



Strategic Plan for Outreach and Education on Dual Use Research Issues



Michael Imperiale, Ph.D.
Chair

NSABB Working Group on Outreach and Education



Impetus for Working Group

- **Ongoing concern about lack of awareness of the dual use issue**
- **Need for concerted efforts**



Laying the Foundation

- **Before embarking on the development of an outreach plan, the NSABB first had to**
 - **Formulate concepts and definitions**
 - **dual use research of concern**
 - **Identify key stakeholders**



Laying the Foundation

- **Proposed Framework for the Oversight of Dual Use Life Sciences Research**
 - **Criterion**
 - **Guiding principles for oversight**
 - **Key features of an oversight system**
 - **Roles and responsibilities**
 - **Risk assessment and risk management**
 - **Responsible communications**
 - **Code of conduct**
 - **Outreach and education**



Prior and ongoing outreach efforts

- **NSABB members and staff**
 - **Educate scientific community and public at large**
 - **Apprise research community on the status of Federal policy making**
 - **Promote thoughtful input from stakeholders**



Prior and ongoing outreach efforts

- **Website as the portal for NSABB information**
 - **Meetings**
 - **Work products**
 - **Email inbox for public queries**
 - **Listserv**



Office of Biotechnology Activities



Dual Use Research

The Dual Use Research Program is a focal point for the development of policies addressing life sciences research that yield 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** (NSABB)

The purposes of the NSABB are to:

- Advise the Federal government on strategies to minimize the risks and harm that could result from malevolent use of legitimate research.
- Support development of Federal and institutional oversight guidelines.
- Promote awareness in the research community about the dual-use issue.
- Foster international collaboration on issues related to dual-use research.

<http://www.biosecurityboard.gov>

or

http://oba.od.nih.gov/biosecurity/biosecurity_documents.html

About NSABB

News and Events

NSABB Meetings

Frequently Asked Questions

NSABB Documents

Participating Agencies



Email

- **Email address for public queries regarding NSABB**
 - **nsabb@od.nih.gov**
- **OBA listserv**
 - **listserv@list.nih.gov**
 - **In the body of the message, type: subscribe oba_news**



Prior and ongoing outreach efforts

- **Presentations and workshops to key constituency groups**
 - **Nature of the dual use issue**
 - **Origins of the NSABB**
 - **Activities and work products of the NSABB**
 - **standard slide sets**



Sampling of Organizations to Whom NSABB Members and Staff Have Presented

- 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

National Science Advisory Board on Biosecurity

(Add name of meeting here)

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The "Dual Use" Issue

Good science can be put to bad uses

2

NRC Report on Dual Use Research

3

Life Sciences: Need for Biosecurity

- "Dual use" potential of certain life science 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 science research while ensuring that any impact to the free flow of scientific inquiry is minimized.

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National Science Advisory Board on Biosecurity (NSABB)

- Advisory to the Secretary of Health, Human Services, Director of National Institute of Health, and heads of other Federal departments and agencies to conduct or support life science research
- Will recommend specific strategies to efficient and effective oversight of life science research federally conducted or supported by the Department of 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/process 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 life science research
- National guidelines on communication and dissemination of dual use research methodology and research results
- Strategies for promoting international dialogue on dual use research issues

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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 Institute of Health, Department of Health and Human Services

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NSABB Expertise

- Molecular/genomics
- Microbiology
- Clin. ID/diagnostics
- Lab biosafety/security
- Phlepidemiology
- 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, IAC

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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 Dept. of Agriculture
- Department of the Interior
- National Science Foundation
- Department of Justice
- Department of State
- National Aeronautics and Space Administration
- Intelligence Community

Role of NSABB ex officios

- Represent the views and perspectives of their Agency
- Attend 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 science 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

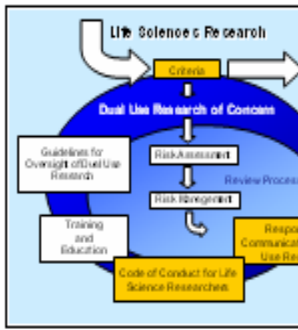
- WGs conduct subsets of NSABB voting members and ex officios
 - Consult experts as needed
 - Convene by teleconference and in person between NSABB meetings
 - Present findings and draft products periodically to full NSABB for input
 - Consult with stakeholder groups through presentations, roundtable discussions, focus groups, panel discussions at WG meetings, etc.
- Full NSABB approve 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 work products once they are integrated into a proposed oversight framework for dual use research (currently under development)

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

—Samuel Johnson

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IRB Administrator 101, IBC Basics, and Essentials of IACUC Administration

September 18-20, 2006
San Francisco, CA



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.



