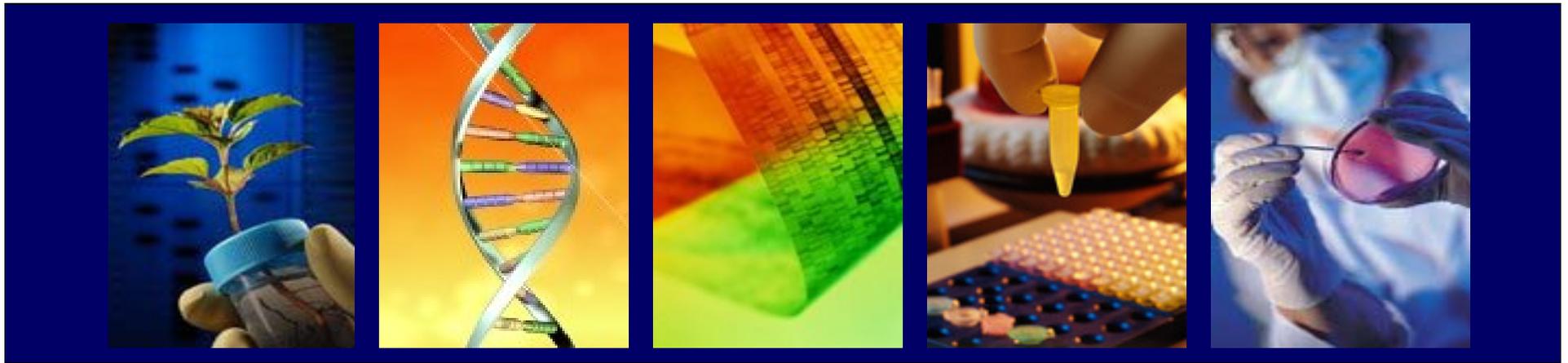


The Dual Use Research Issue and the National Science Advisory Board for Biosecurity



NPDRS Workshop
Paul Lewis, Ph.D.
March 7, 2011



The “Dual Use” Dilemma



- ***Life sciences research underpins:***
 - Biomedical and public health advances
 - Improvements in agriculture
 - Safety and quality of food supply
 - Environmental quality
 - Strong national security and economy
- ***However, good science can be put to bad uses***

NSABB: A USG-wide Initiative



- **Reports directly to the HHS Secretary**
 - Staffed by NIH OBA
- **Advises 15 departments and agencies that conduct, fund or have an interest in life sciences research**
- **Charged to make recommendations on strategies for mitigating the potential for misuse of dual use biological research**
 - Consider both national security concerns and the needs of the research community

NSABB Expertise



- Molecular/genomics
- Microbiology
- Clinical ID/diagnostics
- Lab biosafety/security
- Public health/epidemiology
- Health physics
- Pharmaceutical 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

NSABB Reports

NATIONAL
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BOARD FOR
BIOSECURITY

ADDRESSING BIOSECURITY CONCERNS
RELATED TO THE SYNTHESIS OF
SELECT AGENTS

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Strategic Plan for Outreach and Education
On Dual Use Research Issues



NATIONAL
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BOARD FOR
BIOSECURITY

ADDRESSING BIOSECURITY CONCERNS RELATED
TO SYNTHETIC BIOLOGY



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Proposed Framework for the Oversight
of Dual Use Life Sciences Research:
Strategies for Minimizing the Potential
Misuse of Research Information



A Report of the National Science Advisory Board for Biosecurity (NSABB)

June 2007

Report of the
National Science Advisory Board for
Biosecurity (NSABB)

December 10, 2008

NATIONAL
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BOARD FOR
BIOSECURITY

Enhancing Personnel Reliability among
Individuals with Access to Select Agents



Report of the
National Science Advisory Board for Biosecurity
(NSABB)

