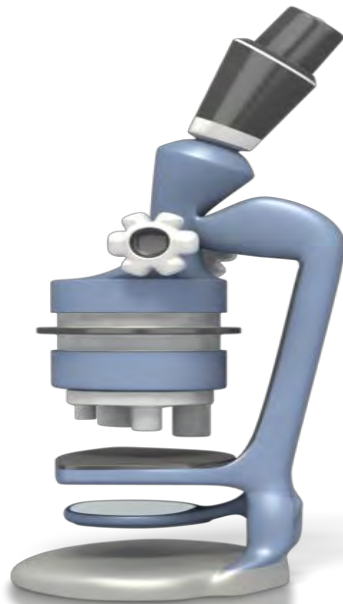


Enhancing Responsible Science
Considerations for the Development and Dissemination of
Codes of Conduct for Dual Use Research



Report of the
National Science Advisory Board on Biosecurity

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Abbreviations and Acronyms

CCWG	Codes of Conduct Working Group
DUR	Dual Use Research
DURC	Dual Use Research of Concern
HHS	Department of Health and Human Services
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
OBA	Office of Biotechnology Activities
PI	Principal Investigator
RCR	Responsible Conduct of Research
USG	United States Government

Executive Summary

The National Science Advisory Board for Biosecurity (NSABB) was established by the U.S. Government to provide advice, guidance, and leadership regarding the oversight of dual use life sciences research—that is, research with a legitimate scientific purpose that yields information or technologies that may be misused to pose a threat to public health or other aspects of national security. According to the Board’s current charter, one key function of the NSABB is to “advise on the development, utilization and promotion of codes of conduct to interdisciplinary life scientists, and relevant professional groups.”¹ In the performance of this function, NSABB has formed two Working Groups on codes of conduct in dual use research. This report provides a summation of the activities of both Working Groups with a focus on the second Working Group and on the principal outcomes of its work—a toolkit for individuals and groups interested in formulating codes of conduct for dual use research and an educational module on dual use research.

Codes of conduct for dual use research exemplify a long tradition in morality. For millennia, individuals and groups have used codes, along with oaths, as tools for several interrelated aims: to prevent or encourage certain morally significant behaviors and to form and solidify the moral identity of a group. The Oath of Hippocrates and the American Medical Association’s Code of Ethics (first formulated in 1847) are statements of moral precepts that have been, and continue to be, central to the moral and professional identity of physicians. Many scientific societies have also adopted codes in an effort to promote certain ethical principles in such activities as research and publication.

In recent years, interest in codes of conduct has intensified within and beyond the global “community” of scientists, mainly in response to concerns spawned by 9/11 and the subsequent anthrax attacks. The latter incidents revealed both the risks and the vulnerabilities associated with life sciences research of dual use potential. Given the risks, many within the scientific community have argued that scientists themselves must lead the way in developing and instituting measures to raise awareness about—and inculcate responsibility for—dual use research. Among these measures are codes of conduct. Although codes, whether of ethics or of conduct, have been utilized in differing domains, in the context of dual use research, they often raise questions of *what*, *why*, and *how*: in *what* should a code of conduct consist, *why* are codes of conduct useful in dual use research, and *how* might a code of conduct in the context be formulated, disseminated, and sustained?

The first NSABB Working Group on codes of conduct, established in 2005, produced a set of “considerations in developing a code of conduct,” presented as Appendix 3 to the NSABB’s June 2007 *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for*

¹ NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

*Minimizing the Potential Misuse of Research Information.*² With these considerations, NSABB sought to spell out the potential content for any given code of conduct by identifying key individual, group, and institutional responsibilities at each phase of the research process; it thereby addressed the questions of *what* a code of conduct might consist in and *why* a code is justified as a tool in cultivating awareness and responsibility for dual use research among scientists. The Working Group activities that led to the development of the considerations are described and summarized in Part I of this report.

Created in March 2010, the second Working Group on codes of conduct has sought to address the question of *how* a code of conduct can be formulated, disseminated, and sustained as a living document and force in the promotion of awareness and responsibility. The activities the Working Group has undertaken in this effort—a survey, a literature review, and a roundtable—are described in Part II.

Parts III and IV present the culmination and chief outcomes of these activities: a code of conduct toolkit and an educational module. In assembling the toolkit and the module, the Working Group set out from two basic assumptions about codes of conduct: *first*, developing and implementing a code of conduct is ideally a voluntary, grass roots activity, freely undertaken by scientists in any context, be it a professional society, an industrial entity, or an academic institution; and *second*, a code of conduct is optimally used for the purposes of educating and raising awareness among scientists. With these assumptions as its conceptual foundation, the toolkit goes on to provide a series of tools that are adaptable to different settings, including background on the dual use issue and tools for getting started, for formulating a code, for disseminating a code and for evaluating a code within the broader context of initiatives aimed at the creation of cultures of responsibility in dual use research.

² NSABB, Appendix 3, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

Introduction

The scientific community, governmental authorities, and the public have raised the concern that life sciences research conducted for legitimate scientific purposes could be misused for harmful purposes. This type of research is known as dual use research (DUR). To help address concerns regarding DUR, certain scientific and professional societies have advocated the use of codes of conduct as a way to guide scientists' work.

The United States Government established the National Science Advisory Board for Biosecurity (NSABB) to provide advice on oversight of dual use life science research. According to the Board's current charter, one key function of the NSABB is to "advise on the development, utilization and promotion of codes of conduct to interdisciplinary life scientists, and relevant professional groups."³

In its *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007), the NSABB articulated "considerations in developing a code of conduct for dual use research in the life sciences," which includes a set of core responsibilities regarding dual use research of concern and a comprehensive delineation of responsibilities in the research process.⁴

Building on these accomplishments, and in response to the Board's charter in 2010, the NSABB established a Working Group, the Codes of Conduct Workgroup (CCWG). The CCWG's task is to promote the dissemination, awareness, and adoption of codes of conduct by academic institutions as well as by professional societies and individuals engaged in dual use research.

To fulfill the requirements of this task, the CCWG undertook several objective-driven initiatives:

- 1) In order to provide an assessment of "the state of the issue," that is, the extent to which professional societies and institutions have adopted—or are considering the adoption of—codes of conduct, the CCWG, with support from National Institutes of Health's (NIH) Office of Biotechnology Activities (OBA) staff, surveyed scientific associations and academic institutions.
- 2) In order to identify barriers to the formulation and dissemination of codes, along with strategies for the effective accomplishment of these ends, the CCWG, with support from NIH/OBA staff, reviewed the scholarly literature. In addition, and with the same objective in mind, the Working Group convened a roundtable in which representatives of professional societies, academic institutions, and industry discussed the problems with and potential for codes of conduct in dual use research.

³ NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

⁴ NSABB, Appendix 3, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

The Purpose of this Report

This report describes the activities of the NSABB's two Working Groups on Codes of Conduct and the second Working Group's principal outcomes, i.e., a code of conduct toolkit and an educational module for use by institutions and scientific associations with an interest in formulating and disseminating codes of conduct.

Early on in its deliberations, the second NSABB Working Group on Codes of Conduct reached agreement on two basic assumptions that then informed the remainder of its work, especially the content and objectives of the toolkit and the educational module: *first*, developing and implementing a code of conduct is ideally a voluntary, grass roots activity, freely undertaken by scientists in any context, be it a professional society, an industrial entity, or an academic institution; and *second*, a code of conduct is optimally used for the purposes of educating and raising awareness among scientists.

In the course of its deliberations, research, and consultations, the Working Group reached a number of conclusions and findings about codes of conduct—conclusions and findings that have been incorporated into the toolkit presented in Part III. These conclusions and findings are:

1. Codes of conduct can be effective in raising awareness about dual use research.
2. The very process of formulating and developing a code of conduct is rich in opportunities for educating and raising awareness about dual use research.
3. As such, that process should be designed to engage as many stakeholders as possible.
4. Disseminating a code of conduct is not simply a process of distributing the code to affected parties; it is also a process of ensuring that the code will be a “living” document and, as such, a vital force in shaping the day-to-day moral behavior of scientists in a given context. To achieve this aim, the following points should be considered:
 - To make a code effective, strong institutional commitment is needed. This entails that sufficient resources would need to be allocated for developing and disseminating the code.
 - A successful code also depends on a strong commitment by individuals who undertake the responsibility for “championing” the code and for disseminating it throughout the institution. Institutions should identify such individuals.
 - Allocation of time for discussing the code is required. Multiple existing venues can be used, for example, student orientation sessions, faculty meetings, lab meetings, RCR courses, conferences, and workshops, etc.
5. The advantage of utilizing codes in an educational setting is that in these settings a code could be used as a guide for addressing real life case studies.

6. To maintain their effectiveness and relevance over time, codes should be revised and updated on an ongoing basis.

These findings and conclusions have relevance in any organization, i.e., academic institutions, scientific associations, and industry. In any one setting or context, however, they should be “applied” with care and sensitivity, especially to the particular needs and features of that context. An obvious example is this: academic institutions and scientific associations are different in many respects and strategies for developing and disseminating a code of conduct should be designed accordingly.

Part I: The Activities and Accomplishments of the First NSABB Working Group on Codes of Conduct

The first NSABB Working Group on Codes of Conduct (i.e., the CCWG) invested significant effort in evaluating the status of codes of conduct in general, their utility, and how best to formulate them. Its activities and the outcomes of those activities have provided the foundation for the subsequent efforts of the second Working Group on Codes of Conduct.

The charge and objectives of the first Working Group were two-fold. First, the Board’s initial charter specifically stated that NSABB will “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 science research.”⁵ Second, the Working Group will develop standards and principles that can be incorporated into a formal educational and training program to cultivate awareness and appreciation for codes of conduct in the life sciences disciplines.

To fulfill the charge, the Working Group pursued three key activities: (1) it conducted a survey of codes of conduct; (2) it formed and consulted with focus groups of ethicists, scientists, and others, especially with the aim of identifying elements of a code; and (3) it formulated a set of considerations in the development of codes of conduct.

A. The survey:

Before formulating its recommendation on the utility of codes of conduct, the Working Group embarked on an extensive survey on existing codes with the aim of clarifying the kinds of codes of conduct then in use, their components, their differing uses, and the types of organizations that have adopted them. The survey gathered the necessary background knowledge to inform the Working Group’s development of a template code of conduct.

⁵ Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter — Revised*, March 16, 2006.

Seventy codes were selected for analysis and inclusion, on the basis of content, type of organization, and applicability to the scope of biosecurity in the life sciences. Preference was given to codes with well defined elements, and to organizations with large or national memberships. The intent was to include a sufficient number of domestic and international codes of comparable scope originating from a variety of disciplines and professions.

Notable Elements: During the analysis, certain elements were identified in the codes that are considered noteworthy in terms of preparing a code of conduct for dual use research in the life sciences. These elements included:

- **National Security:** Three codes addressed national security concerns.
- **Resources:** Several of the codes included requirements for the proper use of funding or institutional resources, such as equipment, supplies, laboratory, or office facilities.
- **Training:** Although, only one of the codes specified that a mentor must be identified for all trainees and provided specific expectations for that mentor's role, many of the codes addressed the education of future generations, with some specifically requiring ethical training.
- **Dual Use:** Two codes specifically contained text that alluded to dual use dilemmas within particular fields of study.
- **Communication:** Many of the codes surveyed contained statements requiring members to be truthful when communicating with the public about the organization or the field of study, and even more contained statements regarding a responsibility to inform and educate the public on matters fundamental to the field or organization.
- **Review Practices:** Many of the codes described a process for convening an ethical review body to review and arbitrate violations of the code, and several acknowledged that the code is a "living document" that is subject to revision and "adaptable and relevant to new situations as they occur."

Basic Considerations in Code Development: Based on the survey results, it appears that although the mere existence of a code of conduct may lay the foundation for ethical standards within an organization, it does not guarantee compliance. The content of the code, the degree to which leadership is committed to the code, and the degree to which it becomes embedded in the organization's standard operations are all critical to the effectiveness of the code in reducing unethical behavior. It is also important to recognize that codes are not intended to be static documents and should be developed with sufficient flexibility to encourage review and revision by the sponsoring group as responsibilities, expectations, and biotechnologies evolve.

The survey helped the Working Group crystallize some findings with regard to developing and disseminating codes of conduct, including:

- Code language should be simple, concise, and readily understood by all persons affected.
- The code should state expected behaviors and avoid a legalistic tone, unless legal restrictions apply. Codes do not supersede existing regulations or ordinances, but they may elevate the ethical norms beyond the minimum expectations outlined by law.
- The code should be sufficiently general and global in scope.

- In recognition that a single issue may have multiple perspectives and consequences, the code should be written, reviewed, and edited by a multidisciplinary team, including members of the public, to ensure consistency with other communications and policies that may be in effect and to facilitate acceptance by the affected constituents.
- Although it is difficult to fully anticipate all the consequences of an activity, all relevant risk areas with appropriate plans for abatement should be considered prior to initiation.
- Codes should be revised and updated to reflect changes in professional values and advances in technology.
- When considering the development of a code, an evaluation component and objective criteria should be included.

Content Considerations: The survey also helped in identifying appropriate content for codes of conduct. Although the specific content of a code varies according to the purpose, intended audience, and sponsoring organization, almost every code should include some standard components:

- An introductory section that sets a tone and emphasizes the importance of ethics and compliance.
- Guiding principles that articulate the profession's underlying core values and guiding principles to the highest degree possible.
- Models for decision making to assist an individual in making the right choice about a possible course of action. Such constructs can contain straightforward examples or a decision framework to guide the individual in making a decision.
- Provisions for dissemination of the code to appropriate audiences and recommendations for the proper education and training of these individuals.
- Procedures for reporting suspected misconduct and advice on mechanisms for the protection from retribution of those who report violations.
- Implementation mechanisms to establish individual and organizational accountability and enforcement procedures to censure unethical behavior.
- A listing of any additional ethics and compliance resources with applicable supplementary policies and procedures.
- A list of available educational and training resources.

The survey and its lessons remain a valuable resource that can be consulted when deciding to pursue a code of conduct for dual use research. These lessons were incorporated into the Second Working Group's efforts.

B. Focus Groups:

The second task the first Working Group undertook was to solicit input from focus groups for the purpose of developing a draft code. Participants in these focus groups included practicing scientists, administrators, leaders of scientific and professional organizations, local oversight personnel, and ethicists. General attitudes towards codes and dual use research concerns were sampled.

Most participants had experience with codes and found that they had a positive impact personally. One issue of particular relevance to the current context is the mixed views about the level of detail that is helpful in a code of conduct. In general, codes that are detailed might provide concrete guidance but would fail to apply when new circumstances arise. More general codes have the advantage of leaving room for interpretation as they direct attention to the major concerns. However, such codes do not give specific guidance which is often needed.

Opinions of participants also varied regarding the ability of codes to influence behavior. There was a general agreement that those who intend to do wrong will not be deterred by a code. For others, one of the main contributions of a code is that it can be helpful in clarifying or reinforcing behavioral principles, particularly for those inexperienced in research or in contexts where the standards may not be obvious. Moreover, participants expressed the view that a code can make good people better.

Many participants agreed that a code would be an effective tool to raise awareness about “Dual use” research concerns in the life sciences. Three specific benefits were mentioned: a code can catalyze discussion in the community about dual use, it can serve as an educational tool for individuals, and it can enhance sensitivity to the possible misuse of research results.

Focus Groups were also asked about what a code should include, they suggested that in general, a code of conduct should:

- include principles unified by a clear underlying philosophy regarding the dual use research concern;
- add value and not redundancy to the body of existing codes in the life sciences;
- have a clear scope, including specific target audiences;
- be concise and compelling;
- articulate realistic expectations;
- have a peer-oriented voice, speaking to scientists as professionals; and
- be positive in tone and convey the value of the scientific endeavor.

Based on the results of the survey and the focus groups, the Working Group formulated a set of considerations in developing a code of conduct.

C. Considerations in Developing a Code of Conduct

A pivotal challenge in formulating a code of conduct for dual use research is determining the specific content of the document. To help interested individuals and groups meet this challenge, the first NSABB Working Group sought to catalog and delineate all of the responsibilities inherent in every phase of the process of scientific research. The results of this effort were presented as Appendix 3 to the NSABB’s June 2007 report, entitled *Proposed*

*Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information.*⁶

In addition to describing the utility and potential applications of a code of conduct, the considerations articulate a set of core responsibilities related to dual use research, along with an additional responsibilities specific to the various phases of the research process and research related activities. The core set of responsibilities and delineation of specific responsibilities offer interested individuals and groups several potential uses: they may be adopted verbatim, modified, or used as the basis for a code of conduct in dual use research.

CORE RESPONSIBILITIES OF LIFE SCIENTISTS IN REGARD TO 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 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; and
- 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

⁶ NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

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 material;
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; and
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:

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; and
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 research 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:

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 research of concern; and
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:

1. Observing safe practices⁷ 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; and
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:

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.

⁷ Safe laboratory practices are embodied in such documents as *CDC-NIH Biosafety in Microbiological and Biomedical Laboratories* (www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm), *NIH Guidelines for Research Involving Recombinant DNA Molecules* (www4.od.nih.gov/oba/rac/guidelines/guidelines.html), and *Biological Safety: Principles and Practices* (ASM Press, www.asm.org/), and applicable occupational and safety regulations and standards.

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; and
3. 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.

Part II: The Activities and Accomplishments of the Second NSABB Working Group on Codes of Conduct

A. Working Group Charge

In its current charter, the NSABB charge included the provision to, “advise on the development, utilization and promotion of codes of conduct to life scientists and relevant professional groups.”⁸ This basic charge was expanded by the Codes of Conduct Working Group to include specific tasks that are intended to promote the dissemination, awareness, and adoption of codes of conduct in specific venues such as in academic institutions or professional societies, and among individuals engaged in dual use research.

Specifically, the Working Group’s tasks are to:

- 1) Advise on ways to promote the adoption of Codes by academic institutions and scientific societies; and
- 2) Provide guidance on how to maintain Codes’ effectiveness and relevance over time.