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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, HBSoc, 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 BIOCONTAINMENT 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 Fiko, 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)



Prior and ongoing outreach efforts

- **Exhibits at major meetings**
 - **In conjunction with recombinant DNA**
 - **Stand alone NSABB exhibit**



Office of Biotechnology Activities

OBA PROGRAMS
Recombinant DNA Program

The Recombinant DNA Program promotes scientific advancement and safety in the conduct of basic and clinical recombinant DNA research.

- NIH Guidelines for Research Involving Recombinant DNA Molecules
- Oversight, guiding, commitment and safe research facilities
- NIH/CDC
- Federal resources for information and advice in reporting to gene transfer risks
- Recombinant DNA Advisory Committee (RDAC) - highest level of the scientific, safety, and ethical oversight of human gene transfer research
- Scientific Symposia and Policy Conferences
- Diagnosis and analysis of scientific data and biotechnology
- Recombinant DNA Advisory Committee
- Gene Transfer

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: baov@od.nih.gov
- "Subscribe obo_news"
- Email queries: oba@od.nih.gov
- Website: www.od.nih.gov/oba
- FAQs on protocol review, IBC roles and responsibilities
- Scientific and policy reports



MINNEAPOLIS
 1992-1993



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

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**
Fostering international engagement on the issues related to dual use research



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

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**

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.

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 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?



Prior and ongoing outreach efforts

- **Ensuring stakeholder input into NSABB work products**
 - **Roundtables**
 - **Focus groups**
 - **Presentations to stakeholder audiences**



Prior and ongoing outreach efforts

- **Engaging international life sciences community**
 - **International Roundtables**
 - February 2007
 - October 2007
 - November 2008



Goals of Future Efforts

- **Input into federal policymaking**
 - **Publication of proposed requirements and policies for public comment and input**
 - **Public consultation meetings**
- **Educating about formal requirements**
 - **“Roll out” plan**
 - **Electronic and print educational materials**
 - **Model curricula**
 - **Workshops**
 - **Exhibits**



