appropriate
- Seek to stay informed of literature, guidance, and requirements related to dual use research
- Train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern
- Be alert to potential misuse of research

## **RESPONSIBILITIES IN THE RESEARCH PROCESS**

Research is a complex, iterative process, and the potential for dual use may be recognized at many junctures and through different activities. Consequently, while it is valuable to be mindful of the core responsibilities articulated above, those involved in life sciences research may also benefit from a more specific review of their responsibilities in regard to dual use research of concern.

### ***Proposing Research***

When designing and proposing research, the ethical responsibilities of life scientists include:

1. Considering whether the knowledge, products, or technology resulting from the research could be deliberately misused to endanger public health, agriculture, plants, animals, the environment, or materiel
2. Striving to design research that promotes beneficial scientific advances, while avoiding or minimizing elements of study design that raise concerns about dual use
3. Weighing carefully the benefits of study elements presenting dual use concerns that cannot be completely eliminated against the harm that could occur through their deliberate misuse
4. Considering ways to modify the research design to manage and mitigate potential misuse when it is clear that the benefits of the research with dual use potential outweigh the potential harm

### ***Managing Research***

The ethical responsibilities of persons who manage research programs, whether within the public or private sector, include the following:

1. Promoting awareness of dual use research of concern and the ethical responsibilities it entails
2. Developing and maintaining systems, policies, and training to ensure that dual use research of concern is identified and managed appropriately
3. Implementing federal, state, and other appropriate guidelines specific to dual use research of concern

### ***Reviewing Research***

The ethical responsibilities of those responsible for establishing and managing the review process (e.g., funding agencies) include the following:

1. Ensuring that when research proposals are reviewed, appropriate systems are in place to identify the possibility of dual use of concern and to address related issues. Examples of common means of reviewing research proposals include Institutional Animal Care and Use Committees (IACUCs), Institutional Biosafety Committees (IBCs), Institutional Review Boards (IRBs), and peer review groups.

2. Ensuring that both researchers and reviewers are knowledgeable of, and adhere to, all ethical, institutional, and legal requirements that apply to the review of possible dual use research of concern.
3. Reconsidering institutional review systems periodically to ensure that they reflect current criteria defining dual use research of concern and are consistent with applicable federal and state guidelines.

The ethical responsibilities of individuals serving on peer review groups or otherwise engaged in research review include the following:

1. Becoming well educated about dual use research of concern and related ethical, legal, and institutional requirements, as well as applicable federal and state guidelines
2. Being mindful during the review process of whether the research could meet the criteria for dual use of concern
3. Using methods in keeping with the reviewer's charge and context to make appropriate people aware that the research being reviewed meets the criteria for dual use research of concern

### ***Conducting Research***

The ethical responsibilities of life scientists engaged in research include the following:

1. Observing safe practices<sup>1</sup> and ethical behaviors in the laboratory, clinic, field, and classroom and ensuring that subordinate personnel do so as well
2. Using appropriate security measures and continually reassessing their adequacy as concerns about potential misuse evolve
3. Observing applicable guidelines for the responsible conduct of dual use research of concern
4. Being attentive to the dual use potential of the knowledge, products, or technology resulting from research activities as they emerge
5. Alerting responsible institutional officials when dual use research of concern is identified and when decisions must be made to manage associated risks

### ***Collaborating on Research***

Research endeavors frequently involve the participation and cooperation of multiple laboratories and disciplines, which can be subject to different management, codes of conduct, cultural values, or operating procedures. Besides the ethical responsibilities associated with conducting research, scientists involved in such collaborations have the additional obligations of:

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<sup>1</sup>Safe laboratory practices are embodied in such documents as *CDC-NIH Biosafety in Microbiological and Biomedical Laboratories* (<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>), *NIH Guidelines for Research Involving Recombinant DNA Molecules* (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>), and *Biological Safety: Principles and Practices* (ASM Press, <http://www.asm.org/>), and applicable occupational and safety regulations and standards.