To achieve these tasks, the Working Group reviewed previous NSABB work addressing codes of conduct (see Part I), and conducted a survey of existing codes among professional societies and institutions and a literature review. Based on the findings of the previous Working Group, and the 2010 survey and literature review, a Roundtable was held in October 2010. The Roundtable’s goal was to gather input from relevant Working Group members, researchers in the life sciences, and representatives of the Office of Research Integrity’s Responsible Conduct of Research (RCR) programs regarding best practices for promoting and adopting codes of conduct by academic institutions and scientific societies.

B. Survey of Professional Societies

To prepare for the October 2010 Roundtable, NSABB staff conducted an online survey in 2010 to identify organizations with DUR-related codes. The survey was intended to update the 2006 list of existing society and institutional codes of conduct, ascertain how many relate specifically to DUR, and to help identify questions for exploration at the Roundtable of the barriers or challenges the societies or institutions experienced in the process of adopting codes of conduct. The survey was conducted as an environmental assessment of scientific societies and professional organizations and, initially, did not involve direct contact with any of the organizations surveyed. However, several of the organizations with codes of conduct were

⁸ Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter*, March 10, 2010, available at oba.od.nih.gov/biosecurity/PDF/NSABB%202010%20Charter_Renewal%20.pdf.

subsequently invited to participate in the Roundtable to provide additional information about their code and the process of its development.

Organizations were surveyed based on the 2006 survey and also included societies identified through the activities of the first Working Group. However, there are limitations to the amount of information the survey provides as it did not involve follow up questions or other direct contact with societies or associations, was conducted online, and it did not include academic institutional codes of conduct, where much of the dual use research is conducted. In addition, the survey did not reveal how scientific societies promote, disseminate or use their codes, whether there are sanctions for members, or whether society members even know about these codes or use them.

The survey included 50 associations and found that 20 societies had either a general code of conduct or statements related to ethics, and 14 had either a specific code devoted to dual use research, statements on social responsibility or bio-security, or statements indicating their intention to develop a code (see Appendix H). Those with specific codes relating to dual use research include the American Society of Microbiology (ASM), the American Phytopathological Society (APS), and the American Medical Association (AMA). ASM, for example, adopted a Code of Ethics in 1988 that was revised in 2000 and that contains sections that specifically “seek to discourage ASM members from activities that involve misuse of microbiology.”⁹ Following the terrorist incidents of 2001, ASM made further revisions to its code and, by 2005, had adopted specific policies and procedures establishing “that it is the responsibility of microbiologists to conduct research that is beneficial to humankind and that openness of research activities provides the transparency necessary to help prevent activities that could result in the misuse of microorganisms as biological weapons.”¹⁰

Those with a statement of social responsibility include the Society of Toxicology and the Biotechnology Industry Organization (BIO). The BIO’s statement is of particular note, as it represents the international biotechnology industry’s response to the issue of dual use research, and the commitment of an important partner with academia and professional societies in promoting awareness of DUR. Although not designated as a code of conduct, their statement notes the organization’s commitment to “the socially responsible use of biotechnology to save or improve lives, improve the quality and abundance of food, and protect our environment.”¹¹ The BIO board of directors adopted this Statement of Ethical Principles, established a standing committee on bioethics in 2006, and continues to refine “a comprehensive vision of ways to ensure biotechnology is used for the betterment of humankind and not abused.”¹²

⁹ American Society for Microbiology, *Code of Ethics*, 2005, available at www.asm.org/ccLibraryFiles/FILENAME/000000001596/ASMCCodeofEthics05.pdf.

¹⁰ Ibid.

¹¹ Biotechnology Industry Organization (BIO), *Ethics - BIO is committed to the socially responsible use of biotechnology*, available at www.bio.org/articles/ethics.

¹² Ibid.

In addition to the 14 associations with codes or statements, 3 societies (the Institute of Medicine, the American Association for the Advancement of Science, and the Federation of American Scientists) have organized conferences, created resources, or initiated projects on dual use research. The FAS, for example, has developed educational tools on its website (www.fas.org/biosecurity/education/dualuse/) that include case studies in dual use for biological research. These case studies are provided in three languages and “help define the issues associated with “dual-use” research and security in the research lab” and “include interviews with researchers whose legitimate scientific work could potentially be used for questionable or harmful endeavors, as well as a historical perspective on their research, bioterrorism, and research regulations.”¹³ The AAAS has also actively engaged its members on the topic of DUR; this includes organizing symposia, such as the 2010 forum on Minimizing the Risks of Synthetic DNA,¹⁴ developing an online database of existing resources and programs for educating practicing scientists about dual use life sciences research,¹⁵ and the dissemination of professional and graduate-level programs on DUR and biosecurity through its Center for Science, Technology and Security Policy for scientists working in the biological sciences (cstsp.aaas.org/dualuse.html). In addition, the AAAS participated in 2007 in a collaborative effort with the National Research Council to survey attitudes and actions on DUR in the life sciences.¹⁶ The survey yielded some of the first empirical data on US life scientists’ views about the potential misuse of legitimate scientific research and also explored actions scientists might support to reduce the risk of misuse of research.

The findings of the 2010 survey demonstrate a heightened interest among many scientific societies and associations about DUR and a broader commitment to address members’ responsibilities for dual use potential throughout the research process. As compared to the results from the 2006 survey, which identified only 5 societies with codes on DUR, by 2010 there had been a notable increase in the development of codes and resources focused on DUR related issues. In addition, since 2006 there has been an increase in the number of conferences, workshops and symposia focused on this topic. These fora have served as effective venues for disseminating the message about DUR among life scientists and bioengineers, and provided opportunities to reach out to related disciplines, such as non-life scientists and do-it-yourself biologists, whose activities also have a dual use potential.

Analysis of the survey results led to the development of topics and questions for the Roundtable. In addition, since the survey had focused on professional societies and associations and some understanding of the state of codes among those groups had been obtained, the Roundtable invitees included academic representatives and those who teach

¹³ Federation of American Scientists, *Case Studies in Dual Use biological Research*, www.fas.org/biosecurity/education/dualuse/index.html

¹⁴ The American Association for the Advancement of Science, *Minimizing the Risks of Synthetic DNA*, available at <http://cstsp.aaas.org/content.html?contentid=2299>

¹⁵ The American Association for the Advancement of Science, *Educational Programs for Scientists on the dual use dilemma*, available at: <http://cstsp.aaas.org/dualuse.html>

¹⁶ Committee on Assessing Fundamental Attitudes of Life Scientists as a Basis for Biosecurity Education, National Research Council, *A Survey of Attitudes and Actions on Dual Use Research in the Life Sciences: A Collaborative Effort of the National Research Council and the American Association for the Advancement of Science* (National Academies Press, 2009).

Responsible Conduct of Research (RCR). By including individuals responsible for training academic personnel in RCR, the Working Group charge to promote development of codes of conduct among societies as well as in academia would be fulfilled, as would the charge to develop standards and principles for incorporation in formal education and training programs.

C. Literature Review

Aims and Methodology: A review was conducted in PubMed of peer-reviewed articles, professional society and governmental websites, and scientific news articles to identify relevant information on the history and implementation of codes of conduct. This included a review of articles describing the specific development of a code of conduct for dual use research, the legal, cultural and behavioral aspects affecting implementation of a code for dual use research in the United States, and case studies of how codes were implemented in other countries and the lessons learned from those experiences. The information obtained through the review was intended to help identify relevant topics for further exploration at the Roundtable and to inform Working Group members of historical and recent activities related to code of conduct development. Forty articles were chosen and reviewed to ascertain relevant themes and topics pertinent to current NSABB efforts to promote the adoption of codes of conduct for dual use research (see Appendix A – Bibliography of Selected Articles).

Themes and Topics: Major themes that emerged from the review included the historical context and justification for why codes were first developed, the types and utility of various codes and their intended purposes, the relation of codes to the conduct of science and to the regulatory and cultural context in different countries, the identification of gaps in existing codes and best practices, and, most importantly in terms of the NSABB aims, how to implement codes in various venues. Examples and details of these themes include:

- **Historical background:** Many of the articles situated codes of conduct in the context of the development of the scientific process and as a manifestation of science as a self-regulating culture with implicit notions of professional behavior. Atlas proposes that “from the inception of modern science, the community of scientists acknowledged that it needed to act responsibly to protect the public against potentially dangerous scientific information,”¹⁷ and cites Sir Francis Bacon (1626) as one historical example of the philosophical basis for a code of conduct,

And this we do also: we have consultations, which of the inventions and experiences which we have discovered shall be published, and which not; and take all an oath of secrecy for the concealing of those which we think fit to keep secret; though some of those we do reveal sometime to the State, and some not.¹⁸

¹⁷ Atlas RM “Responsible conduct by life scientists in an age of terrorism,” *Sci Eng Ethics*. 2009 Sep;15(3):293-301.

¹⁸ Ibid.

These articles note other precedents and historical codes of ethics and conduct, such as the Nuremberg Code, and the emergence of formalized bioethical considerations of scientific activities, particularly in the U.S., as other essential contextual elements leading to current efforts to develop codes of conduct.

- **Justification for development of a code for dual use research:** The historical context leading to a heightened interest in code development is explored in several articles, all of which mention the impetus of recent events such as 9/11 and anthrax-laced letters, or cite examples of dual use research, such as adapting pathogens to be drug-resistant.

“While emerging technologies have the potential for many benefits, they also tend to be dual-use, capable of both good and pernicious applications....[and] the progress of scientific research may reach a point where the results could have devastating consequences (so called “existential” or “catastrophic” risks). Such catastrophic risks have only become apparent in recent decades, and create a new and compelling case for restricting some types of scientific research.”¹⁹

These articles justify code development as one mechanism to increase awareness of the potential for bioterrorist threats, and as a non-traditional tool to regulate problematic scientific research. One article situates the development of codes within “the context of the basic conflict between the freedom of science and the duty to avoid causing harm” and as an ethical problem wherein the “freedom of science conflicts with other values”.²⁰ Many of these articles provide a timeline of the recent activities that underlie code development, including the formation of the Biological and Toxic Weapon Convention (BTWC), the Biological Weapons Anti-Terrorism Act of 1989, the National Research Council 2004 report on Biotechnology Research in an Age of Terrorism, establishment of NSABB, the Interacademy Panel on International Issues (IAP), and other governmental responses to threats of terrorism, biological weapons, and the potential for dual use research.

- **Types of Codes/Utility of Codes:** Several articles delineate codes by type. Three basic types of codes are proposed by Brian Rappert as serving specific purposes and functions.²¹ This includes aspirational codes that propose principles, educational codes that provide guidelines, and enforceable codes that are embedded within wider systems of professional and legal regulations. Rappert distinguishes between and among advocacy codes that provide general life science principles, adopted codes with “elements specific to matters of biosecurity and biological weapons,” and advisory codes which is language that is developed by international scientific societies for inclusion into other existing codes.²²

Types of Codes	Purpose
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¹⁹ Marchant GE, Pope LL, “The problems with forbidding science,” *Sci Eng Ethics*, 2009 Sep;15(3):375-94.

²⁰ Ehni H-J, “Dual use and the ethical responsibility of scientists,” *Arch. Immunol. Ther. Exp.* 2008, 56:147-152.

²¹ Rappert B, “Responsibility in the life sciences: assessing the role of professional codes,” *Biosecur Bioterror*. 2004;2(3):164-74. Rappert B, “Coding ethical behaviour: the challenges of biological weapons,” *Sci Eng Ethics*. 2003 Oct;9(4):453-70.

²² Rappert B, “Codes of conduct and biological weapons: an in-process assessment,” *Biosecur Bioterror*. 2007 Jun;5(2):145-54.

Aspirational codes	Philosophical – set out ideals that practitioners should uphold
Educational codes	Awareness raising – provide guidelines suggesting how to act appropriately
Enforceable codes	Regulating - seek to codify what counts as acceptable behavior and delineate illegal or sanctionable behavior

Advocacy codes	Principles for the life sciences
Adopted codes	Principles specifically related to biosecurity and biological weapons
Advisory codes	Language for inclusion into existing codes

Several other authors reference Rappert’s categories and explore the relation between the intended goal of a code and the specific functions they are supposed to fill, and provide useful information for how to design and implement an effective code.

“If the primary goal is to educate new as well as current members of a discipline about what is expected in a societal role or professional capacity, then an ethics code should have practical use. In other words, it should be capable of providing researchers or professionals with guidance on the correct course of action in particular cases. If a professional code is intended to be enforceable, it should include procedures for handling allegations of misconduct or unethical behavior.”²³

The articles also explore the general utility of codes and the advantages of the different approaches to “presenting ethical principles in different formats....the less detailed codes of conduct can articulate the profession’s most important ethical precepts, while the more-detailed codes can provide the context and detail needed to apply ethical standards to real life circumstances.”²⁴ Ultimately, the utility of a specific code may be whether it addresses “questions about who needs to do what and how to reduce security concerns.”²⁵

- **Relation of codes to conduct of science:** Codes of conduct for scientific research are proposed as an analogue to the Hippocratic Oath for physicians, and “send important signals to scientists about professionalism in the practice of a discipline; codes make explicit many tacit assumptions about scientific practice; and codes convey a rejection of improper research behavior”.²⁶ Articles propose implementing codes as Standard Operating Procedures in laboratories, discuss the culture of mentorship in science, and the influence of this type of relationship on the adoption of new guidelines. Several articles provide arguments that address some of the perceived barriers to developing or implementing

²³ Bullock M, Panicker S, “Ethics for all: differences across scientific society codes,” *Sci Eng Ethics*. 2003 Apr;9(2):159-70.

²⁴ Iverson M, Frankel MS, Siang S, “Scientific societies and research integrity: what are they doing and how well are they doing it?” *Sci Eng Ethics*. 2003 Apr;9(2):141-58.

²⁵ Rappert B, “Codes of conduct and biological weapons: an in-process assessment,” *Biosecur Bioterror*. 2007 Jun;5(2):145-54.

²⁶ Association of American Medical Colleges, *Developing a Code of Ethics in Research: A Guide for Scientific Societies*, 1997.

codes, such as their lack of enforcement. For example, Frankel and Bird, propose that when developed by scientific societies, a code becomes a part of the

...hidden curriculum, i.e., what individuals learn implicitly from observing the actions of others and reflects the recognition that professional societies are the ideal setting in which peers can clarify their professional standards and values, make explicit their expectations regarding colleague's behavior, and influence each other to conform.²⁷

The articles delineate the structural components of scientific institutions within which codes operate. These structural components include the inter-related responsibilities for dual use research among individuals (researchers, lab technicians, and administrative staff) and academic units, and the larger framework provided by Federal, State, and local regulations, certification and licensing requirements of funding entities, professional society standards, and international conventions. The development of codes is envisioned by these authors as one means of establishing "a discipline's norms and traditions" and for "codifying the community's conventions and standards." In addition,

...the research community [could] demonstrate, through its various professional and scientific associations, a clear and tangible concern about the integrity of federally-funded research programs. Codes.....are an important embodiment of this concern and, apart from leading to more responsible behavior, they may offer convincing evidence of the research community's intent to use federal resources responsibly.²⁸

- **Relation of codes to legal/regulatory frameworks:** Several of the articles explored how even non-enforceable codes have become 'codified' in law, and often represent the only written guidance on a particular topic.

A court's inclusion of a professional standard or guideline in its analysis may result in the professional norm's becoming the legally accepted standard of care; particularly in cases where "clinical practice guidelines help courts discern whether professional conduct was reasonable and consistent with accepted practices." In such cases, "ethics codes [may] guide their assessment of the moral underpinnings of professional choices and behaviour."²⁹

Other articles examined codes in an international context under the premise that "research in the life sciences is a global endeavor"³⁰. These articles identified barriers to harmonizing or standardizing codes internationally and the specific cultural differences, or differences in

²⁷ Frankel MS, Bird SJ, "The role of scientific societies in promoting research integrity," *Sci Eng Ethics*. 2003 Apr;9(2):139-40.

²⁸ Association of American Medical Colleges, *Developing a Code of Ethics in Research: A Guide for Scientific Societies*, 1997.

²⁹ Campbell A, Glass KC, "The legal status of clinical and ethics policies, codes, and guidelines in medical practice and research," *McGill Law J*. 2001 Feb;46(2):473-89.

³⁰ Atlas RM, "Responsible conduct by life scientists in an age of terrorism," *Sci Eng Ethics*. 2009 Sep;15(3):293-301.

the historical context for concerns that will require a “dialogue across cultural, religious and philosophical perspectives that [can] shape ethical decisions and professional behaviour”.³¹

- **Best practices:** A sub-set of articles expounded on what has worked and what has not worked in the development and implementation of codes. Although, this literature is not focused exclusively on codes for dual use research, it includes case studies from The Netherlands and Australia that may be applicable to the challenges faced by the NSABB in its development of a toolkit. In Australia, for example, a proposed medical practice code

...aims to define ‘clear, nationally consistent standards of practice’ that can be applied to regulate standards of practice...and used in the assessment of complaints and allegations of unprofessional conduct. The Code is not a mere statement of principles, a discussion document, or a hortatory guide for practitioners seeking to respond to the complexities of daily practice; it is a comprehensive statement of how doctors must behave.³²

Although, the Australian code’s immediate relevance is for medical practice, the principles it embodies are applicable to code development for dual use research in terms of codifying norms of professional behavior. The case study from Netherlands focused on the utility of codes which the authors propose is not self-evident in influencing scientific practice. For these authors, the utility of a code “largely depends on the implementation phase following their establishment – a phase which often receives little attention”.³³ This article is based on interviews among researchers about a newly established code of conduct.

...although researchers perceive the principles within the code to be almost self-evident, the application of these principles in practice may lead to morally complex situations” and the researchers “did not see how the principles were meant to guide conduct in practice. They considered the code too general to apply.”³⁴

Examples of the limitations of codes might prove useful guidance to the NSABB, or provide clues to what should and should not be included as necessary elements of a flexible, adaptive, and effective ‘living’ code. For, if codes are too prescriptive they may have the unintended consequence of lowering awareness rather than providing a framework for researchers to learn how to recognize the potential for dual uses in their research.

Codes of conduct can foster and reinforce the strength and effectiveness of professional communities and moral norms and processes. However, they can also provide a vehicle for oversimplifying the moral world, stripping ethics of its context and supporting an

³¹ Komesaroff PA, Kerridge IH, “The Australian Medical Council draft code of professional conduct: good practice or creeping authoritarianism?” *Med J Aust.* 2009 Feb 16;190(4):204-5.