May 2009



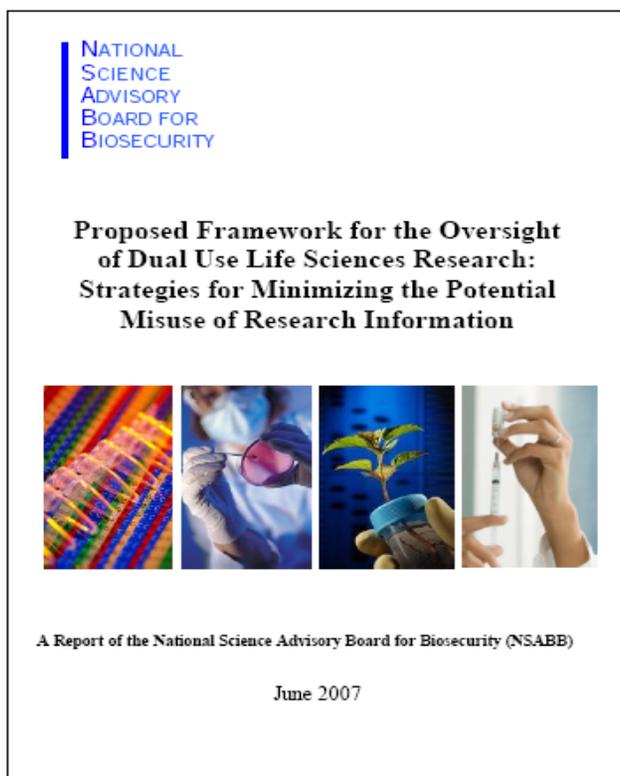
Advisory Board for
Biosecurity

Proposed Oversight Framework for DURC



Charge: Propose an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential

- **NSABB developed a framework for the oversight of DUR including:**
 - Steps in the local oversight of DUR
 - Criterion and guidance for identifying DUR *of concern*
 - Tools to assess and manage the dual use risks associated with certain research
 - Tools for the responsible communication of research
 - Responsibilities of those conducting life sciences research
 - Code of conduct for dual use research



DUR vs. DURC



- Development of new technologies and generation of information with potential for benevolent and malevolent purposes = **dual use research (DUR)**
- But most life sciences research has *some* potential for misuse – most could be considered DUR
- Goal is to identify the subset that has highest potential for generating information that could be misused = **DUR of concern (DURC)**

Criterion for Identifying DURC



- 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
- Agriculture
- Plants
- Animals
- Environment
- Materiel

**Elements of
national security**

Considerations for Identifying DURC



The NSABB described several categories of research that may be more likely to meet the criteria for DURC. Knowledge, products or technologies that enable the following should be assessed especially carefully:

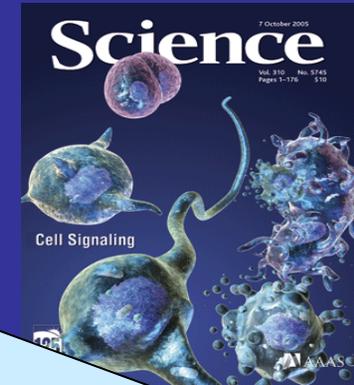
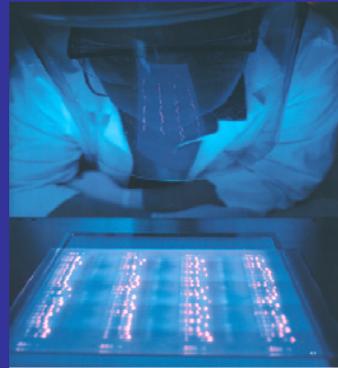
- 1. Enhance harmful consequences of a biological agent or toxin**
- 2. Disrupt immunity or effectiveness of an immunization without clinical/agricultural justification**
- 3. Confer to a biological agent/toxin resistance to clinically/agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies**

Considerations for Identifying DURC



- 4. Increase the stability, transmissibility, or the ability to disseminate a biological agent/toxin**
- 5. Alter the host range or tropism of a biological agent/toxin**
- 6. Enhance the susceptibility of a host population**
- 7. Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent**

Culture of Awareness and Responsibility Throughout the Research Life Cycle



**Conceptualize
project**

**Funding
review**

**Conduct
research**

Discuss work:

