Outreach and Education on Dual Use Research and the NSABB:

Efforts of the NIH Office of Biotechnology Activities

NSABB Session on Outreach and Education
February 28, 2008

Outreach and Education Goals

- **Short-term**
  - **Educate scientific community and public at large about the dual use issue (nature of issue, importance, relevance)**
  - **Apprise research community on the status of Federal policy making**
  - **Promote thoughtful input from stakeholders on NSABB work products and Federal policies**

Outreach and Education Goals

- **Long term**
  - **Educate about specific Federal requirements that emerge from the policy making process**
  - **Sustain awareness and a culture of responsibility**

Key Considerations

- **Target audiences**
  - **Who are the key stakeholders?**
  - **How do understanding and educational needs vary for each audience?**
  - **What kind of input is best sought from various constituencies?**
- **Message development**
  - **What are the key points to convey to different stakeholder communities?**

Key Considerations

- **Vehicles for information dissemination**
  - **What are the most effective means of communicating about the issue of dual use research?**
  - **Who are the most credible and effective communicators?**
- **Coordination of input**
  - **How should solicitation and compilation of stakeholder commentary on evolving Federal policy be accomplished?**

Aims and Modes of Outreach

- **Keep the community current on the status of the Federal policy making process, including the activities of the NSABB.**
  - **Website as the portal for information on the NSABB, its meetings, work products; email inbox for public queries; listserv for updates**

http://www.biosecurityboard.gov

Welcome

The NSABB has been established to provide advice to federal departments and agencies on ways to minimize the possibility that knowledge and technologies emanating from vitally important biological research will be misused to threaten public health or national security. The NSABB is a critical component of a set of federal initiatives to promote biosecurity in life science research.

The NSABB is charged specifically with guiding the development of:

- A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns;
- Guidelines for the identification and conduct of research that may require special attention and security surveillance;
- Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research; and
- Materials and resources to educate the research community about effective biosecurity.
- Strategies for fostering international collaboration for the effective oversight of dual use biological research.

The NSABB is chartered to have up to 25 voting members with a broad range of expertise in molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and related field. The NSABB also includes nonvoting ex officio members from 15 federal agencies and departments.

Please visit this site frequently for updates on the NSABB and its activities.

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National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892-7985

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Phone: 301-496-9838
Fax: 301-496-9839

Email

- **Public queries regarding NSABB activities can be address to:**
  - **nsabb@od.nih.gov**
- **OBA's listserv**
  - **Send a message to: listserv@list.nih.gov**
  - **In the body of the message, type: subscribe oba_news**

Aims and Modes of Outreach

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  - **Presentations to key constituency groups on the nature of the dual use issue, origins of the NSABB, activities and work products of the NSABB, etc.; standard slide sets**

Sampling of Organizations to Whom NIH OBA Staff Have Presented about NSABB and Dual Use Research

- American Association for the Advancement of Science
- American Biological Safety Association
- American Society for Microbiology
- Association of American Medical Colleges
- Center for Strategic and International Studies
- Chesapeake Area Biological Safety Association
- Council on Government Relations
- Global Health Security Initiative – Ministerial Meeting
- Howard Hughes Medical Institute
- Massachusetts Society for Medical Research
- Midwest Area Biosafety Network
- NAS Committee on New Gov't-Univ Partnership for Science and Security
- NAS Committee on Biodefense Analysis and Countermeasures
- Northeast Biological Safety Association
- Princeton University – Biosciences Oversight Workshop
- Public Responsibility in Medicine and Research
- University of Hawaii
- University of Michigan – Symposium on Academic Freedom and National Security
- University of Pittsburgh Medical Center – Center on Biosecurity
- University of Texas System
- World Health Organization

Microsoft PowerPoint - [NSABB master slides Sept 06 update.ppt]

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National Science Advisory Board on Biosecurity

(Add name of meeting here)

1

The "Dual Use" Issue

Good science can be put to bad uses

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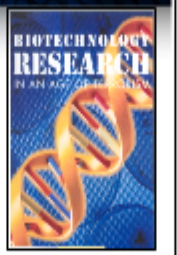
NRC Report on Dual Use Research

Report of the National Research Council of the National Academies:

"Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma" (October 2003)



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Life Sciences: Need for Biosecurity

- "Dual use" potential of certain life sciences research requires consideration of biosecurity measures
  - In this context, "biosecurity" refers to processes and procedures designed to minimize the likelihood that biological research findings will be misused for production and enhancement of biological weapons.
- Goal (and challenge) is to enhance biosecurity protections for life sciences research while ensuring that any impact to the free flow of scientific inquiry is minimized.