³² Ibid.

³³ Schuurbiers D, Osseweijer P, Kinderlerer J, “Implementing the Netherlands code of conduct for scientific practice-a case study,” *Sci Eng Ethics.* 2009 Jun;15(2):213-31.

³⁴ Ibid.

excessively rigid, restrictive and narrow moral regime. They can either expand the ability of individuals to make their own decisions and maximize their opportunities for ethical action, or they can claim authority beyond their capacity and encourage the belief that good practice simply involves following a formula or applying rules.³⁵

Moreover, this attention to the potential limitations of codes is of particular importance in the development of a code for dual use research, as many of the potentially negative uses of biological materials and technologies are difficult if not impossible to foresee. A 'living' code would be most effective if it provided ways to evaluate and respond to the potential for dual use, rather than establish a set of fixed rules for known select agents or identifiable misuses of technology. Other articles provide suggestions for the promotion of codes by scientific societies or by (senior) scientific leaders in academia as proven best practices for implementation.

- **Gaps in existing policies and codes:** A particularly useful theme that emerged in the review was identification of gaps in existing codes. Examples of such gaps include not having a process in place for protecting whistleblowers, the need for guidance on the implementation of codes in settings with limited resources, the undue emphasis on individual rather than organizational (shared and inter-related) responsibilities, and the need to resolve contradictory, overlapping, or confusing sets of guidelines. Sutton notes in her commentary on the document "Responsible Conduct by Life scientists in an Age of Terrorism" that

"In the U.S. regulatory framework for ensuring biosafety and biosecurity, the focus on life scientists has left a number of gaps in the framework...In fact, the goals of biosafety and biosecurity may not be sufficiently met because researchers are the target of the regulation almost exclusively."³⁶

As other authors have done, Sutton notes the range of stakeholders and institutional entities that are involved in dual use research, and the layers of local, national and international laws and policies that regulate scientific research of select agents. Her strong warnings against putting a "disproportionate burden on the individual researcher" reflects her understanding of the complexity of the scientific enterprise; as does her injunctions to "rethink the regulatory framework for the nation's biodefense research" and de-emphasize timely filing of reports and filling out forms as the primary means of complying with a code.³⁷

Additional important omissions in existing codes were related to the lack of enforceability, the need to maintain the relevance of codes within rapidly changing biotechnologies and

³⁵ Komesaroff PA, Kerridge IH, "The Australian Medical Council draft code of professional conduct: good practice or creeping authoritarianism?" *Med J Aust.* 2009 Feb 16;190(4):204-5.

³⁶ Sutton V, "Smarter regulations: commentary on "Responsible conduct by life scientists in an age of terrorism", " *Sci Eng Ethics.* 2009 Sep;15(3):303-9.

³⁷ Ibid.

ever novel potentials for misuse, and the need to identify metrics for evaluating codes, as “little is known about their effectiveness in practice”.³⁸ This literature strongly suggests the need for further research to evaluate best practices in designing and implementing codes; and particular areas that should be addressed when developing or disseminating codes of conduct.

- **Implementation of Codes:** Several articles examined the issues involved in institutional enhancement of the culture of research ethics and provided strategies for initiating institutional change. Topics explored in these articles included the barriers to the full uptake of codes of conduct; how the introduction of a new code may disrupt traditional norms by providing an alternative counter-norm; and the process of effective self-regulation. Ferguson et al. (2007) note the shift in terminology in discussions about research behaviors from detecting and punishing undesirable behaviors to “promoting desirable behaviors.”³⁹ These authors propose that cultural change in the academic setting is an obtainable goal,

...if we assume that the usual and/or collective beliefs and behavior of the majority of the individuals in an institution reflect institutional culture, then an institution’s ethical culture for research is reflected in what is perceived to be appropriate ethical behavior and the manner in which the majority of its members deal with ethical issues (Ferguson et al., 2007).⁴⁰

Anderson’s analysis of data from two national surveys of 4,000 faculty and doctoral students in scientific disciplines showed the “significant effects of departmental climate on normative orientations.”⁴¹ For Anderson, an institution’s norms “are generally viewed as critically important to the group and are communicated as such to newcomers through the socialization process. Norms are not specific rules or regulations but fundamental principles that support appropriate behavior and relationships within the group, which views violations of the norms as serious offenses.”⁴² All of these articles suggest the efficacy of promulgating codes of conduct through academic and society leadership, i.e., senior scientists and professional society leaders acting in a mentoring capacity to disseminate new norms and guidelines for behavior.

Analysis: The literature review provided an understanding of the contextual influences on the development of codes of conduct, the inter-relations of stakeholders in the process and their overlapping areas of responsibility, notable gaps in existing codes, and the challenges of identifying time, resources, and the expertise needed to develop and implement codes at the local level. The themes identified through the literature review were used to inform

³⁸ Rappert B, “Responsibility in the life sciences: assessing the role of professional codes,” *Biosecur Bioterror*. 2004;2(3):164-74.

³⁹ Ferguson, K, et al, “Enhancing the Culture of Research Ethics on University Campuses,” *Journal of Academic Ethics*, 2007; 5: 189-198.

⁴⁰ Ibid.

⁴¹ Anderson, MS, “Normative orientations of university faculty and doctoral students,” *Science and Engineering Ethics*, 2000; 6, 443–461.

⁴² Ibid.

organization of the Roundtable and helped to identify specific challenges that, although discussed in the literature, may yet require creative thinking and coordinated efforts to resolve. Two such matters that emerged in the literature review must be emphasized:

1. the need to gather more information and data on what makes a code effective, and what makes it evolve and remain a vital source of moral inspiration; and
2. how to identify best practices for implementing codes, integrating them into the culture, and keeping them relevant.

It was anticipated that participants at the Roundtable might offer specific recommendations for how to make codes effective, provide suggestions for how to integrate codes into academic culture, and help in the identification of best practices based on their experiences.

D. The Roundtable

The NSABB Code of Conduct Roundtable was organized to involve relevant individuals within academic institutions and professional societies who have the respective authority and reach to disseminate codes. The Roundtable also included the participation of instructors in the Responsible Conduct of Research who represent the front line of outreach and education for many institutions.

The aims of the Roundtable were to provide advice on ways to engage these individuals on the issue of Codes, identify barriers to awareness and adoption of codes of conduct in these settings and ways to overcome these barriers, and identify strategies for realizing the potential of codes in shaping behaviors and practices.

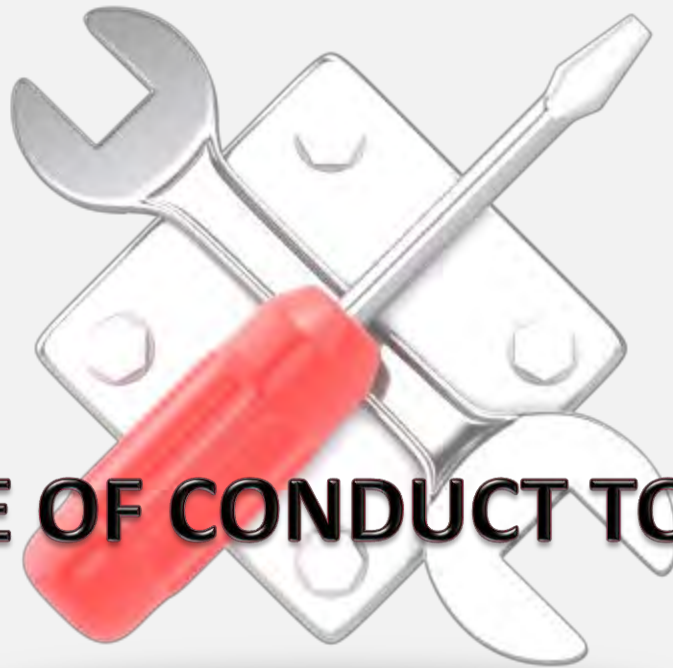
The Roundtable explored considerations for developing codes of conduct that had been advanced as part of an NSABB recommended oversight framework for dual use research in 2007. One key consideration was to identify the essential “raw material” that any comprehensive code should include. Other considerations included the formulation of realistic strategies for promoting codes of conduct in the settings of professional societies, academic institutions, and industry and the identification of relevant individuals who might best promote adoption of a code of conduct by an institution or professional association.

The Roundtable presentations and discussions explored the general utility of codes for changing behavior, the need for national guidelines on how to develop and implement codes, the key role academic leadership and scientific mentors play in promoting codes as the new norms of life science research, and the advantages and disadvantages of top-down vs. bottom-up development of codes. Discussions also touched upon the resources needed at the local level to develop, implement, and regularly update codes, whether academia or scientific society meetings are the most appropriate venues for disseminating codes, and the challenges of identifying what disciplines to include, and at what stage in the career or educational path to focus on when promoting codes of conduct.

Although, the presentations and discussions at the Roundtable covered a wide range of topics and opinions, a consensus on several key points emerged. First, codes should be aspirational and educational in purpose, rather than enforceable or compliance oriented. Second, codes should be dynamic rather than static—the focus of regular discussion and reflection within a particular setting and, indeed, an evolving element of the culture of the setting itself. Third, efforts should be made to ensure that codes are not perceived as restrictions on academic freedom but rather as expressions of the responsibility critical to the conduct of ethical, socially aware research. Finally, to succeed in any one setting, a code of conduct will need leaders and champions to ensure its advance and its status as a living, evolving document.

To ensure that codes become an integral part of the culture of research in a given setting, the participants and Working Group coalesced around a central recommendation—that NSABB undertake the development of a codes of conduct tool kit adaptable to different settings. Suggestions for such a tool kit included sample components for a code of conduct, a summary of best practices for formulating, finalizing, and disseminating codes of conduct, and a selection of the often fascinating literature on codes of conduct in general and in dual use research in particular. Subsequent to the Roundtable, and after review of the many suggestions and recommendations made by participants, the NSABB staff has developed this toolkit, and it is included in Section IV.

Promoting Awareness and Responsibility in Dual Use Research



A CODE OF CONDUCT TOOL KIT

Appendix A

a project of the

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Dual use research of concern—**research that may be used for beneficent goals as well as malevolent purposes**—presents scientists in multiple disciplines and fields with two challenges. One is to become and remain **aware** of the dual use potential of their work. The other challenge is to become and remain **responsible** for the dual use research of concern that they themselves and their colleagues conduct.

Professional societies, academic institutions, industries, private corporations, and individual scientists can use a variety of strategies to raise awareness and to cultivate responsibility in dual use research of concern. A code of conduct for scientists engaged in dual use research is one such strategy. Here, several tools useful in contemplating and perhaps implementing this strategy are offered. This toolkit, a project of the National Science Advisory Board on Biosecurity, distills the scholarly reflections and practical experience of groups and individuals who have long wrestled with a paradox at the heart of science: that science can be used to benefit, but also to harm human and other living beings.



Suggestions for use

Before you get started

- Essential background on dual use research and codes of conduct

Tools for getting started

- Assessing the need for a code of conduct
- Assessing feasibility and support
- Recruiting leaders and champions
- Defining the process

Tools for formulating a code

- Determining the content: the key responsibilities
- Determining the content: some examples
- Navigating the extremes of generality and specificity
- Drafting, vetting and finalizing a code

Tools for disseminating a code

- Developing a dissemination plan
- Utilizing existing venues
- Designing educational interventions

Tools for evaluating a code

- Confronting the challenges of determining impact
- Utilizing realistic measures for code evaluations

Selected resources

ADAPTABILITY & AUDIENCE The tools in this code of conduct tool kit have been designed and produced for adaptability to the needs of different audiences: with thought and care, they can be deployed in any one of several settings, including professional societies, academic institutions, and industry—*wherever dual use research is conducted and the researchers themselves are committed to the responsible conduct of research.*

FIRST, EXPLORE THE ENTIRE TOOL

KIT The tool kit is designed for anyone interested in formulating and disseminating a code of conduct or in exploring such a possibility in a given setting. To make the best use of this tool kit, readers are encouraged to read through the entire kit before picking up any one of the tools described in the following.



THE ULTIMATE GOAL This tool kit offers a set of means to an end or ultimate goal: a community of researchers who are aware of—and take responsibility for—dual use research. There are other means to this end, including educational interventions targeted at graduate students, faculty, staff scientists, members of professional societies, and others. Choosing the right means is a matter of knowing your specific context and figuring out which of the available means is best for your context.

ESSENTIAL BACKGROUND Before embarking on the multiple steps of a code of conduct process, it is useful either to become aware of or to review key points about dual use research and codes of conduct.

A PERENNIAL PROBLEM WORTHY OF HEIGHTENED CONCERN 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.

The development of new technologies and the generation of information with the potential for benevolent and malevolent purposes are “dual use research.” 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.

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.

CALLS TO ACTION (continued) Concerns about the dual use potential of biotechnology research were central to the establishment of the National Science Advisory Board for Biosecurity (NSABB) in 2005. A federal advisory commission, NSABB was created to advise the US government on the formulation and implementation of appropriate policies for the oversight of dual use research. In June 2007, NSABB published its *Proposed Framework for the Oversight of Dual Use Life Sciences: Strategies for Minimizing the Potential Misuse of Research Information*.

At the center of the NSABB report is the conviction that scientists themselves are the most critical tool for oversight: through their own efforts to be aware of and responsive to the dual use potential of their own research, they are a cornerstone of any effective system of oversight.



Thus, initiatives by scientists themselves and by scientific societies and associations—initiatives designed to raise awareness and cultivate responsibility—are crucial to the effective oversight of dual use research. As voluntary, “grass roots” efforts, codes of conduct exemplify the sort of approach that the NSABB envisions as pivotal to the effective oversight of dual use research.

CODES IN GENERAL: Asking moral questions—questions like *what should or should not be done*—is an activity that defines humankind. Ever since we, as a species, began to answer such questions, we have sought to gather the resulting insights and convictions in ways that lend themselves to remembrance and communication to others, be they contemporaries or successive generations. We have, that is, **codified** our answers to moral questions and disseminated them by word of mouth and via oral traditions, in written codes, and in oaths that are publicly sworn.

Such codifications of precepts governing moral behavior have often been the outcome of efforts (1) to form and solidify the identity of a group and (2) to address and prevent immoral behavior. The Nuremburg Code of 1947 is a good example of the latter: it was crafted with the explicit aim of preventing the unethical use of human beings in biomedical research horrifically exemplified in the infamous Nazi experiments. The Oath of Hippocrates and the 1847 Code of Ethics by the American Medical Association are statements of moral precepts that have been—and continue to be—considered central to the moral and professional identity of physicians.

CODES OF CONDUCT IN DUAL USE RESEARCH A code of conduct for scientists engaged in dual use research serves both aims. Such a code makes explicit a key aspect of the social responsibilities of scientists—and it

CODES OF CONDUCT IN DUAL USE RESEARCH (cont) does so in a way that is voluntary and, in itself, reflects an ethic of responsibility. At the same time, such a code usually seeks to identify behaviors critical to prevention of misuse.

For individuals and groups interested in codes of conduct for dual use research, this toolkit brings together various tools for use in each of several successive phases of code development. Before these phases and the relevant tools are introduced, it might be helpful to specify further the types of research that constitute what the NSABB has defined as “dual use research of concern.” In its June 2007 report, NSABB proposed a criterion for identifying dual use research of concern:

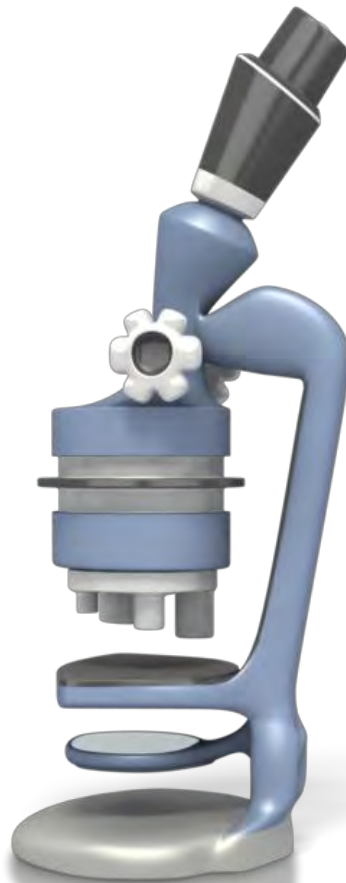
Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.



In addition, NSABB identified seven categories of research might satisfy this criterion and thus be identified as dual use research of concern. This research could encompass knowledge, products, or technologies that would:

- 1) Enhance the harmful consequences of a biological agent or toxin.
- 2) Disrupt immunity or the effectiveness of immunization without clinical and/or agricultural justification.

- 3) Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies.
- 4) Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
- 5) Alter the host range or tropism of a biological agent or toxin.
- 6) Enhance the susceptibility of a host population.
- 7) Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.



ASSESSING THE NEED FOR A CODE OF CONDUCT:

A code of conduct is one of several potential means to the end or goal of a culture of responsibility in dual use research. Formal educational interventions and mindful mentoring are other means to the same end. If the aim is to create or enhance such a culture within the setting of an institution (e.g., in a research center, an academic department or division, or a specific laboratory), or to foster a sense of heightened awareness and responsibility among members of a professional society, it is important to consider the anticipated benefits *and* the associated costs of each of these various means.

Potential advantages of formulating a code:

- Undertaken as a voluntary, grass roots initiative, the process of formulating a code of conduct can be very effective in raising awareness about dual use dilemmas.
- The process of debating and reaching agreement on the content of a code—the specific responsibilities or values that will be spelled out in its provisions—can be very empowering and can inculcate a sense of “ownership,” commitment, and achievement among engaged individuals.

Potential costs of formulating a code:

- Time is money. Formulating, finalizing, communicating, and sustaining a code of conduct—as a living document—are all essential but time-consuming activities.
- Depending upon the nature and extent of dual use research underway in your institution, the effort that might be devoted to a code of conduct may be better expended on other related initiatives.

ASSESSING THE NEED FOR A CODE OF CONDUCT, *continued*: There are other important questions to ask and answer in assessing the need for a code of conduct, especially in the institutional setting. For example:

- What is the extent of dual use research in your institution? How many faculty are engaged in dual use research? In what departments, divisions, or centers/institutes?
- Are there are other programs or initiatives underway in your institution to promote awareness and responsibility in dual use research? Is the topic of dual use research addressed in your institution’s programs for the responsible conduct of research? How effective have these programs or initiatives been?

