DUAL USE RESEARCH AND THE NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

FREQUENTLY ASKED QUESTIONS

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Dual Use Research and Dual Use Research of Concern

1. What is "dual use research" and "dual use research of concern"?

Life sciences research is vital to improving public health, agriculture, and the environment, and to strengthening our national security and economy. Yet the very research designed to find ways to better the health, welfare and safety of mankind can also yield information or technologies that could potentially be misused for harmful purposes. For instance, information from certain life sciences research can be misapplied to create dangerous pathogens for employment as weapons, bypass or diminish the effectiveness of medical countermeasures, or threaten in other ways the health and safety of humans, animals, plants, and the environment. Research yielding new technologies or information with the potential for both benevolent and malevolent applications is referred to as "dual use research."

Some degree of dual use potential may be inherent in a significant portion of life sciences research. However, the small subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or national security is referred to as "dual use research of concern."

The National Science Advisory Board for Biosecurity (NSABB) has defined dual use research of concern as research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel.

Administration/Functions of the NSABB

2. What is the NSABB? What is the role of the NSABB?

The NSABB is a Federal advisory committee chartered to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research to all Federal departments and agencies with an interest in life sciences research. The NSABB advises on and recommends specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration national security concerns and the needs of the research community.

3. How long will the NSABB exist?

As with all Federal advisory committees, the NSABB is chartered for two-year intervals and will continue its work pending biennial renewals of the charter by the Secretary of the Department of Health and Human Services (HHS).

4. What are the current tasks of the NSABB?

The NSABB is currently tasked with:

- Recommending strategies and guidance for enhancing the culture of responsibility among individuals with access to biological select agents and toxins;
- Providing recommendations on outreach, education and training in dual use research issues for scientists, laboratory workers, students and trainees in relevant disciplines;
- Advising on polices governing publication, public communication, and dissemination of dual use research methodologies and results;
- Recommending strategies for fostering international engagement on dual use life science research issues;
- Advising on strategies for fostering the development, utilization and promotion of codes of conduct to interdisciplinary life scientists and relevant professional groups;
- Advising on policies regarding the conduct, communication, and oversight of dual use research and research results;

- Advising on the Federal Select Agent Program, as requested; and
- Addressing any other issues as directed by the Secretary of HHS.

5. Who serves on the NSABB? How long do members serve?

The NSABB has 25 voting members who serve for overlapping terms of up to four years. The NSABB members provide expertise in areas such as molecular biology, microbiology, clinical infectious diseases, laboratory biosafety and biosecurity, public health/epidemiology, health physics, pharmaceutical production, veterinary medicine, plant health, food production, bioethics, academia, national security, biodefense, intelligence, national security, law and law enforcement, medical and scientific journal and publishing perspective, industry perspective, public perspective institutional biosafety committees, recombinant DNA, and export control. In addition there are 18 non-voting *ex officio* members representing Federal agencies that have an interest in life sciences research.

6. How are NSABB members selected?

The NSABB members are appointed by the Secretary of HHS in consultation with other Federal departments and agencies with an interest in life sciences research. The public can submit nominations for future NSABB membership through the *ex officio* agencies or directly to the Office of Biotechnology Activities (OBA) at nsabb@od.nih.gov.

7. What Federal agencies are represented on the NSABB?

The Board includes nonvoting *ex officio* members from relevant Federal departments and agencies that have an interest in life sciences research. These include:

- Executive Office of the President
- Department of Health and Human Services
- Department of Energy
- Department of Homeland Security
- Department of Veterans Affairs
- Department of Defense
- Department of the Interior
- Environmental Protection Agency
- Department of Agriculture
- National Science Foundation
- Department of Justice
- Department of State
- Department of Commerce
- National Aeronautics and Space Administration
- Intelligence Community
- Others as appropriate

8. How often does the NSABB meet? Are the meetings open to the public?

The NSABB meets at least once or twice per year, and may also be convened on an as-needed basis. All meetings of the NSABB are announced in the Federal Register and on the NSABB web site at www.biosecurityboard.gov. NSABB meetings are open to the public, except as determined otherwise by the Secretary of HHS, in accordance with the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act.

9. Does the NSABB review or approve all dual use research?

No. The NSABB does not approve the conduct of specific experiments. The NSABB advises on the development of national policies governing oversight of dual use life sciences research. At the request of the Secretary of HHS, the NSABB may review and provide guidance on experiments that exemplify a notable or novel category of dual use research or on an especially sensitive communication that may be considered dual use research of concern.

10. How has the NSABB contributed to advising the United States Government on biosecurity concerns related to dual use research?