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National Science Advisory Board for Biosecurity (NSABB)

- Advisory to the Secretary of Health and Human Services, Director of National Institutes of Health, and heads of all federal departments and agencies that conduct or support life science research
- Will recommend specific strategies for efficient and effective oversight of federally conducted or supported dual use biological research

NSABB Charges

Recommend:

- Criteria for identifying dual use research of concern
- National guidelines for oversight of dual use research at both local and federal levels, including
  - Local review and approval processes e.g., Institutional Biosafety Committees (IBCs)
  - Criteria/processes for referral of issues to NSABB
- Strategies for oversight of new classes of experiments and technologies

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NSABB Charges

Advise on:

- Program for biosecurity education and training for all scientists and laboratory workers at federally funded institutions
- A code of conduct for scientists and laboratory workers in the life sciences research
- National guidelines on communication and dissemination of dual use research methodology and research results
- Strategies for promoting international dialogue on dual use research issue

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NSABB Structure and Operations

- 25 voting members appointed by Secretary of Health and Human Services, after consultation with other Federal Agencies
- Meetings open to public, unless otherwise determined by the Secretary, HHS
- Managed by National Institutes of Health, Department of Health and Human Services

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NSABB Expertise

- Molecular/genomics
- Microbiology
- Clin. ID/diagnostics
- Lab biosafety/security
- Philepidemiology
- Health physics
- Pharm. production
- Veterinary medicine
- Plant health
- Food production
- Bioethics
- National security
- Intelligence
- Biodefense
- IBCs
- Export controls
- Law, law enforcement
- Scientific publishing
- Perspectives from academia, industry, public, RAC

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NSABB ex officios

- Exec. Office of the President
- Department of Health and Human Services
- Department of Energy
- Department of Homeland Security
- Department of Veteran's Affairs
- Department of Defense
- Environmental Protection Agency
- United States Department of Agriculture
- Department of Interior
- National Science Foundation
- Department of Justice
- Department of State
- Department of Commerce
- National Aeronautics and Space Administration
- Intelligence community

Role of NSABB ex officios

- Represent the views and perspectives of their Agency
- Assist in planning NSABB meetings
  - Identify issues for NSABB input
  - Identify and provide background materials
- Participate in NSABB meetings
  - Serve as a resource and sounding board
  - Contribute to discussions (remembering that the purpose is to attain outside advice)
  - Provide input and guidance on NSABB work products

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NSABB's Approach to Fulfilling its Mission

- Establish Working Groups to ensure progress between public meetings:
  - Criteria for identifying dual use research
  - Code of conduct for life scientists
  - Responsible communication of dual use life sciences research
  - Strategies to foster international dialogue
  - Biosecurity concerns associated with synthetic genomics
  - Framework for oversight of dual use research

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NSABB's Approach to Fulfilling its Mission

- WGs consist of subsets of NSABB voting members and ex officios
  - Consult experts as needed
  - Convene by teleconference and in person between NSABB meetings
  - Present findings and draft products periodically to full NSABB for input
  - Consult with stakeholder groups through presentations, roundtable discussions, focus groups, panel discussions at WG meetings, etc.
- Full NSABB approves work products prior to transmission to USG

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Progress on NSABB Activities

- 3 draft work products approved at July 2006 NSABB meeting
  - Criteria for identifying dual use research
  - Tools for the responsible communication of dual use research
  - Recommendations for a code of conduct to address dual use research in the life sciences
- Will seek broad public comment on products once they are integrated into a proposed "oversight framework for dual use research" (currently under development)