ASSESSING FEASIBILITY AND SUPPORT: If there is a clear need for a code of conduct, then the next step is to assess the feasibility of effectively meeting the need and garnering support for the requisite effort:

- Are there individuals who can be enlisted as champions, leaders, or supporters of an effort to formulate and disseminate a code of conduct?
- Is there administrative support for such an effort?
- Is there any financial support for such an effort?
- In a given institution, laboratory, or professional society, are there existing organizational venues and processes that might be utilized in formulating a code, publicizing and finalizing drafts, and disseminating an approved code?

RECRUITING LEADERS AND CHAMPIONS The inspiration to formulate a code of conduct for dual use research—or to incorporate dual use provisions in an existing code of conduct—may strike an individual or individuals at any “level” of an organization (e.g., rank-and-file members of a professional society) or institution (e.g., graduate students or post-doctoral fellows, younger or more senior faculty). Such an inspiration and the resolve to move forward can yield a grass-roots initiative with the promise of success, especially as a voluntary effort by group of individual scientists to define and commit themselves to a collective understanding of the responsibilities inherent in their work as scientists, an understanding that they have forged among themselves through debate and discussion.

Early on, however, it is important to identify and recruit leaders and champions—individuals who can lend the effort credibility and strategic support. Such individuals



need not occupy *formal* positions of leadership within an organization or institution, but they should be people whose reputations and influence can help to catalyze and sustain the effort through all of its phases. Almost every group has more than one individual, at multiple “levels,” whose opinions are valued and sought out: such “thought leaders” may be found among graduate students, younger faculty, as well as more

DEFINING THE PROCESS A code of conduct process has three phases:

1. formulating the code (or provisions regarding dual use research for an existent code);
2. disseminating the code; and
3. ensuring the ongoing vitality of the code

The activities specific to each phase will depend upon the specific circumstances, but at the outset of the effort, it is important to envision what those activities might be. And it is important, as well, to define the specifics of each activity in terms of:

- *Who* will be responsible for the activity and who, beyond those responsible, will be engaged in the activity
- *When* the activity will occur or over what time period
- *What* the anticipated outcome of the activity will be

It is likely that revisions in the process will be made in the course of each phase, but it is, nonetheless, useful to project forward and envision the process as a whole.

All phases of the process, however, should be distinguished by three traits:

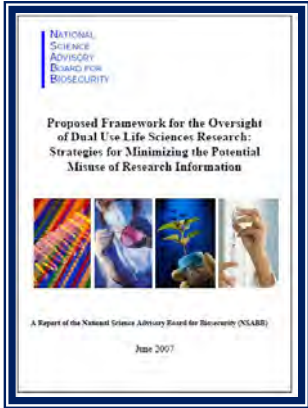
- **Transparency:** Catalysts, leaders, and champions of the process should conduct their activities in a way that is public, accessible, and inclusive
- **Communication:** They should strive to ensure that all relevant stakeholders—those who will be expected to live by the code—are kept informed of the process as it moves forward
- **Engagement:** They should also ensure that all relevant stakeholders are engaged and have the opportunity to contribute their thoughts, opinions, suggestions, and recommendations to catalysts, leaders, and champions.

What should a code of conduct say? And how? How general or how specific should its provisions be? How long or short? These are among the questions encountered at the stage of formulating a code of conduct. To help you through this stage, several tools are presented here:



- **Some considerations in the development of codes of conduct for dual use research.** Developed by the National Science Advisory Board for Biosecurity, these considerations provide the basic “raw material” for a code of conduct and identify who is responsible for what in dual use research, from the initial stages of conceiving and designing the project or study to the publication of its results.
- **Some examples of adopted codes of conduct.** Several professional societies have developed and adopted codes of conduct with specific reference to dual use research.
- **Some thoughts on the question of how general or how specific the provisions of a code should be, along with some suggestions for how to go about the key task of formulating a code of conduct.**

Considerations in Developing a Code of Conduct for Dual Use research in the Life Sciences is Appendix 3 to the NSABB's June 007 report, Proposed Oversight Framework for Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information.



The “considerations” enunciate a basic ethical principle:

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.

The principle is relevant and applicable to all stages of the research process:



Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences, (continued)



The basic ethical principle is “fleshed out” in 5 core responsibilities of scientists engaged in dual use research. These core responsibilities are to

1. ***Assess*** their research for dual use potential
2. ***Stay informed*** regarding relevant literature, guidance, and requirements
3. ***Train others*** to identify and appropriately manage and communicate dual use research of concern
4. ***Serve as role models*** of responsible behavior
5. ***Be alert*** to potential misuse of research

SOME EXAMPLES OF ADOPTED CODES OF CONDUCT

Other organizations in the life (and other) sciences have adopted codes of conduct with specific provisions for dual use research. Their work is provided here, in part or whole, as examples of how such provisions might be specifically formulated.

American Society for Microbiology (ASM) Code of Ethics. The following provisions are from the current version, which was reviewed and approved by the organization's Council in 2005.

Preface: The American Society for Microbiology is dedicated to the utilization of microbiological sciences for the promotion of human welfare and for the accumulation of knowledge. These goals demand honesty and truthfulness in all activities sponsored or supported by the Society.

Guiding Principles

(1) ASM members aim to uphold and advance the integrity and dignity of the profession and practice of microbiology.

(2) ASM members aspire to use their knowledge and skills for the advancement of human welfare.

(6) ASM members are obligated to discourage any use of microbiology contrary to welfare of humankind, including the use of microbes as biological weapons. Bioterrorism violates the fundamental principles upon which the Society was founded and is abhorrent to the ASM and its members. ASM members will call to the attention of the public or the appropriate authorities misuses of microbiology or of information derived from microbiology.

American Medical Association (AMA) Code of Medical Ethics: The AMA's Code of Ethics dates back to 1847 and has, since then, evolved in tandem with the profession of medicine and the delivery of health care. The Code enunciates eight principles of medical ethics (each beginning with the phrase "A physician shall..."), but also includes a series of opinions rendered by the Association's Council on Ethical and Judicial Affairs and providing ethical guidance on a wide range of issues, including dual use research.

Opinion 2.078 - Guideline to Prevent Malevolent Use of Biomedical Research

- Physicians who engage in biomedical research are bound by the ethical obligations of the medical profession and also are required to meet responsibilities of the scientific community. Beyond their commitment to the advancement of scientific knowledge and the betterment of public health, physician-researchers must strive to maintain public trust in the profession through their commitment to public welfare and safety, as demonstrated through individual responsibility, commitment to peer review, and transparency in the design, execution, and reporting of research.
- Biomedical research may generate knowledge with potential for both beneficial and harmful application. Before participating in research, physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit from biomedical innovation against potential harms from corrupt application of the findings.

American Medical Association (AMA) Code of Medical Ethics: Opinion 2.078 - Guideline to Prevent Malevolent Use of Biomedical Research (continued)

- In exceptional cases, assessment of the balance of future harms and benefits of research may preclude participation in the research; for instance, when the goals of research are antithetical to the foundations of the medical profession, as with the development of biological or chemical weapons. Properly designed biomedical research to develop defenses against such weapons is ethical.
- The potential harms associated with some research may warrant regulatory oversight. Physician-researchers have a responsibility not only to adhere to standards for research, but also to lend their expertise to the development of safeguards and oversight mechanisms, both nationally and internationally.
- Oversight mechanisms should balance the need to advance science with the risk of malevolent application. After research has been conducted, consideration should be given to the risk of unrestricted dissemination of the results. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against dangerous misuse.
- These ethical principles should be part of the education and training of all physicians involved in biomedical research. (II, III, V, VII)

The InterAcademic Panel (IAP) Statement on Biosecurity. The IAP describes itself as a global network of science academies, which are national organizations whose members are leaders in their respective disciplines and that often advise governments on issues that may be illuminated through scientific research. In November 2005, it issued this statement enunciated the obligations and responsibilities of scientists engaged in dual use research.

1. **Awareness.** Scientists have an obligation to do no harm. They should always take into consideration the reasonably foreseeable consequences of their own activities. They should therefore:

- always bear in mind the potential consequences – possibly harmful – of their research and recognize that individual good conscience does not justify ignoring the possible misuse of their scientific endeavour;
- refuse to undertake research that has only harmful consequences for humankind.

2. **Safety and Security.** Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or common practice.

The InterAcademic Panel (IAP) Statement on Biosecurity, continued

3. **Education and Information.** Scientists should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research.

4. **Accountability.** Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or international customary law should raise their concerns with appropriate people, authorities and agencies.

5. **Oversight.** Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation and act as role models in this regard.

FORMULATING A CODE OF CONDUCT: SOME RULES OF THUMB

There is no “magic” formula that can be followed in formulating a code—some method that is *guaranteed* to have good results. Some rules of thumb, however, are useful in thinking through the process of formulating and finalizing a code of conduct:

Rule of Thumb #1

It is useful to assign the drafting of a code to one or two individuals. The drafts, however, should be reviewed and revised by a group of individuals who represent various “constituencies” within an institution or professional society. Although the group should be populated with individuals sympathetic to the process and the anticipated outcome (a draft code of conduct), it should also include some skeptics.

Rule of Thumb #2

In determining the specific content of a code of conduct, a careful review of the NSABB considerations and of the preceding examples would be helpful. The NSABB considerations offer examples of relatively general precepts (in the key obligations), as well as detailed descriptions of roles and responsibilities at various phases of the research process. Determining how general or specific the provisions of a code should be will depend, in large measure, on the particular aims that individuals or organizations hope to achieve: to offer general guidelines or to provide precise prescriptions of expected behaviors.

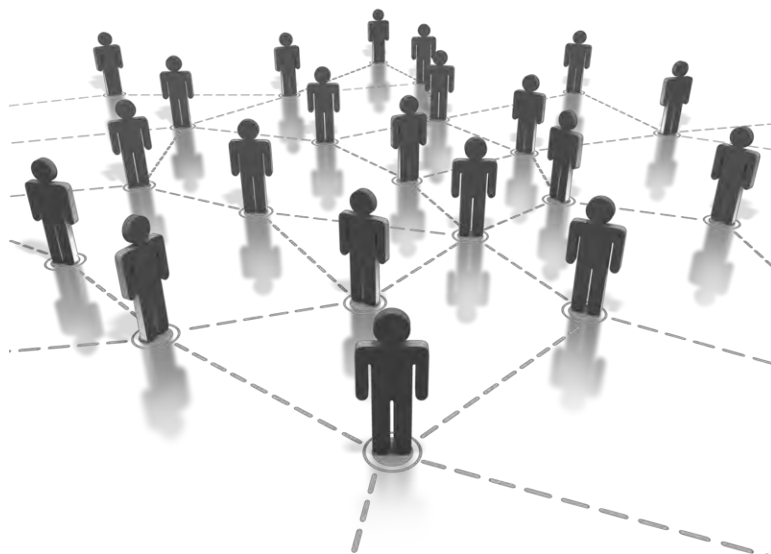
Rule of Thumb #3

Once a draft is complete, the drafting committee should seek reactions and suggestions for revision through a broad-based consultative process.

FORMULATING A CODE OF CONDUCT: SOME RULES OF THUMB (continued)

Rule of Thumb #4

Before initiating the code development process, it is important to determine how a draft code will be finalized and approved. In most institutions and professional societies, there are established procedures: an academic institution may require approval by a faculty senate or a professional society may require a referendum by its membership. In finalizing a code of conduct for dual use research, however, in addition to following these established procedures, it is important to emphasize a key goal: that the code will be sustained as a living document. Thus, it is critical to underscore the need for periodic re-examinations of the code and its provisions, especially in light of developments in dual use research, both in general and within a given institution, organization, or professional society.



DEVELOPING A DISSEMINATION PLAN The importance of envisioning the whole process, from start to finish, has already been emphasized. If that advice is followed, then ideas for how a formulated and approved code of conduct could and perhaps should be disseminated in a given a context will already have been developed, before this phase of the process commences. Such a plan will specify the methods and venues for disseminating a finalized code:

Methods: Dissemination is communication and communication occurs either through the written or the spoken word. Both types of communications can and should be deployed in disseminating a code of conduct.

- **Written communications** include email, letters, newsletters, announcements and press releases, syllabi, etc.
- **Spoken communications** include speeches and addresses, informal talks, lectures, formal dialogues, and unstructured conversation and discussion

Venues: In disseminating a code of conduct, existing venues, as well as venues specifically designed for this purpose, can and should be used. Most organizations and institutions have vehicles for internal and external communications that might be tapped—newsletters, magazines, journals, broadcast email announcements, etc. They also have routine gatherings—annual meetings for professional societies, international and national scientific conferences and assemblies, faculty and staff meetings in academic institutions—that should be exploited for the purpose of disseminating a code of conduct.

UTILIZING EXISTING VENUES In fact, a case can be made for the proposition that existing venues are *critical* to this phase of the process. Using existing venues—new faculty or graduate student orientation, faculty meetings, lab meetings, professional society meetings, etc.—helps to integrate a code of conduct within the daily life and, ultimately, culture of an institution.

DESIGNING EDUCATIONAL INTERVENTIONS

Educational interventions—continuing educational courses for faculty, courses and seminars for graduate and undergraduate students, symposia—are ideal vehicles for disseminating a code of conduct. In designing such interventions, it is important to keep in mind some suggestions, based on well-tested principles of adult learning:

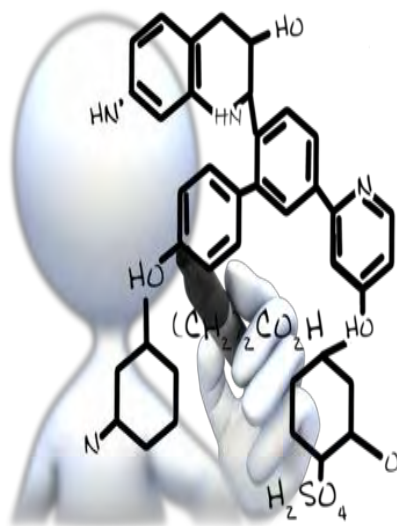
Case-based learning engages learners immediately and vividly: The concrete examples of dual use research provided in the BEFORE YOU START section of this tool kit present dilemmas that challenge the moral imagination and problem solving skills of learners at all levels.

Interactive discussion is often more effective than more didactic modes of teaching and learning: Learners are more apt to become immersed in the content of an educational intervention if they have the opportunity to question, discuss, and debate. Retention of material is also aided by this method.

ENSURING THE VITALITY OF A CODE OF CONDUCT FOR DUAL USE RESEARCH

Any written statement of moral precepts is at risk of being forgotten or trivialized or of becoming irrelevant—unless steps are taken to avoid these fates and to ensure that a code remains a living document. A “living” code of conduct is one whose import and relevance is actively promoted and demonstrated by its champions, as well as renewed in light of developments in science, regulation, and the law. Here, too, a few suggestions are in order:

- In most academic institutions, scientists at all levels are required to undergo periodic education in the responsible conduct of research (RCR). RCR programs are ideal for the integration of materials about an approved (or even contemplated) code of conduct for dual use research—along with specific examples, especially if drawn from the immediate context.
- Developments in the relevant laws and regulations (e.g., the *NIH’s Guidelines for Research Using Recombinant DNA Molecules*) should be tracked and, if necessary, provide the impetus to revisions in the code. Such revisions should be widely publicized within the institution or professional society to ensure awareness.
- Developments in the life (and other) sciences should also be tracked and used to challenge, test, and illustrate the various provisions of a code of conduct.



A FORMIDABLE CHALLENGE: The end, the overarching goal, of a code of conduct for dual use research is a *culture of responsibility* within a particular discipline or institution or organization devoted to scientific research. A code of conduct is only one of several possible means to this end. Determining how effective a means it is or has been *in the concrete circumstances of a particular setting* is an exceptionally difficult challenge.

In part, this is due to the complexity of morally significant behavior. The “causes” of such behavior—our fidelity to, ignorance or rejection of certain norms—are very difficult to isolate and weigh. An individual’s “upbringing,”; her habitual predispositions to embrace or eschew what is good, right or just; the influences of others; the immediate circumstances: these are just a few of the factors that impinge on and shape our moral behaviors and decisions.

Because the goal of a code is a culture of responsibility, it makes sense to integrate specific measures of a code within broader attempts to assess the “state” of such a culture within a given a setting. For example, it might prove useful to ask individuals within a given setting—e.g., graduate students and faculty—whether they are aware of the dual use dilemma and, if they are, how their awareness was developed and formed: through educational interventions; engagement in specific projects with dual use potential; and/or involvement with, knowledge of or commitment to a code of conduct. Such an evaluation is an **outcomes** evaluation.

Such an evaluation is distinct from a *process* evaluation, focused on the process of formulating and disseminating a code of conduct. A process evaluation seeks “feedback” on the methods and venues utilized in the various phases of code development. Such an evaluation focuses on how well the process was conceived and executed.

TOOLS FOR EVALUATION Both types of evaluation—outcomes and process—make use of various tools:

- **Focus groups:** With focus groups, the aim is to gather a representative sample of individuals from a group and to solicit evaluative information of a qualitative nature from them through well designed questions. Usually, focus groups are professionally facilitated.
- **Surveys (paper-based and on-line):** Surveys utilize simple binary questions (yes/no, true/false) or questions whose answers are rendered in the form of a Likert scale.
- **Evaluations embedded within educational interventions, e.g., examinations, etc.:** Evaluations that are used to assess individuals’ understanding or knowledge may incorporate specific questions or exercises that are designed to gauge awareness of a code of conduct—of its rationale, background, and specific provisions.

ON-LINE EDUCATIONAL RESOURCES Tools for educating individuals and groups about dual use research can be used in lieu of or in conjunction with the development of a code of conduct for dual use research. There are several on-line educational tools available, including:

Case Studies in Dual Use Biological Research, an 8-module resource that has been developed by the Federation of American Scientists and that is accessible at <http://www.fas.org/biosecurity/education/dualuse/index.html>.

Biosecurity, a brief but useful introduction to the background, relevant regulations and guidelines, and resources on dual use research accessible at the website, Resources for Research Ethics Education: <http://research-ethics.net/topics/biosecurity>.

