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NSABB Meeting July 13, 2006



Life Sciences Research

Criteria

Dual Use Research of Concern

Risk Assessment

Review Process

Risk Management

Responsible Communication of Dual Use Research

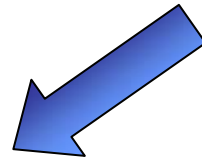
Guidelines for Oversight of Dual Use Research

Training and Education

Code of Conduct for Life Science Researchers

Vote on Components

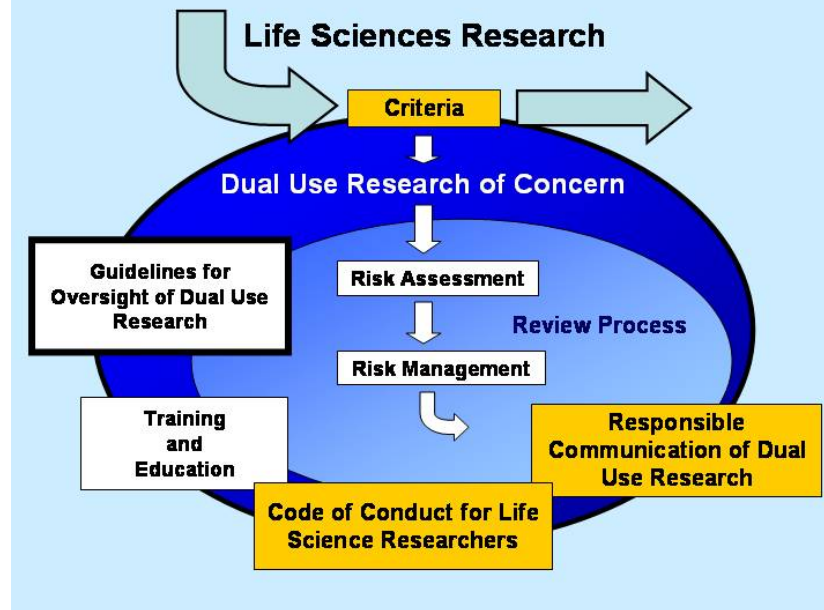
Criteria for Dual Use Research	<input checked="" type="checkbox"/>
Code of Conduct	<input checked="" type="checkbox"/>
Communication Tools	<input checked="" type="checkbox"/>



Send Framework to USG



Further Develop Oversight Framework



USG Seeks Broad Input from Scientific Community and Public



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Draft Criteria for Identifying Dual Use Research of Concern



**Dennis Kasper
Chair
Dual Use Criteria Working Group**



Dual Use Criteria Working Group Members

NSABB Voting Members

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The Issues

- **Dual use biological research is legitimate research that could be misused to threaten public health or other aspects of national security**
- **The dual use potential of certain biological research requires consideration of new biosecurity measures**
- **The challenge is to reduce the likelihood that biological research knowledge, products or technologies could be misapplied while minimizing the impact to scientific inquiry**

Overarching Principles

- Dual use concerns pertain to misapplication of information or technologies resulting from the research, *not* the conduct of the research itself
- A designation of research as “dual use research of concern” simply means that it *may* warrant special consideration regarding conduct and oversight
- It does *not* mean, a priori, that the work should not be performed or that the results should not be published

Draft Criteria for 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**
- **Environment**
- **Materiel**

Research Areas of Concern

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

- a) Enhance the harmful consequences of a biological agent or toxin**
- b) Disrupt immunity or the effectiveness of an immunization without a clinical and/or agricultural justification**
- c) 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**
- d) Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin**
- e) Alter the host range or tropism of a biological agent or toxin**
- f) Enhance the susceptibility of a host population**
- g) Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent**

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Working Group on Communication of Dual Use Research Results, Methods, and Technologies





Working Group Roster

Voting Members:

- P. Keim (Chair)
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- L. Enquist
- D. Franz
- J. Gordon
- S. Ehrlich
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- M. Schmolesky (State)
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NSABB Charge

- **The NSABB Charter states that the NSABB is to “advise on national policies governing publication, public communication, and dissemination of dual use research methodologies and results.”**