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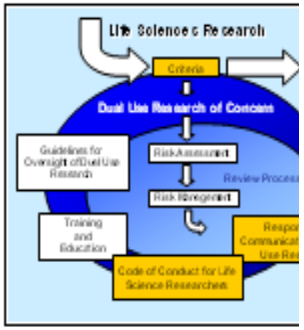

Aims and Modes of Outreach

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  - **Presentations to key constituency groups on the nature of the dual use issue, origins of the NSABB, activities and work products of the NSABB, etc.**
  - **Exhibits at major meetings – either in conjunction with recombinant DNA or alone as an NSABB exhibit**


Office of Biotechnology Activities
OBA PROGRAMS
Recombinant DNA Program
National Institutes of Health
Office of Biotechnology Activities
Promoting safe and ethical science through education, communication, and sound public policy.
OBA accomplishes its mission through analysis, deliberation, and communication of scientific, medical, ethical, legal, and social issues.
Genetic Technologies • Xenotransplantation
OBA PROGRAMS
Outreach & Education
OBA's Outreach and Education activities promote communication and understanding between OBA and its partners in the oversight of recombinant DNA research.
Training courses and workshops
Professional development and policy conferences
–Meetings slides, summaries, videos
Electronic communication tools
–OBA_NEWS listserv:
listserv@list.nih.gov
Subscribe oba_news
–Email queries:
oba@od.nih.gov
–Website:
www4.od.nih.gov/oba
FAQs on protocol review, IBC roles and responsibilities
Scientific and policy reports
Office of Biotechnology Activities
MINNEAPOLIS

OBA PROGRAMS

Biosecurity

The Biosecurity Program is a focal point for the development of policies addressing life sciences research yielding information or technologies with the potential to be misused to threaten public health or other aspects of national security.

OBA's activities to address such "dual use" research include convening and managing the **National Science Advisory Board for Biosecurity**, which provides advice to the Federal government on strategies to minimize the risks and harm that could result from the malevolent use of legitimate life science research information or technologies. Toward that end, the **NSABB** is charged with advising on the development of strategies for:

- **Federal and institutional oversight**
  Guidelines for the identification, review and surveillance of dual use research of concern
- **Education and training**
  Promoting awareness in the research community about the dual use issue and the responsible conduct of research with dual use potential
- **International collaboration**
  Fostering international dialogue on the issues related to dual use research

To learn more about NSABB activities visit www.biosecurityboard.gov

Biosecurity in the Life Sciences

U.S. National Science Advisory Board *for* Biosecurity

The NSABB is advising the U.S. Government on strategies for:

- **Federal and institutional oversight**
  Identifying, reviewing, and responsibly communicating dual use research of concern
- **Education and training**
  Promoting awareness in the research community about the dual use issue and the responsible conduct of research with dual use potential
- **International collaboration**
  Fostering international engagement on the issues related to dual use research

What is Dual Use Research?

Research with legitimate scientific purpose that has the potential to yield information that could be misused to pose a threat to public health or other aspects of national security.

NSABB reports and activities include:

- ***Proposed Framework for the Oversight of Dual Use Life Sciences Research***
- ***Addressing Biosecurity Concerns Related to the Synthesis of Select Agents***
- **International Roundtable on Dual Use Life Sciences Research**

How Does the NSABB Function?

The NSABB advises the U.S. Government on strategies to minimize the risk of, and harm that could result from the malevolent use of legitimate life science research information or technologies.

The NSABB members are experts in science, medicine, law, security, and the public interest.

NSABB meetings are open to the public and public input is key to the policy development process.

www.biosecurityboard.gov

National Institutes of Health Office of Biotechnology Activities

Biosecurity in the Life Sciences

What is Dual Use Research?

Research with legitimate scientific purpose that has the potential to yield information that could be misused to pose a threat to public health or other aspects of national security.