Applied Dual-Use Biosecurity Education is an on-line distance learning module that has been developed by the University of Bradford School of Social and International Studies. Only enrolled students can access the module, which provides students with 30 Masters level credits once completed. For more information, click on <http://brad.ac.uk/peace/courses/postgraduatecourses/applied-dual-usebiosecurityeducation/>.

Dual Use Research: Promoting Understanding, Cultivating Responsibility is an educational tool developed under the auspices of the National Science Advisory Board for Biosecurity. The tool can be accessed at <http://oba.od.nih.gov/biosecurity.biosecurity.html>.

SCHOLARLY RESOURCES The scholarly (and popular) literature on dual use research is growing. Some of the key resources include:

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Dual Use Research of Concern

promoting understanding • cultivating responsibility

Appendix B

An Educational Tool Developed Under the Auspices of the National Science Advisory Board for Biosecurity

Dual Use Research of Concern

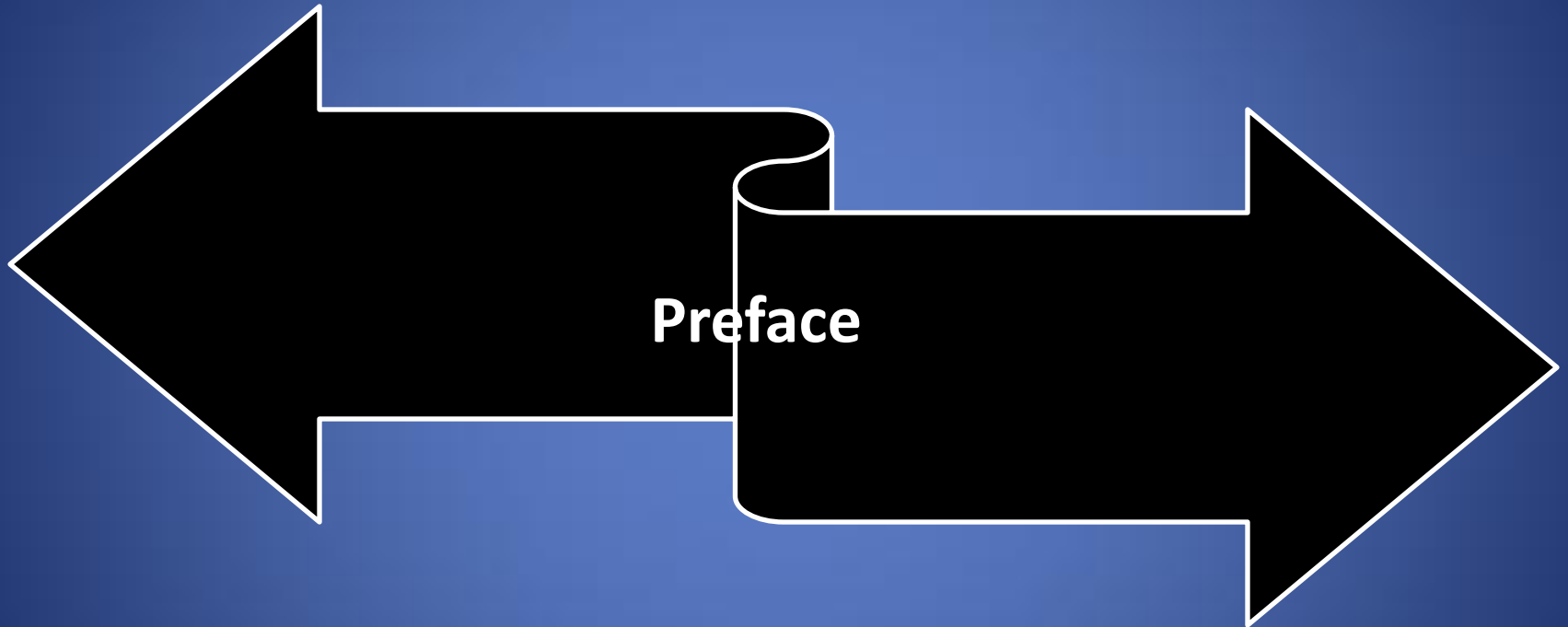
*promoting understanding * cultivating responsibility*

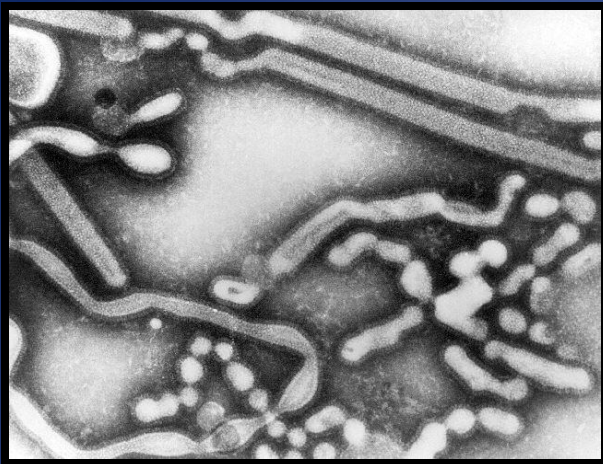
About this educational tool:

This is an introduction to dual use research of concern. It is offered as a tool for achieving several interrelated purposes, including promoting discussion, increasing awareness, and cultivating responsibility for dual use research of concern. It is just one of several available tools for educating individuals and groups about the challenges presented by life sciences (and related) research that may have both beneficial and malicious applications.



Dual Use Research of Concern: Promoting Understanding + Cultivating Responsibility has been designed for adaptation to the needs of different learners. In part or in whole, it can be used for self-directed learning by individuals or for learning and discussion by groups.





In 1918, World War I ended, but a pandemic of influenza, which began in 1917 and ended in 1920, was at its height.



Its impact, in terms of morbidity and mortality, was and remains unprecedented. At least 50 million people, 3 percent of the world's population, died. Approximately 500 million were infected.



These grim statistics account for the controversy spawned by the reconstruction of the previously extinct 1918 flu virus, reported in a paper published by a group of investigators in *Science* in October 2005*.

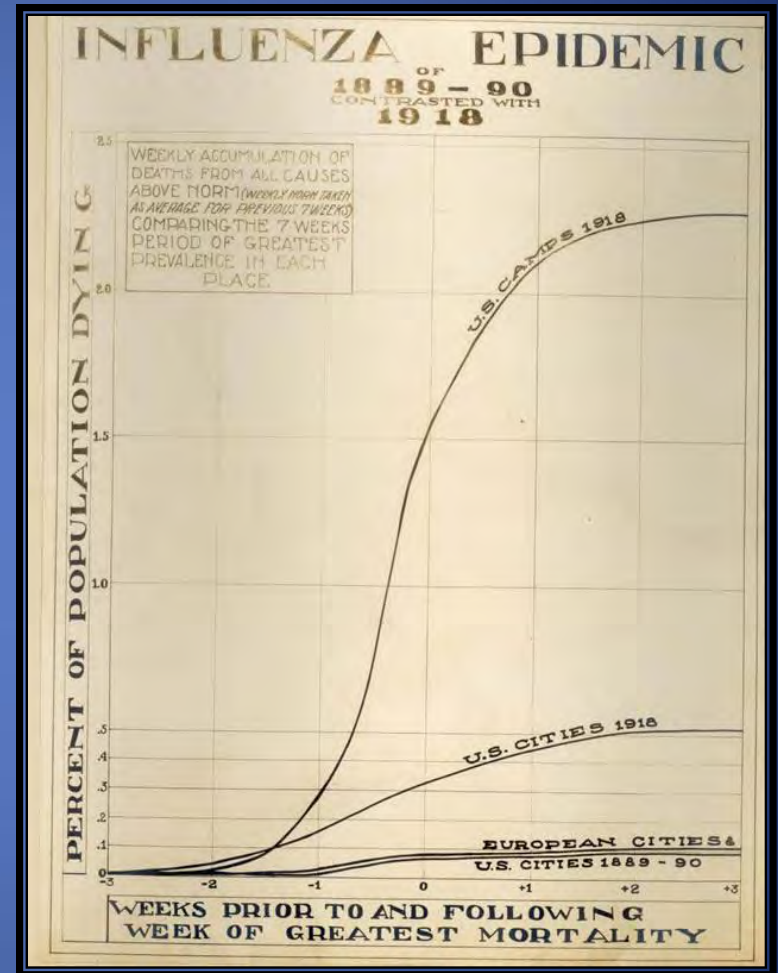
* T.M. Tumpey *et al* , Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus, *Science* 310, 77-80 (2005).

In “Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus,” Terrence M. Tumpey and his colleagues reported on their success in using “reverse genetics” to produce an influenza virus nearly identical to the 1918 pandemic virus.

Their aim was to study the extraordinary virulence of the virus. The results of such research could aid vaccine development efforts to protect the public against future pandemics or in the event of a future outbreak of a similarly pathogenic flu.

But, the research could be misused and put to malevolent purposes—for example, to reconstruct the virus and pose a threat to public health.

The research on the 1918 influenza virus vividly illustrates the dilemmas that can arise with the conduct and publication of *dual use research*.



DUAL USE RESEARCH OF CONCERN

Promoting Understanding - Cultivating Responsibility

contents

- Part 1 - an era of heightened concern: the historical background**
- Part 2 - defining dual use research of concern**
- Part 3 - researcher responsibilities**
- Part 4 - a framework for risk assessment and management**
- Part 5 - communicating research with dual use potential**
- Part 6 - cases with questions for discussion and reflection**



An era of heightened concern

part 1

An era of heightened concern

The 1990s

A decade of mounting concerns about terrorism—including bioterrorism.

WMD BIOLOGICAL AGENTS
 Signs & Symptoms

Agent	Signs & Symptoms
Bacillus anthracis	... (detailed symptoms listed in columns)
Breathable spores	... (detailed symptoms listed in columns)
Botulinum toxin	... (detailed symptoms listed in columns)
Smallpox	... (detailed symptoms listed in columns)
Yersinia pestis	... (detailed symptoms listed in columns)

September 11, 2001



September 18, 2001

Letters containing spores of *Bacillus anthracis*, the causative agent of anthrax, were mailed to two U.S. Senators and several news media offices. Five people died; 17 others were infected.



1990s

2000

2001

An era of heightened concern

2001

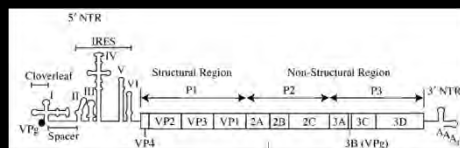
In the *Journal of Virology*, Australian researchers report that in re-engineering a mousepox virus, they unexpectedly produced a much more virulent virus—raising fears about the potential for bioterrorism.



2001

2002

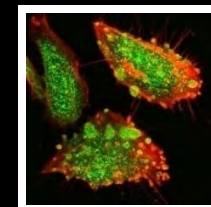
In *Science*, investigators report that they have reconstructed the poliovirus from chemically synthesized oligonucleotides that were linked together and then transfected into cells.



2002

2002

In *PNAS*, researchers report on their investigations into the immune response to a virulence gene from vaccinia, including information on how to increase viral virulence.



An era of heightened concern

2004

The National Research Council publishes the Fink Report recommending that scientists be educated about their responsibilities with regard to dual use research.



2004

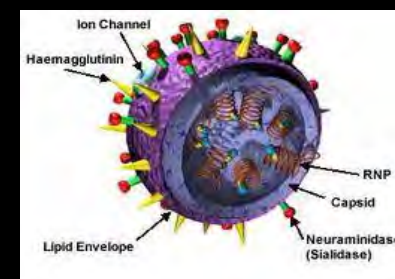
2004

The National Science Advisory Board for Biosecurity is established to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research. Holds first meeting in 2005.

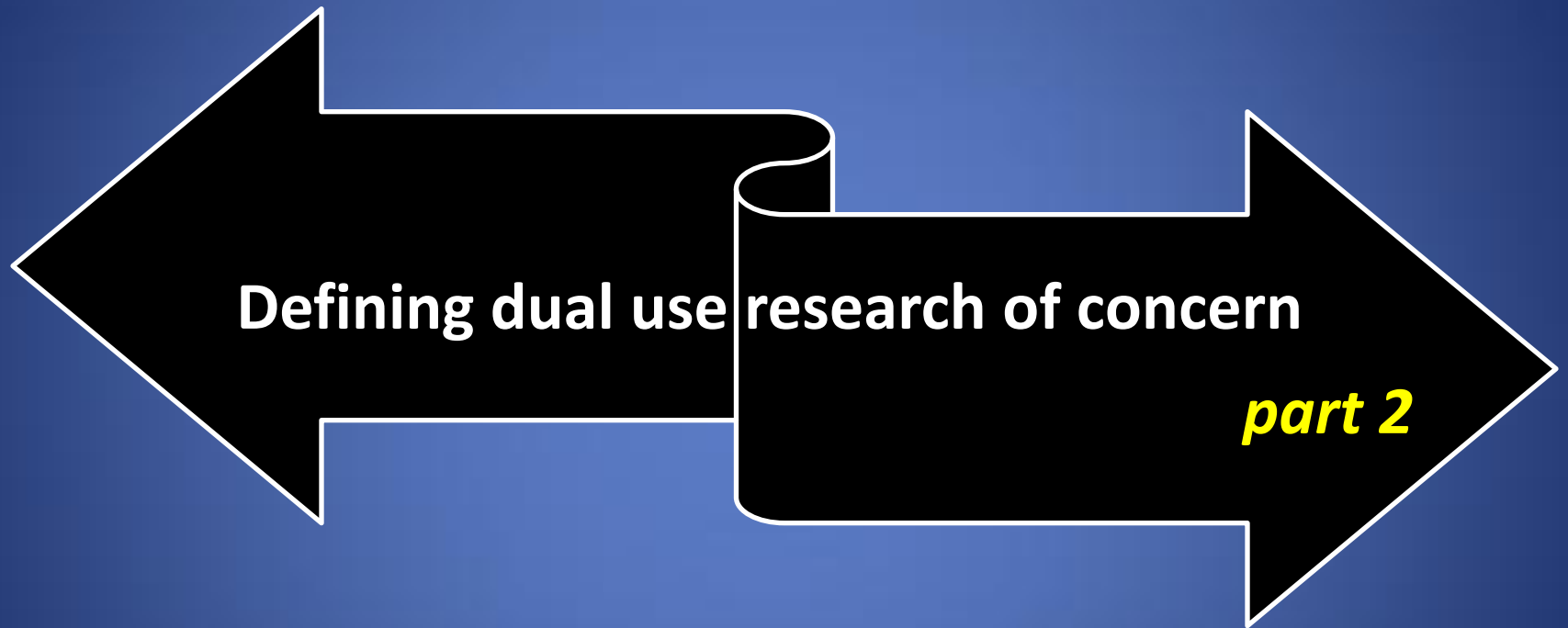


2005

In *Science*, researchers from the Centers for Disease Control and their colleagues report that they have successfully reconstructed the influenza virus that caused the 1918 flu pandemic.

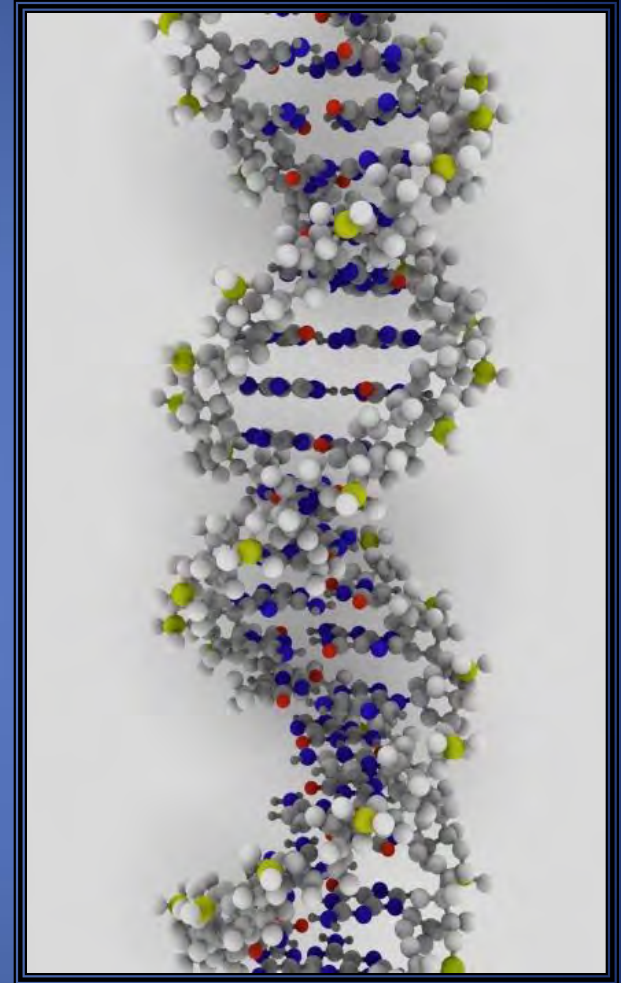


2005



If dual use research is distinguished from other types of life sciences research *by its potential for benevolent and malevolent application*, then few of the products of life sciences research—information or technologies—lack that potential.

The challenge: formulating a definition that enables identification of research warranting concern, vigilance, and perhaps oversight.



Dual use research of concern

A definition proposed by the National Science Advisory Board on Biosecurity

According to National Science Advisory Board for Biosecurity (NSABB), dual use research of concern is “[R]esearch that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.”*

* Established in 2005, the NSABB is a Federal advisory committee chartered to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research to all Federal departments and agencies with an interest in life sciences research. The NSABB advises on and recommends specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration national security concerns and the needs of the research community. The definition of dual use research is from the NSABB’s 2007 report, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*.

The NSABB has identified **7 categories of research** that might qualify as **dual use research of concern** and should therefore receive **closer scrutiny during its design, conduct, and perhaps publication**. *These include research that might*

1. Enhance the harmful consequences of a biological agent or toxin.

Example: Information on how to make a seasonal strain of the influenza virus as deadly as the 1918 pandemic strain.

2. Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification.

Example: information on the insertion of an immunosuppressive cytokine into a viral genome to render the antiviral immune response less effective.