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?**

The Outreach and Education Continuum

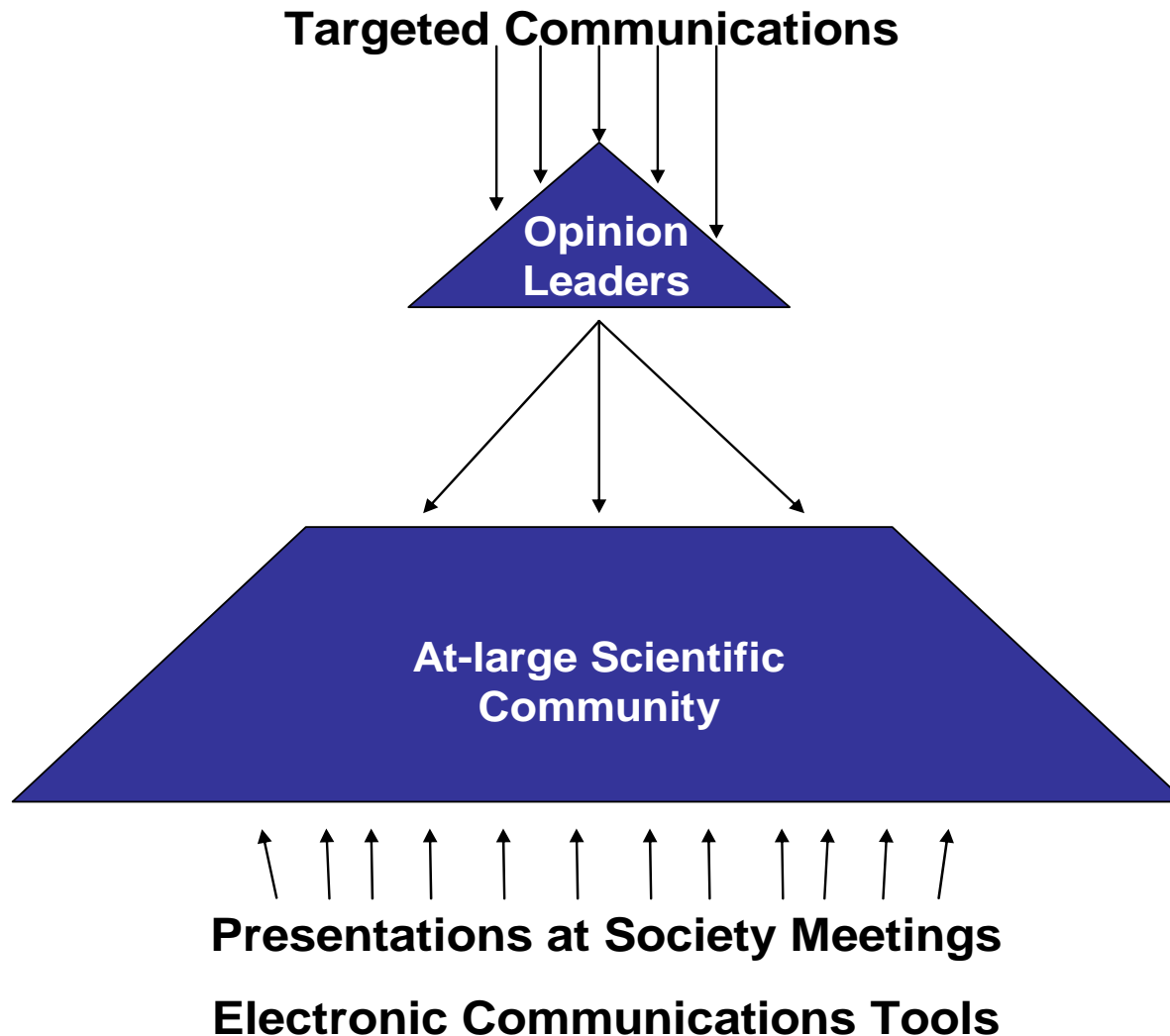




Target Audiences

- **Scientists**
- **Professional associations and scientific societies**
- **Peer-reviewed scientific journal**
- **Students and trainees**
- **Popular media**
- **Public health professionals, veterinarians, agriculturalists**
- **Congress**
- **Public at large**

Opinion Leaders and At-Large Constituencies





Opinion Leaders

- **Nationally respected scientists, leaders of scientific societies, professional associations, and institutions**
 - ❑ **Can be compelling spokespersons and educators**
 - ❑ **Can create opportunities for reaching broader audiences**
 - ❑ **Tailored communications**



At-Large Constituencies

- **Members of scientific societies, professional associations; employees of institutions**
 - **Can urge attention to the issues**
 - **Communication strategies must be broad-reaching**



Message Points

- 1. Life sciences research is a critically important national endeavor**
- 2. The potential for inflicting harm exists**
- 3. Culture of responsibility**



Message Points

4. Ongoing vigilance

5. Broad stakeholder engagement by the scientific community

6. Maximize awareness



Message Points

7. Foster public trust

8. Reduce risk of misuse



Other Recommendations

1. Coordinated Federal effort

2. Use existing NIH-mandated training programs.



Other Recommendations

3. Educate at the secondary school level

4. Educate U.S. commercial research entities and international audiences.



Other Recommendations

5. Facilitate efforts by NGOs

6. Standardize

7. Evaluate



Working Group Members

Voting

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Paul S. Keim, Ph.D.
Northern Arizona University

Susan A. Ehrlich, J.D.
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**Gretchen Lorenzi, Ph.D.
Federal Bureau of
Investigation**

**Daniel Strickman, Ph.D.
US Department of
Agriculture**

**Scott Steele, Ph.D.
Office of Science and
Technology Policy**



NSABB Working Group on Outreach and Education Strategic Plan



**NSABB Meeting
December 10, 2008**