THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

PURPOSE

The purpose of the National Science Advisory Board for Biosecurity (NSABB) is to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. The NSABB will advise the Secretary of the Department of Health and Human Services (HHS), the Director of the National Institutes of Health (NIH), and the heads of all federal departments and agencies that conduct or support life science research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community. NIH shall manage and provide support services for the NSABB.

AUTHORITY

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The NSABB is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The NSABB will advise the Secretary of HHS, the Director of NIH, and the heads of all federal departments and agencies that conduct or support life science research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community.

The NSABB will be composed of non-government subject matter experts as well as ex officio members from federal departments and agencies listed below, and will perform the following activities:

- Develop criteria for identifying dual use research and research results.
- Propose a framework for the oversight of dual use research, to serve as a springboard for the US government to develop guidance and guidelines for dual use life sciences research.
- 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.

- Provide recommendations on the development of programs for outreach education and training in dual use research issues for all scientists and laboratory workers at federally-funded institutions.
- Advise on national policies regarding the conduct of dual use biological research. This includes strategies for addressing national security concerns while at the same time fostering continued rapid progress in public health research and food and agriculture research (e.g., new diagnostics, treatments, vaccines and other prophylactic measures, and detection methods).
- Advise on national policies governing publication, public communication, and dissemination of dual use research methodologies and results.
- Advise on national policies governing local review and approval processes for dual use biological research, including the development of guidelines for the case-by-case review and approval by Institutional Biosafety Committees (IBCs).
- Advise on criteria and processes for referral of classes of research or specific experiments by IBCs to the NSABB for guidance.
- Review and provide guidance on specific experiments insofar as they exemplify a significant or particularly complex permutation of an existing category of dual use research, or represent a novel category of dual use research that requires additional guidance from the NSABB.
- Respond to requests submitted by research institutions for the interpretation and application of the guidelines to specific research proposals in instances where a proposal has been denied by an IBC and the institution seeks additional advice.
- Recommend strategies for fostering international engagement on dual use biological research issues.
- Address any other issues as directed by the Secretary of HHS.

As necessary, subcommittees may be established by the Executive Secretary or other designated Government official to perform functions within the Board's jurisdiction. The advice/recommendations of the subcommittee must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. Subcommittee members who are not members of the parent committee may attend closed sessions of the parent committee meeting but they may not count towards the quorum of the parent committee and they cannot vote on committee actions. The Department Committee management Officer shall be notified upon establishment of each standing subcommittee and shall be given information on its name, membership, function and estimated frequency of meetings. The NSABB may call upon special consultants; assemble ad hoc working groups; and convene

conferences, workshops, and other activities necessary to the fulfillment of the NSABB's responsibilities.

The Director, OBA, will assign a full-time or permanent part-time OBA employee to serve as the Executive Secretary (also known as a Designated Federal Official or government official) of the committee.

STRUCTURE

The NSABB shall consist of not more than 25 voting members, including the Chair. Members will be appointed by the Secretary, HHS in consultation with the heads of federal departments and agencies that conduct or support life science research. The Secretary will designate the Chair. All members will hold security clearances at the level of Secret or higher. A member of the NIH Recombinant DNA Advisory Committee (RAC) will serve as a voting member of the NSABB. None of these members serve as Representatives.

Areas of expertise/perspectives to be represented on the NSABB, include *inter alia:*

- Molecular Biology/Genomics
- Microbiology (Bacteriology)
- Microbiology (Virology)
- Clinical Infectious Diseases/Diagnostics
- Laboratory Biosafety and Biosecurity
- Public Health/Epidemiology
- Health Physicist/Radiation Safety
- Pharmaceutical Production
- Veterinary Medicine
- Plant Health
- Food Production
- Bioethics
- National Security
- Military Biodefense Programs and Military Medicine
- Intelligence
- Biodefense
- Law
- Law Enforcement
- Academia
- Scientific Publishing
- Industry Perspective
- NIH Recombinant DNA Advisory Committee Experience/Perspective
- Public Perspective
- IBC perspective
- Export Controls

There may be non-voting ex officio members from each of the following departments and agencies:

- 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
- Intelligence Community
- National Aeronautics and Space Administration
- Others as appropriate

Members shall be invited to serve for overlapping terms of two to four years; terms of more than two years are contingent upon the renewal of the NSABB's Charter by appropriate action prior to its expiration. A member may serve after the expiration of the member's term until a successor has been appointed.

Management and support services for the NSABB shall be provided by the Office of Biotechnology Activities, the Office of Science Policy, and the Office of the Director, NIH. HHS and NIH staff will hold security clearances at the level of Secret or higher, as needed to provide support to the NSABB.

MEETINGS

Meetings shall be held at least twice a year, and may be convened on an as-needed basis, at the call of the HHS Executive Secretary or other designated Government official. A Government official shall also give advance approval of the agenda and be present at all of the meetings of the Committee and its subcommittees.

Meetings of the NSABB shall be open to the public except as determined otherwise by the Secretary of HHS in accordance with the subsection (c) of 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and Departmental policies.

QUORUM

A quorum for the NSABB and each of its subcommittees shall consist of a majority of the appointed members eligible to vote. The nonvoting agency representatives shall not be counted in calculating a quorum. Of the voting members, any who are disqualified from participating in an action on a particular issue, (e.g., due to a conflict of interest), shall

not be counted in calculating the quorum. All votes relating to any review of a recommendation by the NSABB shall be open to the public unless the meeting has been closed to the public in accordance with the Government in the Sunshine Act and the Federal Advisory Committee Act.

COMPENSATION

Members shall be paid at the rate of $200 per day for each meeting day, plus per diem and travel expenses as authorized by Section 5703, Title 5 U.S.C., as amended, for persons in Government service employed intermittently. Members who are officers or employees of the United States Government shall not receive compensation for service on the NSABB.

ANNUAL COST ESTIMATE

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $382,986. The estimated annual person-years of staff support is 2.9, at an estimated cost of $369,423.

REPORTS

Annual reviews and reports will be prepared, filed, and retained as required by applicable laws and Departmental policies. In the event a portion of a meeting is closed to the public, as determined by the Secretary, HHS in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report shall be prepared which shall contain, at a minimum, a list of the members and their business addresses, the NSABB's functions, dates and places of meetings, and a summary of the NSABB's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the National Science Advisory Board for Biosecurity shall expire April 7, 2010.

APPROVED

MAR 2 8 2008

Date

Secretary

CHARTER FILING DATE 4/7/08