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7 categories of research that might qualify as dual use research of concern—research that might



Staphylococcus aureus

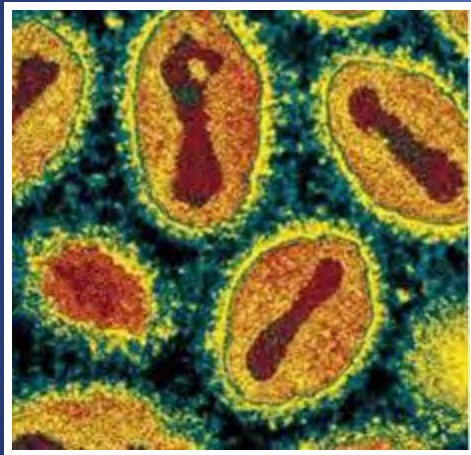
3. Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies.

Example: Information on how to confer doxycycline resistance to Vibrio vulnificus or antibiotic resistance to agriculturally relevant microbes, such as rendering Erwinia amylovora resistant to streptomycin.

7 categories of research that might qualify as dual use research of concern—research that might

4. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.

Examples: information on 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.



Variola virus

5. Alter the host range or tropism of a biological agent or toxin.

Example: Knowledge of how to convert nonzoonotic agents into zoonotic agents, altering the tropism of viruses, and expanding the varieties of the same plant that an altered pathogenic agent could infect.

7 categories of research that might qualify as **dual use research of concern**—research that might

6. Enhance the susceptibility of a host population.

Example: Information on how to create 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.

7. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent .

Examples: Information on how to construct a de novo microbial pathogen using unique gene sequences or combinations of sequences that do not exist in nature; or on how to reconstitute a pathogen that no longer exists in nature, such as the 1918 pandemic influenza virus.



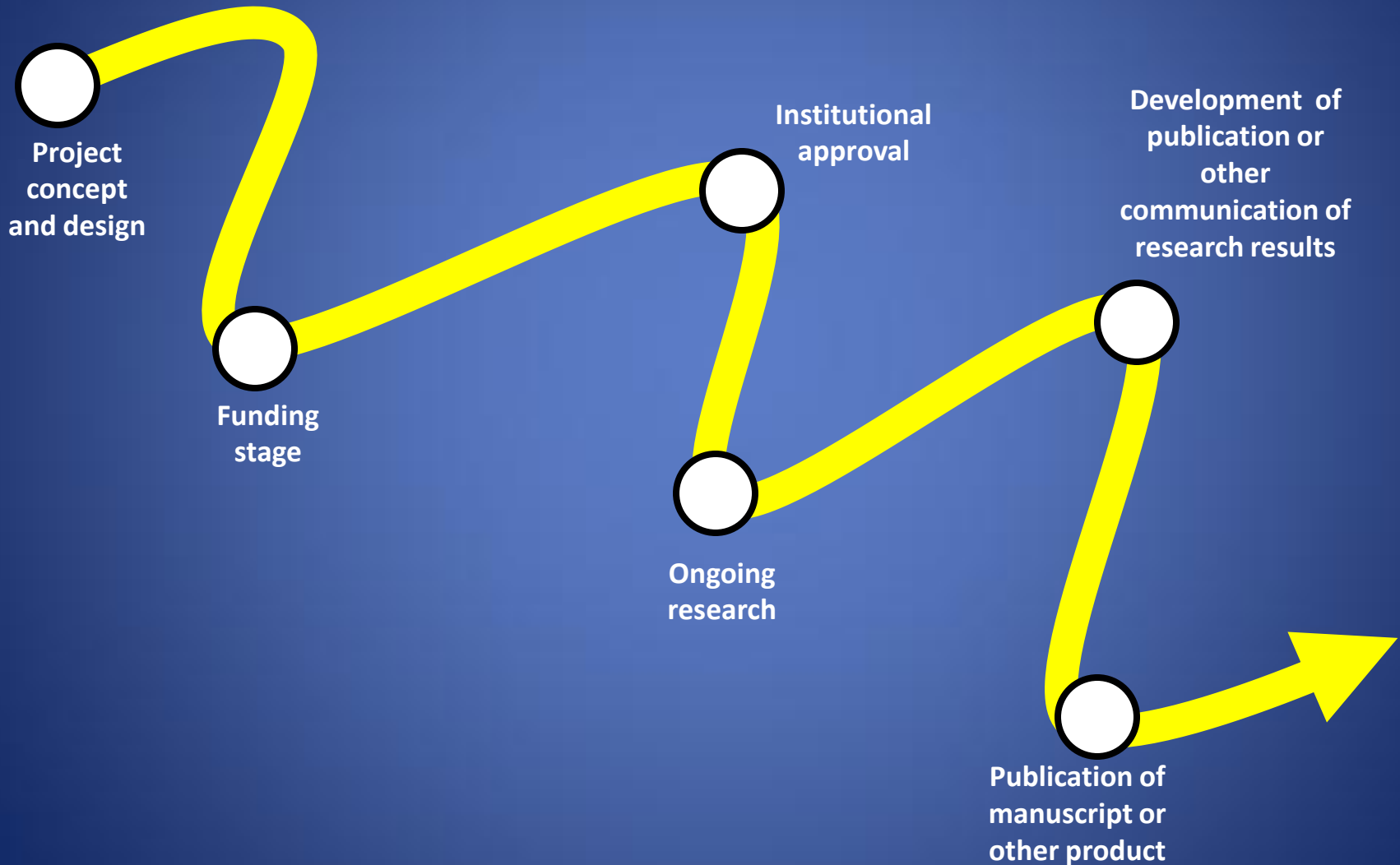
The responsible conduct of dual use research

The critical role of researchers

Although the responsible conduct of dual use research requires the active, thoughtful engagement of funding organizations, institutions, and others, the researchers themselves *can* and ***must*** play a central role ...

... After all, they know their research 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.

Researcher responsibilities span the successive phases of the research process



Researcher responsibilities

*See
part 2*

Being cognizant of the concept of dual use research of concern, and aware of the risks of misuse

Being knowledgeable about and complying with all local and federal policies for oversight

Keeping their institutions informed of the dual use potential of their research

Assessing, on an ongoing basis, their research for dual use potential, beginning with research design and including publication of the results

Ensuring that laboratory staff, students, and other research personnel are trained in dual use issues and risk mitigation

Communicating dual use research responsibly

*See
part 4*

*See
part 5*



**A framework for risk assessment
and management**

part 4

Is this dual use research of concern?

A framework for assessing and managing risks

QUESTION 1:
Could this research yield information that could be intentionally misused to threaten public health and safety or other aspects of national security?

QUESTION 2:
What is the nature of the threat that could be posed from intentional misapplication of the information and what are the potential consequences?

QUESTION 3:
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?

QUESTION 4:
Could this research yield information that could potentially benefit the life sciences and/or public health and safety and other aspects of national security?

QUESTION 5:
Do the potential risks outweigh the potential benefits?

The framework's 5 key questions

Is this dual use research of concern?

A framework for assessing and managing risks

1. 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 the information? Is it novel?
- Is the information applicable to other, perhaps common organisms, biologics, etc.?
- Could the information be directly misused to pose a threat? Does the information need to be combined with other information to pose a threat? If so, is that other information already available?

Is this dual use research of concern?

A framework for assessing and managing risks

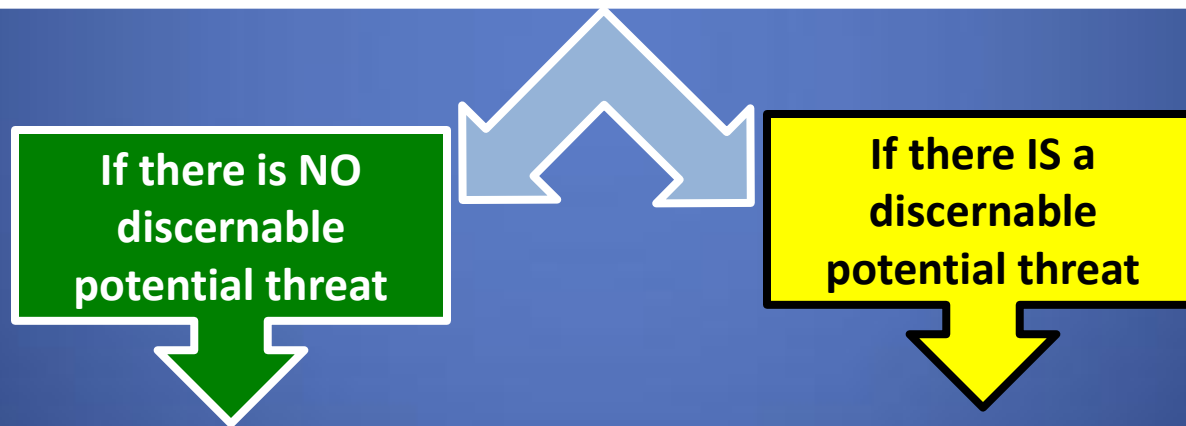
2. What is the nature of the threat that could be posed from the intentional misapplication of the information and what are the potential consequences?

- What is the potential nature (e.g., economic, agricultural, public health) 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?

Is this dual use research of concern?

A framework for assessing and managing risks

3. Based on the preceding 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?



Then, discontinue the analysis and proceed with the research but continue to be vigilant regarding dual use issues that may arise during the conduct of the research

Then, proceed with the analysis

Is this dual use research of concern?

A framework for assessing and managing risks

4. 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?

Is this dual use research of concern?

A framework for assessing and managing risks

5. Do the potential risks outweigh the potential benefits?

- If not, determine applicable risk management strategies.
- If so, consider whether the research should be modified, conducted at a later time when the benefits outweigh the risks, or delayed (perhaps, in rare cases, even discontinued).
- The risk/benefit assessment should be conducted periodically.



Communicating dual use research of concern

part 5



Decisions about the responsible communication of research with dual use potential should address the following in sequence:

1) Content

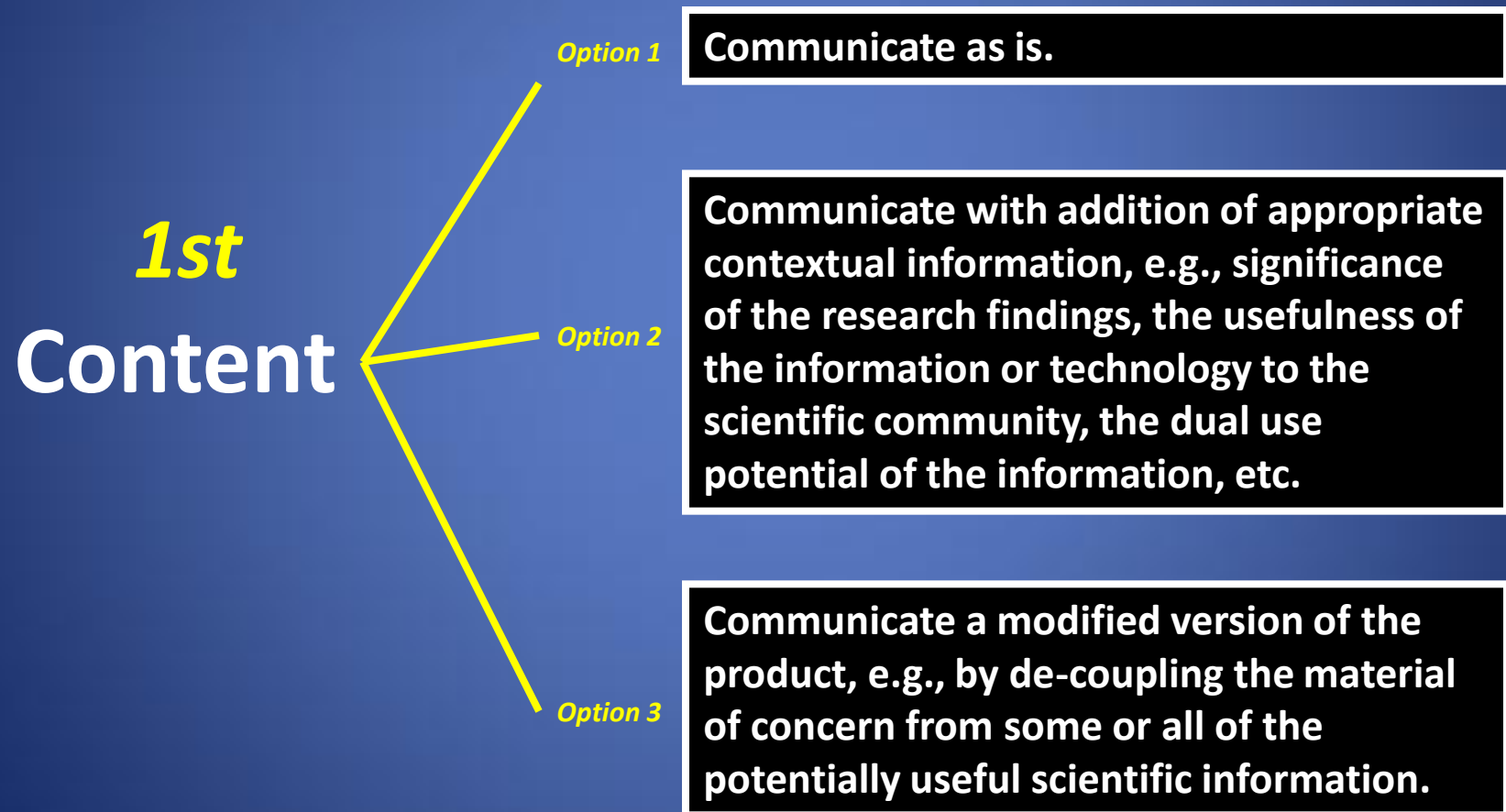


2) Timing



3) Extent of distribution

Dual use research of concern potential: *Communication decisions*



Dual use research of concern potential : *Communication decisions*

2nd Timing

Option 1

Communicate immediately.

Option 2

Defer communication 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.

Dual use research of concern potential : *Communication decisions*

3rd Extent of Distribution

Option 1

Do not limit distribution.

Option 2

Limit access to selected individuals on a “need to know” basis. (Thus, with this option, it would be necessary to identify categories of individuals who should have access and under what circumstances.)

Option 3

Do not publish the product or otherwise make it accessible to the public.



**Cases with questions
for discussion and reflection**

part 6

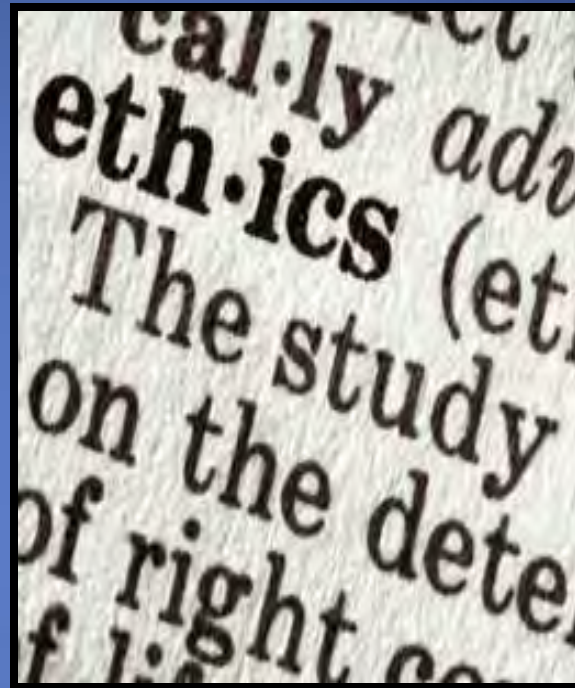
There are several strategies for raising awareness about, and inculcating responsibility for dual use research of concern.



For example, some professional societies have developed codes of conduct for dual use research of concern.

To facilitate the consideration, formulation, and dissemination of such a code, the NSABB has developed a Codes of Conduct Toolkit, available at: [web address]

Educational interventions targeted at students and investigators in the life sciences are crucial to raising awareness and inculcating responsibility.



Case-based interventions
use real or realistic
scenarios
to challenge groups and
individuals to wrestle with
the dual use dilemma and
reason through the question
of
What should you do?
in every phase of the dual
use research process.



The cases:

Objectives for learning and discussion

- Demonstrate an understanding of the dual use dilemma, including “real life” and hypothetical examples of dual use research
- Demonstrate an ability to identify aspects and products of research with the potential for misuse
- Demonstrate an understanding—and ability to formulate—workable strategies for minimizing the risk of misuse
- Delineate responsibilities and define appropriate conduct when designing, conducting, and communicating dual use research

1. Before the Study: Using Adenovirus

Sonia is a doctorate student who is developing a new project in which she plans to test a gene transfer technique to treat colon cancer tumors. The technique uses a modified adenovirus as a vector. It modifies the adenovirus in such a way that it specifically targets colon carcinoma cells and can be used to deliver tumor suppressor genes with the aim of overcoming the mutated genes that are implicated as the cause of the tumors. Modified adenoviruses have been used as vectors for gene transfer before but with only partial success. Sonia's technique is an improvement on existing methods and promises to avert or resolve the problems that have hampered success in the past. Moreover, the method is easy to use and relatively cheap. Although she has not published on the new method as yet, her colleagues have all tested it and are very impressed; indeed, they have encouraged her to patent the method.

1. Before the Study: Using Adenovirus

continued

Sonia's enthusiasm for her work, however, has been dimmed a bit by an off-handed comment by her colleague, Dan, who observed that the technique could be used to deliver toxins and other harmful agents to cause harm to animals, agriculture and perhaps even to humans. Now, Sonia is not sure what to do.

Q: Should Sonia disregard Dan's comment—after all, she is working on a possible treatment for cancer?

Q: Should Sonia inform others about the potential for misuse of her newly developed method? If so, whom should she inform? Her colleagues? The editors and readers of the journal or journals in which she might publish her work?

Q: Is there some other course of action that Sonia should consider?

Q: Are there conditions under which research like Sonia's should be prevented from being carried out?

2. During a Study: Studying *Streptococcus Pneumoniae*

Ann, a post-doctoral fellow is working with Peter, a senior researcher, on a study of antimicrobial resistance in gram-positive pathogenic bacteria. Ann is studying recently isolated strains of *Streptococcus pneumoniae* that have developed antibiotic resistance and cause significantly increased pneumonia morbidity and mortality. She has identified a gene that she believes is responsible for the resistance, one that encodes part of a membrane-bound protein pump that removes materials from bacterial cells. And with that gene, she has created a variant with increased capacity that provides heightened resistance.