Working Group Charge

- **Develop guidance and tools to:**
 - **Facilitate consistent and well-considered decisions about communication of information with biosecurity implications**
 - **Demonstrate to the public that scientists recognize, and are being responsive to, concerns about the security implications of their work**



Communication Tools

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



Communication Tools

- **Possible uses:**

- **Review**

- Research proposals
 - Manuscripts
 - Presentations (oral, abstract, posters)
 - Internet postings

- **Education tool**

- Raise awareness of DUR issues within the scientific community
 - Ethics training



Communication Tools

- **Possible users:**

- **Investigators and research supervisors**
- **Students, postdocs and others involved in the research**
- **Institutional biosecurity review entity**
- **Proposal reviewers**
- **Funding agencies/institutions**
- **Government policy makers**
- **Journal editors, reviewers and publishers**



Principles for Responsible Communication

- **Principles that underpin the responsible communication of dual use research findings**
 - ❑ **Communication is vital for scientific progress**
 - ❑ **Communicate research to the fullest extent possible**
 - ❑ **Need for balance**
 - ❑ **Need to assess risks and benefits of communicating information**
 - ❑ **Consider a range of communication options**
 - ❑ **Communication occurs throughout the research process**
 - ❑ **Need to consider what is communicated, and the way in which it is communicated**



Points to Consider (Assessment Framework)

- **Formulation of Recommendation Regarding Communication**
 - **Decisions about how to responsibly communicate research with dual use potential should address **content**, **timing** and **extent of distribution** of the information**



Points to Consider (Assessment Framework)

Content	Communicate as is
	Addition of contextual Information
	Modify or remove substantive information
Timing	Communicate immediately
	Delay communication
Distribution	No limit on distribution
	Limit distribution on a 'need to know basis'
	Don't communicate

■ Added footnote:

- The relevance and/or feasibility of considering limits on the distribution of dual use research will depend on the specific situation.

E.g., 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 national security.



Communication Plan

- **Critical part of decision to communicate**
 - **Not only what is said, but how it is said**
 - **Promotes public understanding and trust**



Oversight Framework Considerations

- **When and how should dual use research communications be reviewed?**
 - **Identify key points along the research continuum**
 - **Determine necessary expertise for reviewers**
 - **Consider oversight strategies for research not initially identified as dual use**

The logo features a blue background with a grid pattern. On the left, there is a stylized image of a microscope lens or a similar scientific instrument. The text "NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY" is written in white, serif, all-caps font across the top right.

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Codes of Conduct Working Group

**Progress Report
July 13, 2006**



Working Group Participants

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- Claire Fraser
- John Lumpkin
- Mark Nance
- Diane Wara

Ex Officios

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- Jamie Fly (DoD)
- Robert Mikulak (DoS)
- Jan Nicholson (CDC)
- Stuart Nightingale (DHHS)
- Gerald Parker (DHHS Alt.)
- Kerry Patterson (DoD)
- Caird Rexroad (USDA)
- Scott Steele (DoJ)
- Helen Quill (NIH)

Working Group Charge

“To 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.”

- **To identify issues pertinent to the conduct of DUR that a code should address.**
- **To develop standards and principles that can be included in a formal educational and training program.**

Fundamental Operating Principles

- **A code of conduct can make good people better, but probably has negligible impact on intentionally malicious behavior.**
- **A code intended to address dual use research is contingent on a clear understanding of the criteria to identify this type of research.**
- **Participation by the research community during the development of a code helps to define appropriate standards and language and should encourage broader acceptance.**

Working Group Recommendations

A template document for the development of a code of conduct should be made available to the research community that includes:

- General considerations for the “Development of a Code of Conduct for Dual Use Research in the Life Sciences”;**
- Articulation of the “Core Responsibilities of Life Scientists in Regard to Dual Use Research of Concern”; and**
- Specific “Responsibilities in the Research Process”.**

Working Group Recommendations

Professional societies or scientific institutions should be encouraged to:

- Adopt the content of the template, adapting it as appropriate to the research context and other governing documents; and**
- Use the document for educational and training purposes.**

Target Audiences for the Document

- **Life Sciences Societies and Associations**
- **Research Institutions**
- **Industry**
- **Research Leadership**
- **Individual Life Scientists**
- **Technicians, Students, and Others Involved in the Research Process**
- **Funding Agencies/Institutions**
- **Journal Editors, Reviewers, and Publishers**

Core Responsibilities of Life Scientists in Regard to 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.

