

NSABB Draft Guidance Documents

- I. Criteria for Identifying Dual Use Research of Concern**
- II. Tools for the Responsible Communication of Research with Dual Use Potential**
- III. Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences**

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INTRODUCTION

The National Science Advisory Board for Biosecurity (NSABB) was established by the U.S. Government (USG) to provide advice, guidance, and leadership on dual use research oversight. Toward fulfillment of its charges, the NSABB began developing three work products:

- Criteria for identifying dual use research and research results.
- Principles and tools for the responsible communication of dual use research.
- Recommendations for the development of codes of conduct in the life sciences for dual use research.

The NSABB formed Working Groups to ensure steady progress on the three work products. The Working Groups engaged in consultations with the research, ethics, and scientific publishing communities through a series of roundtable discussions and focus groups, and the draft products evolved significantly in response to this feedback.

During the NSABB meeting in July, 2006, the Board reviewed and approved the three work products for transmission to the USG, along with the recommendation that the products be presented for broad public input once they are integrated into a proposed oversight framework. This recommendation was based on a recurring finding of the NSABB Working Groups that informed feedback depends on understanding how and when the products will be used, and by whom. A new NSABB Working Group is drafting principles for, and the features and characteristics of a proposed oversight framework. The three work products contained in this document will be integrated into the proposed oversight framework developed by the NSABB working group.

Further information about NSABB can be found at www.biosecurityboard.gov. Questions can be emailed to: NSABB@od.NIH.Gov.

I.
CRITERIA FOR IDENTIFYING
DUAL USE RESEARCH OF CONCERN

CRITERIA FOR IDENTIFYING DUAL USE RESEARCH OF CONCERN

GOAL

The goal of identifying dual use research of concern is to initiate a process aimed at reducing the potential that knowledge, products, or technology derived from certain biological research could be misapplied to threaten public health or other aspects of national security, *while minimizing any deleterious impact to the progress of science and the important benefits that it yields.*

KEY CONCEPTS

The criteria for identifying dual use research of concern are intended to delineate that biological research which may provide knowledge, products, or technology that can be *directly* misapplied with sufficient *scope* so as to threaten public health or other aspects of national security.

Threats arising from the misapplication of biological research are, in essence, threats to public health, agriculture, plants, animals, the environment, and/or materiel. This would include threats to farming, raising livestock, aquaculture, terrestrial and marine wildlife, companion animals, domestic and wild plants and trees, ecological systems, other natural resources, as well as man made resources.

An assessment of research for its dual use potential will require scientific expertise and a logical, sound judgment about the probability or foreseeability that research results could be misapplied by others.

KEY CONSIDERATIONS

Any area of research could yield knowledge, products, or technologies that can be directly misapplied to pose a threat to public health, agriculture, plants, animals, the environment, and/or materiel. Therefore all life sciences research should be assessed for dual use potential. Careful consideration should be given to research that might yield knowledge, products, or technologies that can be used to:

- Enhance the harmful consequences of a biological agent or toxin by augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated
- Impart to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions, such as first or second line prevention and treatment measures against that agent or toxin
- Enable a biological agent or toxin to evade detection methodologies, thereby restricting the capacity to identify and effectively treat infection and disease

- Enhance the susceptibility of a host population to the harmful consequences of a biological agent or toxin
- Disrupt immunity or the effectiveness of an immunization, or alter the host range or tropism of a biological agent or toxin
- Generate or reconstitute a biological agent or toxin for which there are no known or widely available prophylactic or therapeutic interventions, that could evade detection, or for which there is no known immunity

Criteria and Considerations for Identifying Dual Use Research of Concern

Criteria 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, agriculture, plants, animals, the environment, or materiel.

Careful consideration should be given to knowledge, products, or technologies that:

- a) Enhance the harmful consequences¹ of a biological agent² or toxin³
- b) Disrupt immunity⁴ or the effectiveness of an immunization⁵ without clinical and/or agricultural justification
- c) Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions⁶ against that agent or toxin, or facilitate their ability to evade detection methodologies
- d) Increase the stability⁷, transmissibility⁸, or the ability to disseminate⁹ a biological agent or toxin
- e) Alter the host range¹⁰ or tropism¹¹ of a biological agent or toxin
- f) Enhance the susceptibility of a host population¹²
- g) Generate a novel pathogenic agent¹³ or toxin, or reconstitute an eradicated¹⁴ or extinct¹⁵ biological agent

Footnotes

¹**Harmful Consequences:** The ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

²**Biological Agent:** As is consistent with 18 U.S.C. § 178, any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment.