1. Engaging in open dialog regarding whether knowledge, products, or technology resulting from the research could be considered dual use research of concern; when such research is pursued, ensuring that all parties are aware of their ethical responsibilities
2. Agreeing on specifically assigned responsibilities to ensure ethical oversight of all aspects of research with dual research potential, including its outcomes.
3. Considering and respecting expressions of concern regarding the possible dual use of knowledge, products, or technology resulting from the research and ensuring that these concerns are raised with those charged with responsibility for research oversight
4. Considering appropriate measures to reduce or eliminate risks to public health, agriculture, plants, animals, the environment, or materiel resulting from the research project
5. Maintaining a current awareness of national and international standards and policies regarding dual use research of concern

### ***Communicating the Results of Dual Use Research of Concern***

Regardless of the stage of the research process and the form of the communication, those involved in communications regarding knowledge, products, or technology that can be considered dual use research of concern have the following ethical responsibilities:

1. Being aware of ethical and legal considerations relevant to communications regarding knowledge, products, or technology that can be considered dual use research of concern.
2. Analyzing potential risks to public health, agriculture, plants, animals, the environment, or materiel that could result from research-related communications, balancing them against the potential benefits.
3. Considering options for communication that may reduce or eliminate risks when communicating information with dual use potential is clearly warranted by its benefits. Examples of mitigating strategies may include a delay in releasing the information, the addition of appropriate contextual information, or communicating the information to a more limited audience.

### ***Scientific Education and Mentorship***

Practicing scientists who serve as role models to developing scientists (e.g., their trainees, students, and staff) have the following ethical responsibilities:

1. Raising developing scientists' awareness of what constitutes dual use research of concern and why it matters
2. Informing developing scientists of their ethical, legal, and institutional responsibilities when engaged in dual use research of concern, as well as applicable federal and state guidelines
  - Encouraging open and respectful discussion of issues related to dual use research of concern, including whether or not a particular project could be considered dual use research of concern

## **APPENDIX 4. Points To Consider in Risk Assessment and Management of Research That is Potentially Dual Use of Concern**

Could this research yield information that could be intentionally misused to threaten public health and safety or other aspects of national security?

- What is the nature of that information?
- Is the information novel?
- Is the information applicable to other, perhaps common, organisms, biologics, etc.?
- Could the information be directly misused to pose a threat? For example, even if the information would need to be combined with other information/technologies in order to pose a threat, is that other information/technology currently available?
- Does the information need to be combined with other information to pose a threat?
- If so, is that other information already available?

What is the nature of the threat that could be posed from intentional misapplication of the information, and what are the potential consequences?

- What is the potential nature (e.g., economic, agricultural, public health, and/or public terror), and what is the potential impact of the threat?
- What is the scope of the potential threat (e.g., how many/which people, plants, animals might be adversely affected)?
- Are there currently countermeasures for this threat?
- What type of technical expertise and/or physical resources would be needed to apply the information for malevolent purposes?
- In what timeframe might the information be misused? Is there concern about immediate or near-future potential use, or is the concern about misuse in the distant future?
- Would it require a low or high degree of technical skill and sophistication to use the dual use information for harmful purposes?

Based on the above considerations, how likely (reasonably anticipated) is it that the information could be used to pose a threat to public health and safety or other aspects of national security?

(If there is no discernable potential threat, then there is no need to continue the analysis.)

Could this research yield information that could potentially benefit the life sciences and/or public health and safety and other aspects of national security?

- If so, what is the nature of that information?
- What is the nature of the potential benefit?
- How much of a benefit might there be?

Do the potential risks outweigh the potential benefits?

- If not, determine applicable risk management strategies (see below).
- If so, consider whether the research should be modified or discontinued.

Potential Risk Management Strategies (more than one may be applicable)

- Ongoing review or monitoring of research
- Modification of experiment (e.g., can an alternative antibiotic or a different strain of organism be used?).
- Discontinuation of experiment. This may need to be discussed at a higher level, either within the local institution or at the federal level.
- Utilize the “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential” (Appendix 5):
  - Identify and assess the risks and benefits of communicating research with dual use potential
  - Weigh the risks versus the benefits
  - Formulate a decision for responsible communication; address the content, timing, and extent of communication
- Develop a comprehensive communication plan:
  - Consider the need to address the following issues in a communication:
    - The significance of the research findings for public health and safety, agriculture, the environment, and/or material
    - How the new information or technology will be useful to the scientific community
    - The biosafety measures in place as the research was conducted
    - The communication of less detailed findings
    - The dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to publish
  - Determine whether additional venues are appropriate for conveying the research information and contextual/background information.