The NSABB has submitted a series of reports advising the United States Government (USG) on dual use research:

- Criteria for identifying dual use research and guidance for the responsible oversight, conduct and communication of dual use research (i.e. Oversight Framework)
- Biosecurity concerns related to the synthesis of select agents
- A strategic plan for outreach and education on dual use research issues
- Strategies for enhancing personnel reliability among individuals with access to select agents
- Biosecurity concerns related to synthetic biology

In addition the NSABB has hosted a series of international meetings on dual use research, with the aim of raising awareness of the dual use research issues, and to facilitate international engagement and information sharing on strategies for managing risk(s) posed by dual use life science research.

11. Who manages and staffs the NSABB?

The HHS Secretary designated the National Institutes of Health (NIH) to provide management and support services for the NSABB. The NSABB staff is located in the Office of Biotechnology Activities (OBA) within the Office of Science Policy in the Office of the Director, NIH.

12. How can I contact the NSABB staff?

You may contact NSABB staff through the OBA at 301-496-9838 or by email at nsabb@od.nih.gov. General information about NSABB, such as its membership and upcoming meeting dates, can be accessed on the NSABB Web site at www.biosecurityboard.gov.

Dual Use Research and Biosecurity Policy

13. What is the Administration's policy toward biosecurity and dual use life sciences research and relation to the NSABB

The Administration recognizes the immensely beneficial nature of life sciences research, and its critical role in enabling the development of new therapeutics, vaccines, and technologies that promote public health and well-being. A robust life sciences research enterprise is also important for agricultural and energy production, environmental protection, and a thriving economy.

At the same time, the Administration is mindful that scientific information or technologies can be misused to harm people, animals, or plants, or otherwise threaten national security. To address this challenge, President Obama's *National Strategy for Countering Biological Threats* emphasizes the need to (1) improve global access to the life sciences to combat infectious disease regardless of its cause; (2) establish and reinforce norms against the misuse of the life sciences; and (3) institute a suite of coordinated activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

With regard to dual use life sciences research, the *Strategy* highlights the importance of efforts that reduce the potential for the exploitation of legitimate life sciences research by

(1) managing the risk of misuse of dual use information of concern, (2) optimizing security of known virulent high-risk pathogens and toxins, and (3) addressing potential risks presented by emerging technologies. The *Strategy* also states that "life scientists are best positioned to develop, document, and reinforce norms regarding the beneficial intent of their contribution to the global community as well as those activities that are fundamentally intolerable." To this end, the NSABB views efforts to reinforce norms of safe and responsible conduct by supporting the culture of responsibility in the life sciences as essential and fundamental elements of a balanced approach to risk management in the life sciences.

14. What is the relationship between research involving Select Agents and dual use research? Is there a relationship between the oversight systems for these two areas of research?

Select Agent research is a very specific subset of life sciences research; it involves only those microorganisms and toxins specifically identified in DHHS and USDA regulations as having the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products (for further information see 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121).

Dual use research is a concept that relates to a broad category of life sciences research. Certain research projects that do or do not involve Select Agents may be considered dual use research depending on the nature of the particular experiments and the potential for misuse of the results and/or technology. Within this smaller category there will be some projects that may be considered dual use research of concern. This latter category is the focus of the NSABB's recommendations to the Federal government.

The oversight system for dual use research is likely to be complementary to that of Select Agents in that it will be based on principles and practices for reducing the likelihood that biological organisms, knowledge, and technologies are intentionally misused to pose a risk to public health and national security

15. Do Institutional Biosafety Committees (IBCs) have a role in the review of "dual use Research"?

At this time, the mandated roles and responsibilities of IBCs have not changed to include review of dual use research of concern. IBCs should continue to carry out the duties outlined in the *NIH Guidelines for Research Involving Recombinant DNA Molecules* and any others as determined by their institutions.

The IBC community will be notified directly of any future changes in Federal policies, guideline and/or requirements. Also, any relevant developments will be posted on the IBC pages of the Web site of the NIH Office of Biotechnology Activities: http://oba.od.nih.gov. This will also include opportunities for public input on proposed Federal policies, guidelines, and/or requirements.

16. What happens after NSABB reports are submitted to the US Government?

When the USG receives recommendations from the NSABB, it convenes relevant Federal agencies to analyze the findings and recommendations and to identify options for considering the recommendations. The internal deliberative process may utilize existing forums such as an Interagency Policy Committee of the National Security Council or a committee/subcommittee of the National Science and Technology Council within the Office of Science and Technology Policy. Once options for addressing the recommendations are identified, policy actions are decided upon and the relevant Federal agencies are tasked with implementing those policy actions. Examples of policy actions in response to NSABB recommendations include the development of screening guidance for providers of synthetic double-stranded DNA; clarification of language in the Select Agent Rules regarding their applicability to synthetic genomics; a legal interpretation of the applicability of 18 USC 175c to research involving orthopoxviruses; revision of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* to more explicitly address synthetic nucleic acids; and convening a panel of the National Academies to address scientific milestones needed before a predictive oversight system could be contemplated for select agents and toxins.