³**Toxin:** As is consistent with 18 U.S.C. § 178, any toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes (A) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or (B) any poisonous isomer or biological product, homolog, or derivative of such a substance.

⁴**Immunity:** Encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators).

⁵**Immunization:** Refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids.

⁶**Clinically and/or agriculturally useful prophylactic or therapeutic interventions:** Includes first or second line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients), in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algacides, insecticides, etc.

⁷**Stability:** The ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host.

⁸**Transmissibility:** The ease with which an agent spreads from host to host or from vector to host (e.g., via arthropod vectors).

⁹**Disseminate:** The process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol, or ingestion of a biological agent disseminated through a water supply).

¹⁰**Host range:** The number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing it to become a carrier.

¹¹**Tropism:** The specificity of a biological agent or toxin for a particular host tissue or cell.

¹²**Host population:** A collective of organisms that constitutes a specific group or occur in a specified habitat. In the context of the criteria, the use of this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

¹³**Novel Agent:** A novel agent is an agent that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype). Novel agents of concern are those for which there is no known or widely available prophylactic or therapeutic interventions, those that could evade detection, or those for which there is no known immunity.

¹⁴**Eradicated agent:** A biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero in the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, and the environment. Note: Reconstituted eradicated agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade diagnostics, or those for which there is no known immunity.

¹⁵**Extinct agent:** These agents are thought to no longer exist in nature or in the laboratory.

II.
TOOLS FOR THE RESPONSIBLE
COMMUNICATION OF RESEARCH WITH
DUAL USE POTENTIAL

TOOLS FOR THE RESPONSIBLE COMMUNICATION OF RESEARCH WITH DUAL USE POTENTIAL

INTRODUCTION TO THE COMMUNICATION TOOLS: WHAT ARE THEY AND HOW WILL THEY BE USED?

One of the major charges to the National Science Advisory Board for Biosecurity (NSABB) is to recommend strategies to help ensure that research information with dual use potential is communicated responsibly, in a manner that addresses both biosecurity concerns and the need for open sharing of research results and technologies. Towards this end, the NSABB has developed a set of tools to facilitate consistent decision making about the communication of research information with dual use potential.

These tools currently consist of:

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

The NSABB anticipates that these communication tools will become an integral component of the dual use research oversight system that is currently being developed by the Board. It is important to note that it is *not* the intent of the NSABB that every potential communication of research—be it an abstract, poster, seminar, or manuscript—be assessed using the communication tools. Rather, the tools might be utilized for the subset of life sciences research or research information determined to have dual use potential.

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

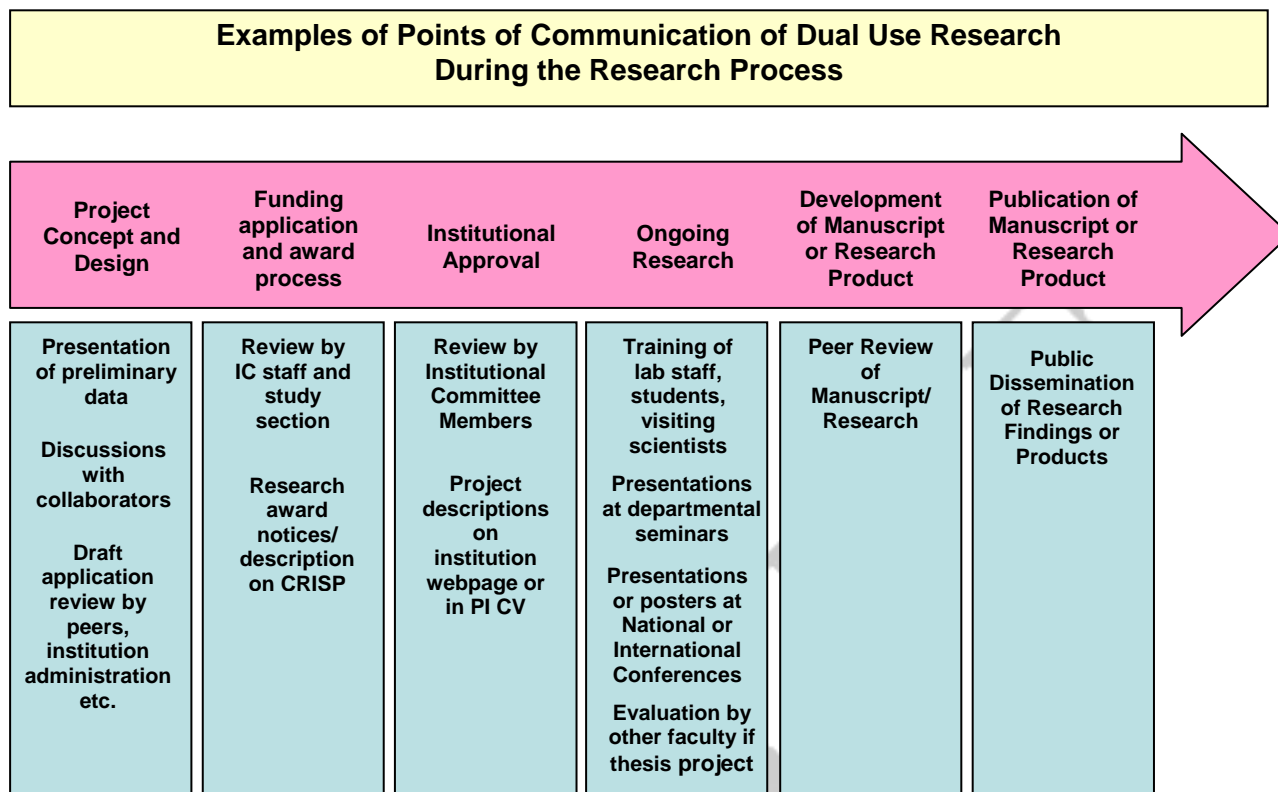
The variety of potential uses and users makes it likely that not all aspect of the tools will be applicable at all times. Users are thus encouraged to tailor and format the tools for their specific