## **APPENDIX 5. Points To Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential**

### *1. General Overview of the Research Information With Dual Use Potential*

- a. What information is provided?
- b. To what extent is it novel?

### *2. Risk Analysis*

- a. Are there reasonably anticipated risks to public health and safety from direct misapplication of this information?
  - i. E.g., is novel scientific information provided that could be intentionally misused to threaten public health and/or safety?
  - ii. E.g., does the information point out a vulnerability in public health and/or safety preparedness?
- b. Is it reasonably anticipated that this information could be directly misused to pose a threat to agriculture, plants, animals, the environment, or materiel (e.g., does the information point out a vulnerability with respect to agriculture, plants, animals, the environment, or materiel)?
- c. If a risk has been identified, in what timeframe (e.g., immediate, near future, years from now) might this information be used to pose a threat to public health and/or safety, agriculture, plants, animals, the environment, or materiel?
- d. If the information were to be broadly communicated “as is,” what is the potential for:
  - i. Public misunderstanding, that is, what might be the implications of such misunderstandings (e.g., psychological, social, health/dietary decisions, economic, commercial etc.)?
  - ii. Sensationalism (i.e., in what way might it result in widespread concern or even panic about public health or other safety/security issues?)

*If no risk has been identified, no further dual use communication considerations are necessary. If a risk has been identified, continue on.*

### *3. Benefit Analysis*

- a. Are there potential benefits to public health and/or safety from application or utilization of this information?
- b. Are there potential benefits of the information for agriculture, plants, animals, the environment, or materiel (e.g., what potential solution does it offer to an identified problem or vulnerability)?
- c. Will this information be useful to the scientific community? If so, how?
- d. If a benefit has been identified, in what timeframe (e.g., immediate, near future, years from now) might this information be used to benefit science, public health, agriculture, plants, animals, the environment, or materiel?

### *4. Risk versus Benefit Assessment*

Based on the risks and benefits identified and considering the timeframe in which these might be realized:

- a. Do the benefits of communicating the information outweigh the risks?

b. Do the risks outweigh the benefits?

5. *Formulation of Recommendation Regarding Communication*

Decisions about how to responsibly communicate research with dual use potential should address content, timing, and possibly extent of distribution<sup>1</sup> of the information.

a. Content

- i. Communicate as is.
- ii. Communicate with addition of appropriate contextual information. For example, it may be important to address:
  - (1) The significance of the research findings for public health and/or safety, agriculture, the environment, or materiel
  - (2) How the new information or technology will be useful to the scientific community
  - (3) The biosafety measures in place as the research was conducted
  - (4) The dual use potential of the information
  - (5) The careful consideration that was given to the dual use concerns in the decision to publish
- iii. Recommend communicating a modified version of the product. For example, is it possible to “decouple” the material that poses security concerns from some or all of the potentially useful scientific information, or should specific information be removed (e.g., technical details about an enabling technology)?

b. Timing

- i. Communicate immediately.
- ii. Recommend that communication be deferred until a clearly defined and agreed-upon endpoint is reached (e.g. a condition is met such that communication no longer poses the same degree of risk).

c. Distribution<sup>2</sup>

- i. No limit on distribution.
- ii. Limit access to selected individuals on a “need to know” basis. It will be necessary to identify categories of individuals who should have access and under what circumstances.
- iii. Recommend that the product not be published or otherwise made accessible to the public.

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<sup>1</sup>The relevance and/or feasibility of considering limits on the distribution of dual use research will depend on the specific situation (e.g., timing of the communication in terms of the maturity of the research, the nature of the information and the risks associated with its communication, and the relevant audience for the information). For example, while limiting distribution is not a consideration for most scientific journals, it might be a reasonable consideration early on in a research project that yielded information of special significance to public health or homeland security experts and for which countermeasures might need to be initiated prior to broader communication of the information.

<sup>2</sup>Ibid.

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