Does Your Research Have Dual Use Potential?

www.biosecurityboard.gov

NIH Biosecurity Program

OBA's activities to address "dual use" research include convening and managing the National Science Advisory Board for Biosecurity, which provides advice to the Federal government on:

- **Federal and institutional oversight**
  Identifying, reviewing and surveilling dual use research of concern
- **Education and training**
  Promoting awareness in the research community about the dual use issues and the responsible conduct of research with dual use potential
- **International collaboration**
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  - **Disseminating NSABB Work Products and FAQs**

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

FREQUENTLY ASKED QUESTIONS

Establishment of the NSABB

1. What is the Administration's policy on biosecurity in life sciences research?
2. Why was the NSABB created?
3. Was the NSABB created in response to the National Academies/National Research Council report "Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma?"
4. What did the NRC report say?
5. How long will the NSABB exist?

Administration/Functions of the NSABB

6. What is the role of the NSABB?
7. What are the specific functions of the NSABB?
8. Who serves on the NSABB? How long do members serve?
9. How are NSABB members selected?
10. What federal agencies are represented on the NSABB?
11. How often does the NSABB meet? Are the meetings open to the public?
12. Who manages and staffs the NSABB?
13. How can I contact the NSABB?

Oversight of Dual Use Research

14. What is "dual use" research?
15. Does the NSABB review or approve all dual use research?
16. 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?
17. How have the roles and responsibilities of Institutional Biosafety Committees (IBCs) changed with the announcement of new Federal biosecurity initiatives, including the establishment of the NSABB and a proposed role for IBCs in the review of "dual use" research?

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Modes of Outreach

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  - **Incorporating material on dual use research into our "IBC Basics" and "Effective IBCs" courses and similar training sessions for researchers and research administrators**

"Integrity without knowledge is weak and useless, and knowledge without integrity is dangerous and dreadful."
—Samuel Johnson

Overview

September 18-20, PRIM&R offered three highly acclaimed educational programs. These courses – IRB Administrator 101, IBC Basics, and Essentials of IACUC Administration – are geared specifically to meet the educational needs of the IRB, IBC, and/or IACUC member, administrator, and staff.

IBC Basics
Monday, September 18, 8:30 AM–5:00 PM

IBC Basics: An Introduction to the NIH Guidelines and the Oversight of Recombinant DNA Research was a full day course on the history, function, and administration of Institutional Biosafety Committees (IBCs).

Delivered by expert staff from the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA), along with institutional biosafety professionals and other members of the IBC community, IBC Basics promotes the professional development of those associated with IBCs, by providing an opportunity to:

- Learn about the NIH OBA, the content of the NIH Guidelines for Research Involving Recombinant DNA Molecules, and the history of IBCs;
- Understand the range of responsibilities that IBCs have under the NIH Guidelines;
- Work through case studies designed to clarify federal expectations with regard to biosafety review and surveillance of recombinant DNA and related research;
- Examine the relationship of IBCs to IACUCs in terms of their respective purviews, roles, and responsibilities; and
- Network with colleagues to share ideas about best practices, resources, innovative approaches, and possible collaborations.

The target audience for this course included IBC members and staff, research administrators, biosafety officers, regulatory affairs officers, members and staff of institutional oversight committees, such as IACUCs, and others interested in the oversight of recombinant DNA research.