purpose(s). For example, students in an ethics course might use the “Framework for Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential” to analyze actual manuscripts, and so would need to provide detailed answers to the questions posed. Alternatively, an institution might want a researcher developing a manuscript or poster about research with dual use potential to attest to having considered the risks and benefits of communicating that research, and so it might be helpful to format the assessment framework with checkboxes to indicate that the points had been considered and perhaps to add a signature line. Scientific journals might find the Points to Consider/Assessment Framework most useful as a hyperlink in whatever system the journal employs for instructing authors and for biosecurity review of accepted articles.

PRINCIPLES FOR THE RESPONSIBLE COMMUNICATION OF RESEARCH WITH DUAL USE POTENTIAL

1. The open and unfettered sharing of information and technologies has been a hallmark of the life sciences and has fostered a steady stream of scientific advances that underpin public health and safety, a strong and safe food supply, and a healthy environment.
2. Progress in the life sciences relies heavily upon the communication of research findings, so that they can be both validated, and built upon.
3. To ensure the continued advancement of human, animal, plant, and environmental health, life sciences research should be communicated to the fullest extent possible. Consequently, any restriction of scientific communication should be the rare exception rather than the rule.
4. There is a need for reasonable balance in decisions about the communication of research with dual use potential. It is important to recognize the potential for deliberate and malevolent misuse of dual use research findings and to consider whether the disclosure of certain information might reasonably pose a threat to national security (i.e., public health, agriculture, plants, animals, the environment, or materiel). If the communication of dual use research does pose potential security risks, the logical next step is a risk-benefit analysis of communicating the information.
5. After weighing the risks and benefits of communicating dual use research, the decision regarding communication is not necessarily a binary (yes/no) one. Rather, a range of options for communication should be identified and considered. The options available will depend on the research setting (e.g., academia, federal, private). They could range from full and immediate communication, to delayed and/or modified communication, to restricted/no communication, and could be recommended singly or in appropriate combinations on a case-by-case basis, depending on the nature of the dual use finding and the potential risks associated with its communication.
6. Paradigms for the responsible communication of research with dual use potential should also take into consideration that the communication of dual use research can occur at multiple points throughout the research process, i.e. at points well upstream of the publication stage

(see figure below). Thus it is important to apply principles and practices of responsible communication at these early stages as well.



7. It is important to consider not only what is communicated, but also the way in which it is communicated. Investigators and sponsors of research with dual use potential should recognize that the communication of certain dual use information is likely to raise biosecurity concerns, not only within the scientific community, but also within the general public. Consideration should be given to the potential for public concern and misunderstanding and for sensationalism. Thought should be given to the need for the inclusion of contextual and explanatory information that might minimize such concerns and misunderstanding.
8. Public trust is essential to the vitality of the life sciences research enterprise. It has always been important for life scientists to participate in activities that enhance public understanding of their research. However, because of the potential for public misunderstanding of, and concerns about dual use research, it is especially important that life scientists conducting research with dual use potential engage in outreach on a regular basis to raise awareness of the importance of the research and to reassure the public that the research is being conducted and communicated responsibly.