2. During a Study: Studying *Streptococcus Pneumoniae* *continued*

Q: *This research has the clear potential to yield public health benefits, but it could also be used for malevolent purposes. What, if anything, should Ann and Peter do to minimize the risks of misuse of the research?*

Q: *Should Ann and Peter be held responsible if the findings of their research are malignantly misused?*

3. The Editor's Point of View: Studying the Interaction between a Virus and the Human Immune System

Sue and David submit to a major virology journal a manuscript describing how the insertion of an immunosuppressive cytokine into Pithecine virus viral genome renders the antiviral immune response less effective. The manuscript has been read by many of their colleagues, all of whom agreed that the findings reported are significant and could lead to better understanding of the interactions between this virus and normal immune function.

Several days later, David receives a call from the journal editor, who tells him that the draft paper will undergo special review due to the 'dual use nature' of the research.

3. The Editor's Point of View: Studying the Interaction between a Virus and the Human Immune System

continued

When David informs Sue of his conversation with the editor, she is understandably very worried that the manuscript may not be accepted for publication as a result of this special review. While the paper is under review, she and David reflect on the new dual use research of concern review policies being adopted by journals to which they regularly submit.

3. The Editor's Point of View: Studying the Interaction between a Virus and the Human Immune System

continued

Q: *What considerations should guide editorial decisions about the publication of manuscripts describing dual use research?*

Q: *Who should be involved in reviewing the paper?*

Q: *If a manuscript is to be published, what measures should editors take to minimize the potential for misuse?*

Q: *If the paper is rejected due to its dual use potential, what, if anything, should be done to ensure that the paper is not published elsewhere?*

4. Conference Talk/Poster Session: Working with *Clostridium Botulinum* – Some Surprising Results

The bacterium *Clostridium botulinum* produces a toxin that causes about 150 cases of food poisoning a year in the United States. Bioterrorists could exploit several of its properties—it is accessible, easy to prepare in large quantities, and would be deadly if added to the food or water supply. To counteract the effects of such an attack, a research team screened a library of compounds with the potential to inhibit the activity of botulinum toxin to determine if they could be used therapeutically after an attack.

4. Conference Talk/Poster Session: Working with *Clostridium Botulinum* – Some Surprising Results

continued

During the studies, the group found a small molecule scaffold that strongly enhances the catalytic activity through an apparent increase in binding affinity—in fact, the compound enhanced the activity of the toxin up to fourteen-fold. This finding could yield both benefits and harms. In minute doses, botulium toxin is used to treat cerebral palsy, spasmodic dysphonia, and other conditions and this finding could make this use even more effective therapeutically. But the discovery could be put to misuse as well in ways that are both easy and frightening to imagine.

4. Conference Talk/Poster Session: Working with *Clostridium Botulinum* – Some Surprising Results

continued

Q: *Should these researchers share the results of their research at a scientific conference? What considerations should inform a decision on whether to share the findings?*

Q: *Are there ways to share findings while minimizing the risks of misuse?*

5. Dual Use of Concern in Another Lab – Cell-matrix Interaction and Tumor Growth and Metastasis

Dr. Gray is interested in cell-matrix interaction and its role in tumor growth and metastasis. She finds that membrane protein X is over-expressed in tumor cells and thinks that it may regulate cell adhesion and invasion. She hypothesizes that the N-terminal domain would make a good dominant-negative inhibitor and discovers that expressing this domain inhibits adhesion and kills tumor cells. To produce pure protein to use as a drug to treat cancer, Dr. Gray and her colleague Dr. White develop a bacterial expression-secretion system and are able to isolate the recombinant N-terminal domain from bacterial culture medium. They are excited to find that it kills tumor cells at remarkably low concentrations (0.1 $\mu\text{g/ml}$), and they name the recombinant fragment "N-statin." They show that it does not kill normal cells until they use 20-fold higher doses.

5. Dual Use in Another Lab – Cell-matrix Interaction and Tumor Growth and Metastasis

continued

Their findings show that exceptionally low doses are needed for an effective cancer drug, but they also have results that suggest that if taken orally, even low doses kill mice. Their work illustrates that apart from being a potential drug for cancer, N-statin could be very cheap rat/mouse poison, because the bacterial expression-secretion system provides an easy source of the material.

Dr. Gray and Dr. White share with you their new methods and findings which you find impressive--especially the potency of the biological drug candidate—but you worry that the method and the findings with respect to toxicity pose real risks with respect to dual use concerns and biosafety.

5. Dual Use in Another Lab – Cell-matrix Interaction and Tumor Growth and Metastasis

continued

Q: *What should you do in this case? Should you alert the researchers? the IBC? Someone else?*

Q: *Should the method and the findings be shared with others working in this area? And if so, should they be notified of the potential dual use of this research?*

Appendix C - NSABB Codes of Conduct Workgroup Charge

NSABB Codes of Conduct Workgroup (CCWG)

Workgroup Charge

I. Proposed Workgroup Charge

According to its charter, one key function of the NSABB is to “[A]dvise on the development, utilization and promotion of codes of conduct to interdisciplinary life scientists, and relevant professional groups.” In its *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007), the NSABB articulated “considerations in developing a code of conduct for dual use research in the life sciences” (appendix 3 of the Framework), which includes a set of core responsibilities regarding dual use research of concern and a comprehensive delineation of responsibilities in the research process. The NSABB Codes of Conduct Workgroup (CCWG) is now charged with several tasks to promote the dissemination, awareness, and adoption of codes of conduct by academic institutions as well as by professional societies and individuals engaged in dual use research.

The Workgroup’s pursuit of its charge is premised on certain assumptions regarding the development of codes of conduct. First, the development and implementation of codes of conduct should be voluntary activities on the part of professional societies, institutions, and groups of researchers (e.g., a laboratory team). Second, especially with regard to the challenges of dual use research, codes are optimally used for the purposes of educating and raising awareness among scientists throughout the organization.

The tasks of the Working Group are to:

- (1) Advise on ways to promote the adoption of Codes by Academic Institutions and Scientific Societies;
- (2) Provide guidance on how to maintain Codes as “living” documents that continue to reflect changes in the field of dual use research.

To achieve these tasks the WG will:

1. Identify the relevant people within academic institutions who have the authority and reach to disseminate Codes (for example, VP for Research, Department Head, etc);
2. Identify the relevant people within scientific associations who have the authority and reach to disseminate Codes;
3. Advise on ways to engage these individuals on the issue of Codes;
4. Identify barriers to awareness and adoption of conduct codes;
5. Advise on ways to overcome these barriers;

6. Identify strategies for realizing the potential of codes in shaping behaviors and practices.

II. Proposed Objectives

- 1) Assessment of “the state of the issue,” that is, the extent to which professional societies and institutions have adopted—or are considering the adoption of—codes of conduct; the response of members of societies and of leadership, faculty, and staff of institutions that have done so, and other relevant parameters.
- 2) Identification of barriers to disseminating, raising awareness about, and adopting codes of conduct.
- 3) Strategies for effectively disseminating, raising awareness about, and encouraging the adoption of codes of conduct.

III. Proposed Approaches

- a. Review of Previous NSABB Work Addressing Codes of Conduct:
 - *Strategic Plan for Outreach and Education on Dual Use Research Issues* (December 10, 2008)
 - *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007)
 - “Principles for the Responsible Communication of Research with Dual Use Potential”
 - “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential”
 - “Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences”

Note: the Codes of Conduct Workgroup will build upon, as opposed to reconsidering, previous NSABB recommendations on this document.

 - Reports from the 1st, 2nd, and 3rd International Roundtable on Dual Use Life Sciences Research
 - **Goal 1:** Ensure that WG members are well informed about the past work of the NSABB on the issues surrounding codes of conduct.
 - **Goal 2:** Summarize the previous work of the NSABB will be summarized for final report.
- b. For objective 1), utilizing direct contacts and literature as well as website reviews, assess the current status of codes of conduct adoption by relevant professional societies and institutions (see appendix for a list of the targeted societies)
 - **Goal 1:** Inform WG members of the results of this survey and the key findings from the survey (especially with respect to any discernible impact of NSABB’s work thus far).
 - **Goal 2:** Summarize survey data and key findings for final report.

- c. For objective 2), on the basis of the survey described in b., select societies and institutions that have adopted and sought to implement codes of conducts, as well as groups that have not, and conduct a more targeted effort aimed at identifying barriers encountered or perceived (i.e., encountered by groups that have adopted codes and perceived or encountered by those that have not). Also, if and where possible, identify strategies that have been effective.
 - **Goal 1:** Identify key barriers to code dissemination, adoption, and awareness.
 - **Goal 2:** Keep working group informed about the results of the survey and the effort to identify barriers.

- d. For objective 3), convene the working group for the purposes of (1) reviewing the information and data gathered through b and c, (2) analyzing the identified barriers to dissemination, adoption, and awareness, and (3) strategizing about ways of circumventing, surmounting, or mitigating these barriers.
 - **Over-arching Goal 1: Encourage adoption of codes of conduct by individuals, professional societies, and institutions.**
 - **Subsidiary Goal 2:** Develop a set of “points to consider” for making codes of conduct “living documents” in multiple contexts (e.g., in professional and scientific societies as well as in institutions and by individuals).
 - **Subsidiary Goal 3:** Develop a plan for communicating the “points to consider”.
 - **Subsidiary Goal 4:** Develop a plan for assessing the impact of the “points to consider”.

Please note: If feasible, the working group should consider holding a public forum (or consultation) as another approach to achieving objective 3). Discussions are underway with other NSABB working groups to determine if such a forum/consultation might be held in conjunction with a similar activity by another working group.

IV. Products/Deliverables

- a. Summary of information/data and key findings from survey of professional societies and institutions.
- b. Summary of key barriers to the dissemination, adoption, and awareness of codes of conduct and of effective strategies for these purposes.
- c. Final report incorporating (a) and (b), along with “points to consider” for realizing the potential of codes of conduct as guides to behavior and practice.

V. Proposed Structure/Organization

- Working Group co-chairs: Kenneth Berns & Andrew Sorensen
- WG Membership: Christine Grant, Paul Keim, Stuart Levy, John Lumpkin, Mark Nance, James Roth
- NSABB staff: Paul Lewis, Allan Shipp, Dan Davis, Ori Lev and Symma Finn.

VI. Outcome/Impact Assessment

Measure impact of “points to consider” at specified intervals after introduction/communication.

Appendix D – NSABB Roster

NSABB Roster

Acting Chair

Paul S. Keim, Ph.D.*

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

Voting Members

Kenneth I. Berns, M.D., Ph.D.*

Director of Genetics Institute
University of Florida
Genetics Institute
Gainesville, FL

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

Professor and Chairman
Dept. of Microbiology and Immunology
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., LL.M. (biotechnology & genomics)

Judge (ret.), Arizona Court of Appeals
Adjunct Professor, Department of Microbiology & Immunology,
University of Texas Medical Branch – Galveston,
Galveston National Laboratory

Lynn W. Enquist, Ph.D.

Professor and Chair
Dept. of Molecular Biology
Princeton University;

Editor in Chief, *Journal of Virology*
Princeton, NJ

J. Patrick Fitch, Ph.D.

Laboratory Director
National Biodefense Analysis and
Countermeasures Center
President, Battelle National Biodefense
Institute, LLC
Frederick, MD

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

General, USAF (Retired)
Alexandria, VA

Christine M. Grant, J.D.*

CEO/Founder
InfecDetect Rapid Diagnostic Tests, LLC
Princeton, NJ

Michael J. Imperiale, Ph.D.

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

Joseph Kanabrocki, Ph.D., C.B.S.P.

Assistant Dean for Biosafety
Associate Professor of Microbiology
Biological Sciences Division
University of Chicago
Chicago, IL

Stanley M. Lemon, M.D.

Professor
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**Appendix E – Roundtable: Promoting Awareness and Responsibility in Dual Use Research:
A Critical Assessment of the Role of Codes of Conduct**

**NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY**

**NSABB Codes of Conduct
Working Group**

**A ROUNDTABLE ON
Promoting Awareness and Responsibility in Dual Use Research:
A Critical Assessment of the Role of Codes of Conduct**

National Institutes of Health
Building 31, 6th Floor, Room 10
Bethesda, MD
October 20, 2010

Agenda

7:45 am Light Refreshments

8:00 am **Session I**

**Codes of Conduct and the Responsible Conduct of Dual Use Research: an
Overview of the work of the NSABB**

Co-Chairs:

Kenneth I. Berns, M.D., Ph.D.
Director of Genetics Institute
University of Florida

Andrew A. Sorensen, Ph.D.
Senior Vice President for Development
Special Assistant to the President for Advancement
President of The Ohio State University Foundation
The Ohio State University

- Presentation on working group activities to date:
 - The “considerations” regarding the core responsibilities of researchers in the life sciences (Appendix 3 of the Oversight Framework of June 2007)
 - Outreach and survey efforts before and after the development of the “considerations”

8:30 am **Session II**

Scholarly Work on Codes – An Overview

Moderator:

Paul S. Keim, Ph.D., Division Director, Pathogen Genomics, The Translational Genomics Research Institute, Northern Arizona University

Speaker: *Brian Rappert, Ph.D.*, University of Exeter

- Presentation informed by an academic literature review on how Codes of Conduct have been developed, promoted, and implemented across different fields – Business, Academia, Government and professional societies- how they were developed and used in the life sciences, as well as in the area of dual use research.
- The purpose of this session is to identify effective strategies for developing, implementing, and ensuring the vitality of codes of conduct, especially in the sciences and particularly with reference to dual use research.

9:30 am Break

9:40 am **Session III**

Lessons Learned: Codes of Conduct and Professional Societies

Moderator:

Stuart B. Levy, M.D., Director, Center for Adaptation Genetics & Drug Resistance, Tufts University School of Medicine

Speakers:

- *Ronald Atlas, Ph.D.*, American Society of Microbiology (ASM)
 - *Jan Leach, Ph.D.*, American Phytopathological Society (APS)
 - *Mark S. Frankel, Ph.D.*, Director, Program on Scientific Freedom, Responsibility & Law, American Assn. for the Advancement of Science (AAAS)
- A session devoted to the discussion of such questions as:
 1. What were the motivating aims in the development and implementation of codes of conduct?

2. Who led the effort?
3. What processes and what individuals or groups were involved in developing codes of conduct?
4. Once formulated, how were codes of conduct adopted and promulgated?
5. How are codes used?
6. Have the codes been modified, and if so, why?
7. Have adopted codes of conduct proven effective in achieving the motivating aims?
8. What lessons were learned with regard to the development, implementation, and dissemination of codes of conduct?
9. NSABB's goal is to promote the development and adoption of codes of conduct by more professional societies. What factors were conducive to the development and adoption of codes of conduct in the professional societies that now have them in place?

10:50 Break

11:00 **Session IV**

Lessons to Be Learned: Strategies and Challenges in Adopting Codes of Conduct in the Academic Setting

Moderator:

Mark E. Nance, J.D., General Counsel, GE Healthcare

Speakers:

- *Carol Whitacre, PhD*, Vice President for Research, The Ohio State University
 - *Scott Steele, PhD*, Director, Office of Research Alliances, University of Rochester
 - *Francis Macrina, PhD*, Vice President for Research, Virginia Commonwealth University
 - *Kenneth L. Dretchen, PhD*, Chairman and Professor, Department of Pharmacology, and Senior Associate Vice President for Regulatory Affairs, Georgetown University Medical Center
 - *Naomi Schrag, JD*, Associate Vice President for Research Compliance, Office of the Executive Vice President for Research, Columbia University
- A session devoted to the overarching question of how codes might be promoted and sustained in the academic setting. Insights from industry will be discussed. Specific questions include:
 1. What might be barriers to the adoption of codes?
 2. How can these barriers be overcome?

3. How should codes be developed in academic settings (top-down, bottom-up, particular offices etc.)?
4. How should codes be disseminated through the institutions?
5. How can the codes “vitality” be sustained?
6. What might be effective ways of promoting the adoption of codes in the wider community?
7. How can the adoption of codes be promoted as a moral versus legal approach?

12:20 Lunch

12:45 **Session V**

Promoting the Responsible Conduct of Dual Use Research: A Conversation with RCR Leaders

Moderator:

Christine M. Grant, J.D., CEO/Founder, InfecDetect Rapid Diagnostic Tests, LLC

Speakers:

- *Michael W. Kalichman, Ph.D.*, Director, Research Ethics Program, University of California – San Diego
 - *John Galland, Ph.D.*, Director, Division of Education and Integrity, Office of Research Integrity, Department of Health and Human Services
 - *John E. Dahlberg, Ph.D.*, Director, Division of Investigative Oversight, Office of Research Integrity
- A session devoted to exploring potential linkages between codes of conduct, promoting awareness of dual use research, and education in the responsible conduct of research. Questions for discussion include:
 1. How can RCR education integrate the issue of dual use in general and the adoption of codes in particular?
 2. Are there good models or best practices for doing so?
 3. What might be the challenges to overcome?