Courses from Past Conferences 1995-2007

2007

1. ABSL-3 FACILITIES DESIGN TO OPERATIONS FOR SMALL, MEDIUM, AND LARGE ANIMALS (Barbara Fox Nellis, SM, RBP, CBSP, Northern Arizona University, Flagstaff, AZ; Kelly Flint, National Biodefense Analysis and Countermeasures Center, Frederick, MD)
2. BSL-3 OPERATIONS: FROM PROGRAM DEVELOPMENT TO IMPLEMENTATION (Dee Zimmerman, University of Texas, Galveston, TX; J. Paul Jennette, MS, RBP, College of Veterinary Medicine, Cornell University, Ithaca, NY)
3. FUNDAMENTALS OF AEROBIOLOGY (Deborah E. Wilson, DrPH, CBSP, NIH, Bethesda, MD; Murray L. Cohen, PhD, CIH, CDIC, Inc., Atlanta, GA)
4. ABSL-3 FACILITIES DESIGN TO OPERATIONS FOR SMALL, MEDIUM, AND LARGE ANIMALS (Barbara Fox Nellis, SM, RBP, CBSP, Northern Arizona University, Flagstaff, AZ; Kelly Flint, National Biodefense Analysis and Countermeasures Center, Frederick, MD)
5. INDUSTRIAL HYGIENE FOR BIOSAFETY PROFESSIONALS (Matthew Finucane, MS, University of Pennsylvania, Philadelphia, PA; Lawrence Gibbs, CIH, Stanford University, Stanford, CA)
6. BASIC VIROLOGY AND VIRUS-BASED GENE VECTORS (Patrick Condreay, PhD, GlaxoSmithKline, Research Triangle Park, NC)
7. GASEOUS DECONTAMINATION METHODS: PAST, PRESENT, AND FUTURE (Betty Kupskay, MSc, RBP, Public Health Agency of Canada, Winnipeg, MB; Steven Theriault, PhD, EMCA, HBSc, Public Health Agency of Canada, Winnipeg, MB; Jay Krishnan, MSc, Public Health Agency of Canada, Winnipeg, MB)
8. MEDIA AND RISK COMMUNICATION BEST PRACTICES FOR THE BIOSAFETY PROFESSIONAL (Barbara Reynolds, MA, CDC, Atlanta, GA)
9. DETERMINING APPROPRIATE LEVELS OF REDUNDANCY IN THE POWER SYSTEMS FOR BIOCONTAIMENT FACILITIES (Harry Goslow, PE, and Reuben Anderson, Hemisphere Engineering, Atlanta, GA)
10. BIOHAZARD RISK ASSESSMENT (Lynn Harding, MPH, CBSP, Chattanooga, TN; Diane O. Fleming, PhD, RBP, CBSP, Bowie, MD)
11. EFFECTIVE BIOSAFETY COMMITTEES (Bruce Whitney, PhD, and Kathryn Harris, PhD, RBP, NIH, Bethesda, MD)
12. BUSINESS CONTINUITY PLANNING (Clark Frederick and John Sammarco, Definitive Business Solutions, Whippany, NJ)
13. SELECT AGENT COMPLIANCE FROM A FEDERAL PERSPECTIVE (Rob Weyant, PhD, CDC, Atlanta, GA; Louise Barden, PhD, CDC, Atlanta, GA; LeeAnn Thomas, USDA, Riverdale, MD; Michael Firko, USDA, Silver Spring, MD)
14. ENGINEERING FOR BIOSAFETY PROFESSIONALS (Theodore J. Traum, PE, World BioHazTec Corporation, Rio Rancho, NM)
15. MOLECULAR BIOLOGY 101 (James W. Klenner, MSc, MPH, MPA, RBP, CBSP, Indiana University-Purdue University at Indianapolis, IN)
16. PATHOGEN STABILITY IN THE WORK PLACE (Nanda Gudderra, M.Sc., M.S., PhD, International Bio- Consultancy Paradigm, Germantown, MD and George Mason University, Manassas, VA)

Aims and Modes of Outreach

- **Ensure stakeholder input into NSABB work products and Federal policy making**
  - **Development of the NSABB work products – criteria, codes, communication tools, and recommendations on synthetic genomics – involved:**
    - **Roundtables**
    - **Focus groups**
    - **Presentations to stakeholder audiences**

Aims and Modes of Outreach

- **Engaging international life sciences community on the issue of dual use research of concern**
  - **International Roundtables**
    - **February 2007**
    - **October 2007**

Future Considerations and Activities

- **Need for more awareness raising**
  - **Widely accessible, multi-media products**
- **Need for robust input into Federal policy**
  - **Regional “townhall” conferences**
- **Future need to educate about requirements that will emerge**
  - **Educational tools and resources**

Future Considerations and Activities

- **Additional outreach opportunities**
  - **There are many additional groups that staff and NSABB members could potentially reach**
- **Diverse audiences**
  - **Life sciences are widely encompassing**
  - **Multiple agencies will need to develop programs tailored to their own research contexts**