POINTS TO CONSIDER: A FRAMEWORK FOR ASSESSING THE RISKS AND BENEFITS OF COMMUNICATING RESEARCH WITH DUAL USE POTENTIAL

1) General Overview of the Research Information with Dual Use Potential

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

2) Risk Analysis

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

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

3) Benefit Analysis

- a) Are there potential benefits to public health and safety from application or utilization of this information?
- b) Are there potential benefits of the information for agriculture, plants, animals, the environment, or materiel?
 - i) e.g., what potential solution does it offer to an identified problem or vulnerability?
- c) Will this information be useful to the scientific community? If so, how?

- d) If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might this information be used to benefit science, public health and safety, agriculture, plants, animals, the environment, or materiel?

4) Risk vs. Benefit Assessment

- a) Based on the risks and benefits identified, and considering the time frame in which these might be realized:
 - i) Do the benefits of communicating the information outweigh the risks?
 - ii) Do the risks outweigh the benefits?

5) Formulation of Recommendation Regarding Communication

Decisions about how to responsibly communicate research with dual use potential should address content, timing, and possibly extent of distribution¹ of the information.

a) Content

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

b) Timing

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

c) Distribution²

- i) No limit on distribution

^{1,2} The relevance and/or feasibility of considering limits on the distribution of dual use research will depend on the specific situation (e.g., timing of the communication in terms of the maturity of the research, the nature of the information and the risks associated with its communication, and the relevant audience for the information). For example, while limiting distribution is not a consideration for most scientific journals, it might be a reasonable consideration early on in a research project that yielded information of special significance to public health or homeland security experts and for which countermeasures might need to be initiated prior to broader communication of the information.

- ii) Limit access to selected individuals on a “need to know” basis. It will be necessary to identify categories of individuals who should have access and under what circumstances.
- iii) Recommend that the product not be published or otherwise made accessible to the public.

CONSIDERATIONS IN THE DEVELOPMENT OF A COMMUNICATION PLAN

Because of the potential for misuse of dual use research results, one can and should anticipate sensitivities on the part of the public (including members of the scientific community) about the sharing of such information. In addition, the public is increasingly sensitized to issues pertaining to research involving dangerous pathogens and the risk of accidental or intentional release of such agents. A lack of public understanding and appreciation for the reason for conducting and communicating dual use research, sensationalism of dual use research findings, and concerns about public safety and national security all serve to undermine public trust in the life sciences research enterprise. It is therefore the responsibility of the scientific community to ensure that dual use research results and technologies are communicated responsibly.

Depending upon the nature of the dual use research result/technology being communicated, and the potential impact of communicating the information, it may be prudent to consider steps to maximize public understanding of, and appreciation for, the research effort and the decision to communicate the information. This can be achieved through the development of a plan for the responsible communication of dual use research information. For example, it may be important to speak to the following issues, both in the content of the work product and in the activities associated with dissemination of the work product:

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

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

- **Editorials**
 - Scientific journal editorial - in the journal that publishes the dual use research manuscript. This type of editorial could be written by an individual who is not

directly involved with the work, perhaps is not even in the same field, but who is nevertheless held in high regard by the scientific community. The editorial might speak to the significance of the research findings for public health and safety, agriculture, the environment, or materiel; how the new information or technology will be useful to the scientific community; the biosafety measures in place as the research was carried out; and might acknowledge the dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to publish.

- Popular press editorial issued at the same time as the manuscript. This type of editorial would be geared toward the general public and should be written in non-technical language to the greatest extent possible. Nevertheless, it should address the same issues as described above, i.e., the nature and importance of the scientific discovery/technology; the significance of the research findings for public health and safety, agriculture, the environment, or materiel; the safety precautions in place as the work was conducted; the dual use aspects of the information; and the consideration that was given to the biosecurity concerns in the decision to publish. Ideally the author would be an individual who is known to and trusted by the general public.
- **Press Release** – This tool is commonly used by government and private sector institutions to highlight significant scientific advances for the media. It also provides an opportunity to provide contextual information (regarding issues that may be of concern to the public) and scientific perspectives on the findings (via comments from other scientists). If the project involves investigators from multiple institutions, it will be important to coordinate the preparation and release of the announcement. In addition to including a description of the findings and their scientific significance, a press release might also address the significance of the research findings for public health and safety, agriculture, the environment, or materiel; the biosafety measures in place as the work was conducted; the dual use aspects of the information; and the consideration that was given to the biosecurity concerns in the decision to publish.
- **Press Conference** – This tool is usually reserved for highlighting the most significant and/or sensitive advances, and provides an opportunity for direct interaction with the media. The investigator(s) and institutional representatives are usually present, but also consider having other experts on hand who could address questions about the potential for misuse of the dual use information, biosafety, etc. A press release is usually provided to the media at a press conference (see above), but additional relevant materials can also be made available, such as backgrounders and fact sheets.
- **Questions and Answers (Qs & As)** - Developed for responding to queries from the press, public, or others. Qs & As might address:
 - The nature of the dual use advance
 - Reasons for conducting the work
 - If the public is/was at risk from the work

