

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Criteria for Identifying Dual Use Research and Results Working Group

Progress Report
November 21, 2005



Key NSABB Task

Develop criteria for identifying dual use research and research results

Working Group established to draft criteria for NSABB's consideration

Criteria Working Group Membership

Voting Members

- D. Kasper (Chair)
- A. Casadevall
- B. Erlick
- J. Gordon
- M. Imperiale
- M. Nance
- M. Osterholm
- D. Relman
- J. Roth
- A. Sorensen
- W. Studeman
- A. Vidaver

Federal Agency Reps.

- M. Henkart (NSF)
- D. Dixon (NIH)
- E. Cameron (DOS)
- P. Jutro (EPA)
- E. George (DHS)
- R. Walters (ITIC)
- S. Steele (DOJ)
- B. Cuccherini (DVA)
- S. Nightingale (DHHS)

What is “Dual Use” Research?

Per NSABB charter:

Dual use research is biological research

- **With legitimate scientific purpose**
 - **That may be misused to pose a biologic threat to public health and/or national security**
- * Any potential oversight system would require more specific guidance for identifying research with dual use potential**

Approach

- **Explore a wide range of possibilities for criteria that could be used to identify research with dual use potential**
- **Consider:**
 - **Dynamic nature and breadth of life sciences research today**
 - **That it may be appropriate to subsequently exempt certain dual use research from further review**
 - **Relevant extant rules and oversight systems for life sciences research**

Principles for Developing Criteria

- A designation of research as “dual use” simply means that it may warrant special consideration regarding conduct, oversight, and communication
- It does not mean, *a priori*, that the research should not be conducted or that the findings should not be communicated
- Although there are both risks and benefits associated with dual use research, for the purpose of developing identifying criteria, risk is the paramount consideration

Principles for Developing Criteria

- **The state of science and technology, as well as our perception of risk, will evolve over time. Consequently, the criteria for identifying dual use research will need to be re-assessed periodically, and possibly modified, to ensure their relevance and applicability**
- **Broad public input is essential to the development of useful, comprehensive criteria, both at this initial development stage, as well as during future re-assessments**

Working Group Discussions

- **Initially considered two components of research that may serve as a starting point for the further development of criteria**
 - The intrinsic properties of an agent used in research
 - The experimental procedures and manipulations
- **Currently focused on four broad categories of research that we feel capture the range of areas where dual use potential may exist**
 - These need to be further discussed and appropriately circumscribed
 - It is important to recognize that not all research in these categories should be considered dual use

Categories for Further Consideration

1. Research with specific agents* with high potential for posing a biological threat to humans, animals, or plants

- **Select agents** (42 CFR Part 73, 7CFR Part 331, 9 CFR Part 121)

- **Other potentially harmful agents**

- **Could consider properties such as those used to identify select agents including:**

Degree of pathogenicity

Environmental stability

Communicability

Ability to genetically manipulate

Available treatment

Ease of dissemination

*** “Agents” needs to be further defined, but could include microbes, biological agents, infectious agents, microorganisms, toxins, and other compounds of biological origin**

Categories for Further Consideration

- 2. Research that could increase an agent's potential for harm**
 - 3. Research that could enhance the susceptibility of the host to harm**
- * For both, consider the seven “experiments of concern” of the NRC/Fink Report as a starting point, but modifications may be necessary**

NRC/Fink Report: “Experiments of Concern”

- **Demonstrate how to render a vaccine ineffective**
- **Confer resistance to therapeutically useful antibiotics or antiviral agents**
- **Enhance the virulence of a pathogen or render a nonpathogen virulent**
- **Increase transmissibility of a pathogen**
- **Alter the host range of a pathogen**
- **Enable the evasion of diagnostic or detection modalities**
- **Enable the weaponization of a biological agent or toxin**

Categories for Further Consideration

4. **Other research, findings, or technologies that can be misused to pose a biological threat to humans, animals, and plants**
 - **“Enabling technologies,” such as:**
 - **Mechanisms for weaponization**
 - **“Facilitating information” that could:**
 - **Identify vulnerabilities in public health and safety**
 - **e.g., mathematical models of threat scenarios**
 - **Enable the synthesis of a dangerous pathogen**

Summary:

Possible Categories of Dual Use Research

Research:

With agents that possess a high biological threat potential

That could increase the potential of an agent to cause harm

That could enhance susceptibility of host to harm

In enabling technologies and facilitating information

that may be misused to pose a biologic threat to public health and/or national security

Apply
Criteria
Developed
from these
Categories

Dual Use
Research

For further discussion

- **Utility of “risk assessment” as a tool for identifying dual use research**
 - Risk assessment methodology might be a helpful tool in this regard
 - i.e. similar to the select agent determination
 - More evaluation is needed before recommending the appropriateness and utilization of any risk assessment methodology

Dual Use Criteria WG

Next Steps

- 1. Evaluate the applicability of the criteria used in identifying Select Agents**
- 2. Further assess the NRC “experiments of concern”. Modify as necessary; consider need for additions**
- 3. Further define the “enabling technologies and facilitating information” category and their applicability to dual use research**

Dual Use Criteria WG

Next Steps

4. **Consider additional criteria or modifications based upon factors such as:**
 - **Economic and public health impact of misuse**
 - **Relevance of research activities outside of the life sciences**
5. **Consider the utility of application of risk assessment, and the most appropriate stage(s) of research evaluation for its use**
6. **Consider criteria/parameters for dual use research that does not warrant or is exempt from further review (this Work Group?)**

Questions to the Board

- **Please comment on the proposed categories of research. For example:**
 - *Are they sufficient for future considerations in developing dual use criteria?*
 - *Are others needed?*
 - *Do any need to be modified?*
 - *How should they be further defined?*
- **Should we consider the utilization of risk assessment in the development of dual use criteria?**