1:45 pm Review of the Roundtable Discussions and Next Steps (**CCWG Members Only**)

2:30 pm Adjournment

Appendix F - Roundtable Participants' Biographical Sketches

- **Ronald Atlas, PhD**, is co-chair of the Public and Scientific Affairs Board Biodefense Committee of the American Society for Microbiology and Professor of Biology at the University of Louisville. He received his BS degree from the State University at Stony Brook, his MS and PhD degrees from Rutgers the State University, and a DSc (honoris causa) from the University of Guelph. He has served as President of the American Society for Microbiology, as a member of the NIH Recombinant Advisory committee, as chair of NASA's Planetary Protection Committee, as chair of the Wellcome Trust Pathogens, Immunology and Population Health Strategy Committee, as a member of the US Department of Homeland Security's Science and Technology Advisory Committee, and as chair of the Board of Directors of the One Health Commission. He is the author of nearly 300 manuscripts and 20 books. He is a fellow in the American Academy of Microbiology.
- **John E. Dahlberg, PhD**, has been the Director of the Division of Investigative Oversight of the Office of Research Integrity, US Department of Health and Human Services, since April 2006. He received a BA from Brandeis University in 1963 and a PhD in microbiology from Purdue University in 1968. After post-doctoral fellowships at the Public Health Research Institute of the City of New York and at Rutgers University, he spent sixteen years at the National Cancer Institute in Bethesda carrying out research on retroviruses with an initial emphasis on ultrastructure and virus classification. Subsequently he focused increasingly on immunoassay development and molecular biology and, using all of these technologies, began research on lentiviruses in 1980. In 1988, Dr. Dahlberg joined a small biotechnology company as director of research and development, where he developed procedures for growing macrophage cells in serum-free medium and using them to test drugs for their ability to inhibit HIV replication. Dr. Dahlberg joined the Office of Scientific Integrity in 1992, just prior to its being reorganized into ORI. While at ORI, he has developed a variety of computer-aided techniques to assist in analysis of data and detection of evidence of data falsification.
- Dr. Kenneth Dretchen currently serves as a professor and chair of the Department of Pharmacology at Georgetown University Medical Center. He is actively involved in teaching the principles of pharmacology to medical and graduate students. Dr. Dretchen previously served as the Dean of Research for 5 years and the Senior Associate Vice-President for Regulatory Affairs for the medical center. In these two positions he was responsible for promoting and facilitating faculty research efforts as well as serving as the Institutional Official for the university. In this regard, he was responsible for all of the regulatory activities of the university

including the IRB, Animal Care and Use Committee, biohazards and radiation safety.

Dr. Dretchen maintains an active research program. In conjunction with General Dynamics he has been involved in the development of a stand-alone detection system for biological and chemical threat agents. Furthermore, he was part of the team including Meridian Medical Technologies and the DoD that developed the antidote kit for chemical weapons of mass destruction. The kit is carried by members of the military and stored in the Strategic National Stockpile.

Dr. Dretchen is a member of the National Biodefense Science Board. This is a thirteen-member federal advisor committee that reports to the Secretary of DHHS. The responsibility of the board includes advising the Secretary on: emerging infectious diseases, pandemic influenza and chemical, biological and radiological threat agents.

- **Mark S. Frankel, PhD**, is director of the Scientific Freedom, Responsibility and Law Program at the American Association for the Advancement of science (AAAS), where he develops and manages AAAS's activities related to professional ethics, science and society, and science and law. At AAAS he has directed or co-directed projects on research integrity and scientific misconduct, codes of ethics in scientific and engineering societies, the ethical and policy implications of human stem cell research, the implications of advances in neuroscience research for the legal system, the use of science in the courtroom, and personalized medicine, among others. Dr. Frankel is a former member of the Board of Directors of the National Patient Safety Foundation and currently serves on the Boards of the Food and Drug Law Institute and the Center for Law, Science & Innovation at Arizona State University. He is also a member of the Science and Ethics Advisory Group at Roche Genetics in Basel, Switzerland. He serves on the editorial boards of *Science and Engineering Ethics*, *Ethics & Behavior*, and the *Journal of Empirical Research on Human Research Ethics*. He is editor of AAAS's quarterly publication, *Professional Ethics Report*, and a Fellow of AAAS.
- **John C. Galland, PhD**, is the Director of the Division of Education and Integrity in the Office of Research Integrity, US Department of Health and Human Services. Before joining ORI on March 27, 2009, Dr Galland was Director of the UC Davis Laboratory Management Institute. While at the Institute, Dr. Galland developed a curriculum and unique pedagogy for educating scientists in the practical business of running a research program. This pedagogy was described in the journals *Nature*, *Science*, *Cell*, *The Scientist*, *The Chronicle of Higher Education*, the National Postdoctoral Association's *The PostdocKET*, and *Laboratory Manager*. The curriculum was delivered through an annual program for postdoctoral scholars at UC Davis and a summer Certificate Program offered to people worldwide. Both programs consisted of 140 contact hours of instruction. Additional educational

programs were conducted for industry, government, national laboratories, other academic institutions, and scientific associations.

Dr. Galland also taught a graduate course for the UC Davis School of Veterinary Medicine entitled “Philosophy and Ethics for the Biological Scientist”. In 2004, Dr. Galland became one of 20 partners in the Howard Hughes Medical Institute/Burroughs Wellcome Scientific Management Program for Postdoctoral Fellows and Faculty and acknowledges their influence on the program at UC Davis.

Dr. Galland received both his MS and PhD degrees from UC Davis. Before returning to UC Davis, he was Professor of Veterinary Medicine at Kansas State University where he taught public health and zoonotic diseases and conducted research on food-borne pathogens.

- **Michael Kalichman, PhD**, is the founding director of the Research Ethics Program at the University of California, San Diego, in La Jolla, California. Since 1988, he has taught multiple seminars and courses to help UCSD Training Grant Program Directors comply with NIH requirements for training in the responsible conduct of research. He has been a consultant or speaker on the topic of research ethics for both national and international workshops and advisory groups, including panels and conferences for the American Association for the Advancement of Science, National Academy of Sciences, National Institutes of Health, and the Office of Research Integrity. With Francis Macrina of Virginia Commonwealth University, he has taught numerous courses for instructors of research ethics courses. He is project director for a Web-based resource for instructors of courses in the responsible conduct of research (<http://research-ethics.net>) and directs NIH-funded projects to assess the effectiveness of teaching research ethics and the standards of conduct in research. Kalichman is also the founding and past president for the Responsible Conduct of Research Education Consortium (RCREC), which is now part of the Association for Practical and Professional Ethics. He is a co-founder and co-director of the Center for Ethics in Science and Technology (<http://ethicscenter.net>) for the San Diego region and founding director of the San Diego Research Ethics Consortium (<http://sdrec.ucsd.edu>).
- **Jan Leach, PhD**, is a University Distinguished Professor at Colorado State University and an Adjunct Scientist at the International Rice Research Institute (Philippines). She is an authority on the molecular biology of plant–pathogen interactions. Her research focuses on understanding the molecular basis of durable disease resistance, particularly in rice–pathogen interactions. Other projects currently underway in her laboratory are related to bioenergy (genetics of biomass production), improving health benefits of crop plants, and the development of novel tools for detection and monitoring of microbes associated with plants. She is a Fellow and a past President of the American

Phytopathological Society. She is also a Fellow of the American Association for the Advancement of Science (AAAS), served as Chair of the AAAS Section O (Agriculture, Food, and Renewable Resources) in 2007, and is currently a member of the Section O steering committee. Leach is a Fellow of the American Academy of Microbiology. Prior to her appointment at CSU, Dr. Leach was named a University Distinguished Professor at Kansas State University in 1998. She served as president of the International Society of Molecular Plant–Microbe Interactions. Leach has served or chaired advisory committees for a number of national and international projects, programs and institutions, including the U.S. Rice Genome Sequencing Project, the Research Core for Interdisciplinary Science (RCIS) at Okayama University (Japan), Rural Development Agency (Korea), and a National Research Council (NRC) study.

- **Francis L. Macrina, PhD**, is the Edward Myers Professor of Dentistry and Vice President for Research at Virginia Commonwealth University (VCU). Dr. Macrina's longstanding scientific interests have been in the molecular pathogenesis of infectious diseases, and his research at VCU was continuously supported by the National Institutes of Health (NIH) for 33 years. This NIH funding included Research Career Development and MERIT Awards from the National Institute of Dental and Craniofacial Research. He has authored over 115 scientific publications. His current scholarly interests also include behavioral and educational research in scientific ethics. Dr. Macrina has served two terms on NIH study sections and was both a member and the chair of the NIDCR Board of Scientific Counselors. He also served a four year term on the NIH National Advisory Dental and Craniofacial Research Council. He has served on the editorial boards of the *Journal of Bacteriology* and *Infection and Immunity*. He was both co-editor-in-chief and editor-in-chief of *Plasmid*, serving in these roles for a total of 13 years. He is frequently invited to speak on scientific integrity teaching, and has been involved in teaching workshops sponsored by PRIM&R, the American Society for Microbiology (ASM), Sigma XI, and the National Academy of Sciences. He has served as a member of the ASM Ethics Committee and the Ethics Committee of the American Association for Dental Research. He was a founding member and officer of the Responsible Conduct of Research Educational Consortium, now a unit of the Association of Practical and Professional Ethics. He has been a consultant to the USHHS Office of Research Integrity, the National Institutes of Health, the National Science Foundation and the National Science Advisory Board for Biosecurity on matters related to scientific integrity and responsible conduct of research. He completed two years of service as a member of the NAS/AAAS Committee on Assessing Fundamental Attitudes of Life Scientists as a Basis for Biosecurity Education. The third edition of his widely used text, *Scientific Integrity, Text and Cases in Responsible Conduct of Research* was published by ASM Press in March, 2005. He is presently writing the 4th edition of this book which is expected to be published in the fall of 2011.

- **Brian Rappert, PhD**, is the Head of Department and an Associate Professor of Science, Technology and Public Affairs in Sociology & Philosophy at the University of Exeter. His long term interest has been the examination of how choices can and are made about the adoption and regulation of technologies, particularly in conditions of uncertainty and disagreement. Over the last 5 years he has undertaken extensive educational engagement efforts with individuals and groups in the life sciences regarding the potential destructive use of their research. In 2010 he published *Education and Ethics in the Life Sciences* (freely available at http://epress.anu.edu.au/education_ethics/pdf_instructions.html). His other books include *Controlling the Weapons of War and Biotechnology, Security and the Search for Limits*, *Biosecurity* (co-ed), and *Experimental Secrets*.
- **Naomi J. Schrag, JD**, is the Associate Vice President for Research Compliance in the Office of the Executive Vice President for Research. She oversees work on such issues as research misconduct, conflict-of-interest and international research compliance, and collaborates closely with other offices across the University to develop integrated approaches to compliance and training. Before joining Columbia in January 2006, Ms. Schrag practiced law for nine years, focusing on regulatory compliance and litigation involving biomedical research, with clients including pharmaceutical companies and not-for-profit organizations. Ms. Schrag also clerked in the Court of Appeals for the Second Circuit. Ms. Schrag graduated from New York University School of Law in 1995. Before entering law school, she worked on an oral history of the Holocaust for the Museum of Jewish Heritage.
- **Scott Steele, PhD**, joined the University of Rochester in December of 2008 and currently serves as the Director of a new Office of Research Alliances. In this role he is identifying and fostering strategic research partnerships and educational alliances between the University's research community and industry, government agencies and laboratories, and other academic institutions. He is actively involved with the University of Rochester Clinical and Translational Science Institute, serving as the Director of the Public-Private Partnership Key Function. Dr. Steele also serves on research and technology related committees at the University of Rochester, including the Technology Transfer Policy Committee and the University Research Group, both chaired by the Provost. Prior to joining the University of Rochester, Dr. Steele served in the White House Office of Science and Technology Policy (OSTP), initially as a representative of the National Science and Technology Council and was later designated as the Executive Director of the President's Council of Advisors on Science and Technology (PCAST). PCAST provides advice and recommendations to the President on a range of science and technology issues and Dr. Steele coordinated PCAST studies exploring issues in nanotechnology, energy technologies, personalized medicine, and approaches to enhance university-private sector research partnerships. Previously, Dr. Steele served as a senior policy specialist at the Federal Bureau of Investigation (FBI). Within the FBI's Weapons of Mass Destruction program, he focused on

developing a number of science and national security policies and plans, including forming partnerships between the scientific, public health, law enforcement and broader national security communities.

- **Caroline C. Whitacre, PhD**, serves as the Vice President for Research at The Ohio State University in Columbus, Ohio. She is a Professor of Molecular Virology, Immunology and Medical Genetics and holds joint appointments in the Departments of Pathology, Internal Medicine and Veterinary Biosciences. She served as Associate Vice President for Health Sciences Research and Vice Dean for Research in the College of Medicine from 2001-2008. Dr. Whitacre received her BA and PhD degrees at Ohio State University and did postdoctoral training at Northwestern University Medical School in Chicago. She returned to Ohio State in 1981 where she has been on the faculty since that time. She served for 12 years as the Chair of the Department of Molecular Virology, Immunology and Medical Genetics in the College of Medicine.

Dr. Whitacre's research is in the area of the immunology of multiple sclerosis (MS). Her laboratory examines the treatment of MS and its animal model using oral tolerance. This research has led to clinical trials in MS, rheumatoid arthritis, uveoretinitis, and diabetes. She has also worked in the area of hormonal regulation of autoimmunity, and more recently focused on sex differences and the effects of pregnancy on autoimmune disease. Dr. Whitacre has served as chair of an NIH study section, as well as Chair of the Task Force on Gender, MS and Autoimmunity for the National Multiple Sclerosis Society. She also chaired the Presidential Commission on University Governance at Ohio State. In recognition of her University activities, she was awarded the OSU Faculty Award for Distinguished University Service in 2001 and the Distinguished Scholar Award in 2008. In 2004, she was named a Fellow of the American Association for the Advancement of Science.

Appendix G – Bibliography of Literature Review

Code of Conduct for Dual Use Research in the Life Sciences

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Appendix H: Survey of Scientific Societies 2010

	General Code	Mention of Dual Use
American Association for the Advancement of Science (AAAS)	no	Center for Science, Technology & Security Policy has a database linking to different educational projects, educational materials, etc. The Center also did research on the topic and organized workshops and conferences. It put out a report "Professional and Graduate-Level Programs on Dual Use Research and Biosecurity for Scientists Working in the Biological Sciences" which recommends integrating this issue into science education. It has a statement on the need to allow unrestricted dissemination of knowledge.
American Institute of Biological Sciences	yes	no
The American Phytopathological Society (APS)	yes	yes, Statement from the APS Council
American Society for Biochemistry and Molecular Biology	yes	no
The American Society for Microbiology	yes	yes, ASM Council Statement
Federation of American Scientists	no	In its mission statement. It has an elaborate program on biosecurity that includes online modules on dual use research that can be used to highlight the issue.
FASEB	no	They have created a sub committee and put out an elaborate statement on dual use research and the need to integrate it into science curricula.
National Academy of Sciences	no	Project in the Board of Life Sciences on biosecurity, collaborates with AAAS on programs and workshops. Links to FAS and others.
The Society for Integrative and Comparative Biology (SICB)	yes	no
Society for Neuroscience	yes	no
Society of Toxicology	yes	They have a very general statement : "Give due consideration to the ethical, legal, social and policy implications of their research and communications."
The American Biological Safety Association (ABSA)	yes	They have a page on biosafety and an "ABSA Biosecurity Task Force White Paper: Understanding Biosecurity".

	General Code	Mention of Dual Use
Biotechnology Industry Organization	yes - ethics statement	No mention of dual use but of social issues.
The American College of Laboratory Animal Medicine (ACLAM)	Adequate Veterinary Care	no
Council for Agricultural Science and Technology (CAST)	paper on ethics	no
Public Responsibility in Medicine and Research (PRIM&R)	mission statement	General statement about social responsibility without any mention of dual use.
American Academy of Forensic Science	yes	
American Mathematical Society*	yes	yes, an excerpt: "Freedom to publish must sometimes yield to security concerns, but mathematicians should resist excessive secrecy demands whether by government or private institutions."
International Union of Microbiological Societies	yes	yes, a specific code for dual use: "IUMS Code of Ethics against Misuse of Scientific Knowledge, Research and Resources".
International Council of Science (ICSU)	no - but has statements on research integrity and other issues.	no mention of dual use
The International Union of Biochemistry and Molecular Biology	yes	Part of their general code of ethics, it does not mention dual use but does invoke biosecurity issues: "7. They will not engage knowingly in research that is intended for the production of agents of biological warfare or bioterrorism, nor promote such agents."
Royal Society of New Zealand	yes	One part of the code focuses on genetics and has some relation to issues of dual use: "The power to genetically modify living organisms lies alongside the power to harness the energy of the atom in placing a special responsibility on those who have the knowledge and skills to do so. It is essential that all scientists and technologists keep firmly in mind the general requirements of this Code of Ethics and that they do nothing that could potentially be detrimental to the community or harmful to the environment."
American Medical Association	yes	Section in their code of ethics: "Opinion 2.078 - Guideline to Prevent Malevolent Use of Biomedical Research".
International Union of Pure and Applied Chemistry	yes	They have a group that is working on a code that includes reference to dual use. The last update on the work of the group is from 2008.
The International Association of Synthetic Biology	no	yes

	General Code	Mention of Dual Use
Institute of Medicine	no	Report on dual use research from 2005 - from the Board on Global Health.
The American Society of Gene & Cell Therapy (ASGCT)	yes	no
Royal Society	no	no, but they published a paper calling for dual use oversight
American Academy of Microbiology	no	no
The American Association of Immunologists	no	
American Society for Virology	no	no
The American Society of Parasitologists	no	no
The Association of Applied Biologists	no	no
The Biophysical Society	no	no
Society for Developmental Biology	no	
Society for General Microbiology	no	no
Society for Industrial Microbiology	no	no
The American Society for Rickettsiology	no	no
The Alliance for the Prudent Use of Antibiotics (APUA)	no	no
Association for Biology Laboratory Education	no	no
European Society for Emerging Infections	no	no

	General Code	Mention of Dual Use
Federation of European Microbiological Societies	no	no
International Society for Interferon and Cytokine Research	no	no
International Society for Molecular Plant-microbe Interactions	no	no
The International Society for Antiviral Research (ISAR)	no	no
Association of American Universities	no	no
Association of American Medical Colleges	no	no
Association of Public and Land-grant Universities	no	no
The American Physiological Society		part of FASEB
American Society For Cell Biology (ASCB)	no	no

Appendix I

Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences¹

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

¹ Excerpted from: NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research*, pp.43-50 (Bethesda, MD: National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

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 text box below 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 anethical 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 material
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 practices² 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:

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

² Safe laboratory practices are embodied in such documents as *CDC-NIH Biosafety in Microbiological and Biomedical Laboratories* (www.cdc.gov/od/ohs/biosfty/bmbI5/bmbI5toc.htm), *NIH Guidelines for Research Involving Recombinant DNA Molecules* (www4.od.nih.gov/oba/rac/guidelines/guidelines.html), and *Biological Safety: Principles and Practices* (ASM Press, www.asm.org/), and applicable occupational and safety regulations and standards.

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 material 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