- The potential for misuse of the research findings
- Safety procedures utilized during experimentation
- The review process prior to publication
- **Talking Points** - Developed and employed for responding to questions from the press, the general public, or others. Talking points might include:
 - An explanation of the biosafety and biocontainment conditions that were employed to safeguard laboratory workers and the public (if applicable).
 - Acknowledgment that, along with significant benefits (to public health and safety, agriculture, the environment, or materiel) of sharing the information widely, there are also some potential risks to publicly disseminating the information.
 - Assurances that the national security implications of making such information publicly available were thoroughly considered.
 - A description of how the information contained within the research findings is critical for developing public health countermeasures.

DRAFT

III.
Considerations in Developing a
Code of Conduct for
Dual Use Research in the Life Sciences

CONSIDERATIONS IN DEVELOPING A CODE OF CONDUCT FOR DUAL USE RESEARCH IN THE LIFE SCIENCES

INTRODUCTION

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

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

The U.S. National Science Advisory Board for Biosecurity (NSABB) has given extensive consideration to the characteristics that define dual use research of concern. Based on the Board’s deliberations and recommendations, the U.S. government intends to issue a framework of criteria, policies, and guidance to help the scientific community identify and manage the risks associated with this type of research.² 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.

² Several documents are being proposed by the U.S. government to address the need to identify dual use research of concern and to assess and manage its associated risks. Additional documents will be released for public comment when they are ready. When finalized, these and the one you are now reviewing will be complementary and reference one another, comprising a coherent and consistent framework.

Using this Document

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

- describing the general utility and potential applications of such a code,
- articulating a core set of responsibilities related to dual use research that can serve as a foundation for a code, and
- 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 science societies and associations. Life science 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 by-laws 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, post-doctoral 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 decision-making roles in the process of communicating scientific information have an ethical responsibility to consider whether the information being considered for publication could be used to endanger public health, agriculture, plants, animals, the environment, or materiel. Depending on their analysis of the risks and benefits of communications regarding information or technology that meet criteria for dual use research of concern, they may choose to proceed in a way that mitigates or manages the risks associated with communication – for example, by adding contextual information not found in the original article, or delaying communication until a time at which the risks would be reduced.

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

The following page identifies 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.

DRAFT

LIFE SCIENTISTS: CORE RESPONSIBILITIES REGARDING DUAL USE RESEARCH OF CONCERN

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

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

Toward that end, scientists should:

- Assess their own research efforts for dual use potential and report as appropriate;
- Seek to stay informed of literature, guidance, and requirements related to dual use research;
- Train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly;
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern; 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 the life sciences research may also benefit from a more specific review of their responsibilities in regard to dual use research of concern.

Proposing Research

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

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

Managing Research

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

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

Reviewing Research

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

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

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

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 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:

1. Observing safe practices³ and ethical behaviors in the laboratory 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 dialogue 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.

³ Safe laboratory practices are embodied in such documents as the DHHS *Biosafety in Microbiological and Biomedical Laboratories*, the NIH *Guidelines for Research Involving Recombinant DNA Molecules*, and applicable occupational and safety regulations and standards.

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 these concerns are raised with those charged with responsibility for research oversight.
4. Considering appropriate measures to reduce or eliminate risks to public health, agriculture, plants, animals, the environment, or materiel resulting from the research project.
5. Maintaining a current awareness of national and international standards and policies regarding dual use research of concern.

Communicating the Results of Dual Use Research of Concern

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

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

Scientific Education and Mentorship

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

1. Raising developing scientists' awareness of what constitutes dual use research of concern and why it matters.
2. Informing developing scientists of their ethical, legal, and institutional responsibilities when engaged in dual use research of concern, as well as applicable Federal and state guidelines.
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.