Responsibilities Associated with the Research Process

Proposing Research

When designing and proposing research:

- Try to anticipate whether the end products of the research could be deliberately misused for harm;
- Design research that promotes scientific advances, while minimizing elements of dual use research that have potential for misuse;
- Consider the benefits of those dual use elements that cannot be avoided in light of the potential harm that might result from their misuse; and
- Modify the research design to manage and mitigate potential misuse.

Responsibilities Associated with the Research Process

Managing Research

When managing research programs in the public or private sectors:

- Promote awareness of dual use research issues and the accompanying responsibilities;
- Develop and maintain systems, policies, and training to ensure appropriate identification and management of dual use research; and
- Implement all guidelines and regulations specific to dual use research of concern.

Responsibilities Associated with the Research Process

Establishing and Managing Review Systems

When overseeing the research review process (e.g., funding agencies, institutional review committees, institutional leadership, etc.) :

- Ensure that all review systems are appropriately prepared to identify and manage dual use research concerns;
- Ensure researchers and reviewers are knowledgeable and compliant with all ethical, institutional, and legal requirements related to dual use research of concern; and
- Reconsider review systems periodically to ensure they reflect current knowledge and guidelines related to dual use research of concern.

Responsibilities Associated with the Research Process

Reviewing Research

When reviewing research:

- Stay informed about dual use research of concern and all applicable ethical, legal, and institutional requirements;
- Consistently assess proposals against the criteria for dual use research of concern during the review process; and
- Advise appropriate parties when the research under review meets the criteria for dual use research of concern.

Responsibilities Associated with the Research Process

Conducting Research

When conducting research:

- Observe safe practices and ethical behaviors in the laboratory and ensure support personnel do the same;
- Use appropriate physical security measures and periodically reassess their adequacy;
- Observe applicable guidelines for the responsible conduct of dual use research of concern;
- Be attentive to the dual use potential of knowledge, products, and technology associated with all research activities; and
- Alert responsible institutional officials when dual use research of concern is identified and when decisions about its management are being made.

Responsibilities Associated with the Research Process

Collaborating on Research

When collaborating on research activities:

- Discuss whether research knowledge, products, or technologies meet criteria for dual use research of concern and understand associated ethical responsibilities;
- Agree on specific individual responsibilities for the oversight of research with dual use potential;
- Respect expressions of concern that research efforts may have dual use potential and raise these concerns with appropriate oversight officials;
- Use appropriate measures to minimize risks to public health, agriculture, plants, animals, the environment, or materiel from research efforts; and
- Maintain a current awareness of national and international policies for dual use research of concern.

Responsibilities Associated with the Research Process

Communicating Research

When communicating about knowledge, products, or technologies associated with dual use research of concern:

- Be aware of ethical and legal considerations in communicating about dual use research of concern;
- Weigh potential risks and benefits to public health, agriculture, plants, animals, the environment, or materiel that could result through research-related communications; and
- Consider options that may reduce or eliminate potential risks associated with research-related communications, while clearly identifying the benefits.

Responsibilities Associated with the Research Process

Scientific Education and Membership

When providing oversight and training to new members of the life sciences community:

- Raise awareness about the meaning and importance of dual use research of concern;
- Inform developing scientists of ethical, legal, and institutional responsibilities associated with dual use research; and
- Encourage collegial discussion of dual use research issues, especially whether or not specific activities meet the criteria.

How the Code Recommendations Interface with Other NSABB Work Products

- **Incorporates the criteria for “Dual Use Research of Concern”.**
- **Incorporates fundamental principles for the responsible communication of dual use research.**
- **Attempts to use language appropriate for international audiences.**
- **References functions associated with the newly formed working group for “Oversight Framework” and “Outreach and Education” strategies.**