

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

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**National Science Advisory Board for
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Working Group on Codes of Conduct

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

1. 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.¹ 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 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.

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 (Section 2 of this document) and the additional specific responsibilities (Section 3) 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 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.

2. 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.

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 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;
- Seek to stay informed of literature, guidance, and requirements related to dual use research;
- Train others to identify dual use research of concern and manage it appropriately;
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern; and
- Identify and report dual use research of concern through appropriate channels.

3. 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 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 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 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 practices² and ethical behaviors in the laboratory and ensuring that subordinate personnel do so as well.
2. Using appropriate physical 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.

² Safe laboratory practices are embodied in such documents as the *CDC Biosafety in Microbiological and Biomedical Laboratories*, the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, and applicable occupational and safety regulations and standards.

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.
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 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.

Closing Note

The Department of Health and Human Services is interested in how the research community makes use of this document. It is hoped that it will be a *living* document that evolves with new understanding about the scope and nature of potential dual use research. Individual scientists, organizations, institutions, and the general public are thus encouraged to contact the staff of the NSABB to relay comments about this document. Staff members also welcome copies of codes or other ethical guidance that have been influenced by this document. Comments and related documents may be sent to:

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