Seminars
Posters
abstracts

Peer review

**Publish or
post online**

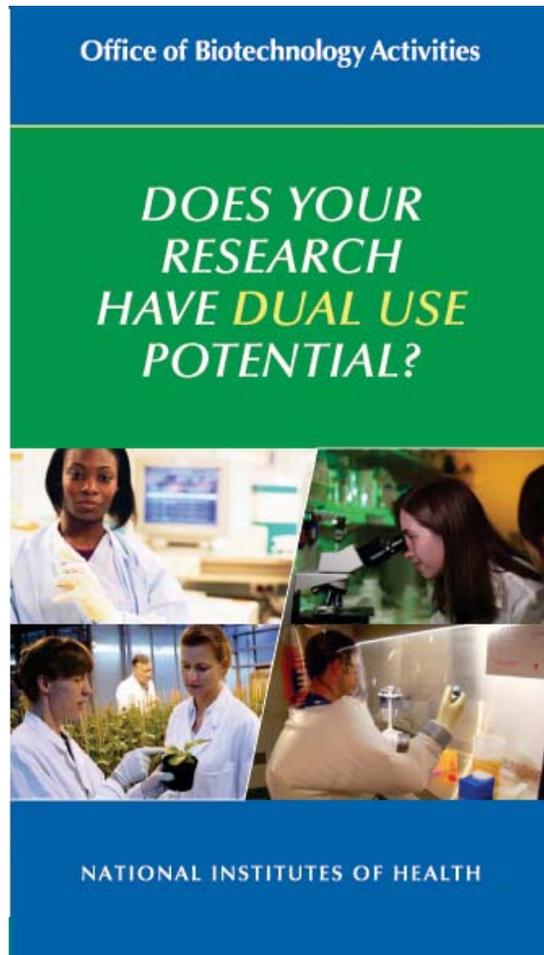


Outreach and Education Efforts



- **Website as the portal for NSABB information**
- **Electronic communications**
 - Listserv, email inbox
- **Presentations and workshops to key constituency groups**
- **Exhibits at major meetings**
- **Ensuring stakeholder input into NSABB work products**
- **Engaging international life sciences community**

Outreach and Education Materials



**Educational Brochure for
Investigators**

Educational Video



**On NIH dual use program page and
YouTube**

International Engagement



Charge: Promote international dialogue on dual use issues

- **International Roundtables on Dual Use Life Sciences Research**
 - February 2007
 - October 2007
 - November 2008
- **Regional Webinars/Video-teleconferences**
 - Pan America-October 2009
 - Europe- September 2010
 - China- November 2010
- **Engaged over 40 countries and over 70 international organizations as well as private industry, philanthropies and NGOs**

International Roundtable on

WORKING GROUP ON INTERNATIONAL COLLABORATION
ROUNDTABLE OCTOBER 10, 2007

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

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3rd International Roundtable
"Sustaining Progress in the Life Sciences:
Strategies for Managing Dual Use Research of Concern"
Co-sponsored by the
United States Government and
World Health Organization
Hosted by the
National Science Advisory Board for Biosecurity
November 5-6, 2008
Bethesda, Maryland

EXECUTIVE SUMMARY

Acknowledging the importance of international efforts to advance the life sciences for the benefit of human health, animal health, and agriculture and the simultaneous need for global efforts to mitigate the possibility that the knowledge generated through life sciences research might be put to nefarious use, the National Science Advisory Board for Biosecurity (NSABB), has hosted a series of International Roundtables on the subject of managing dual use research. The United States Government (USG) and the World Health Organization (WHO) have co-sponsored two of these Roundtables.

Dual use research (DUR) is defined as biological research with legitimate scientific purpose that may be misused to pose a threat to public health and/or national security. The USG/WHO International Roundtables have been aimed at raising awareness of the DUR issue, sharing strategies to manage the risks posed by DUR, and—the focus of this most recent Roundtable—sharing lessons learned from DUR awareness raising and management activities that have been implemented. Over 130 participants from 37 countries and over 72 organizations participated in this third Roundtable to discuss the specific activities of their growth important activities.

This International Roundtable on life sciences research of concern subset that, biotechnology agricultural concerns

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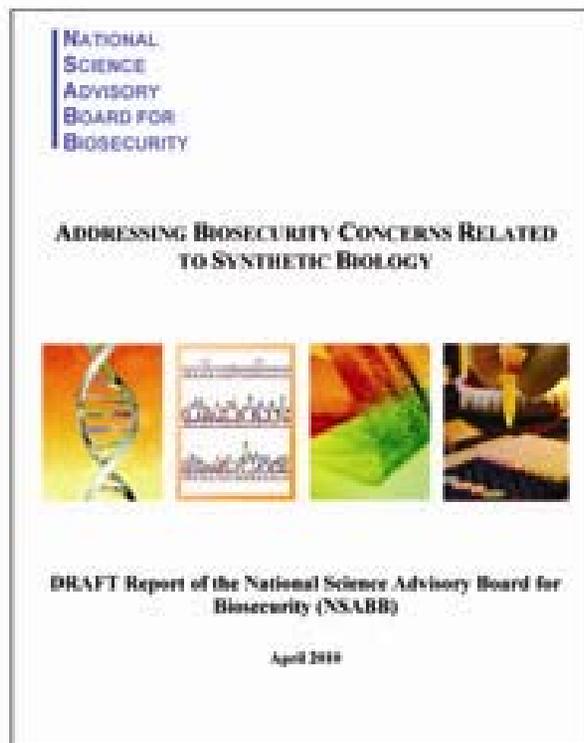
Synthetic Biology



Charge: To identify, assess and recommend strategies to address any biosecurity or dual use research concerns that may arise from work being performed in the nascent field of synthetic biology

- **NSABB recommended:**

- Synthetic biology should be subject to institutional review/oversight since some aspects of this field pose biosecurity and biosafety risks
- Oversight of dual use research should extend beyond the boundaries of life sciences and academia
- Outreach and education strategies should be developed to engage the diverse research communities
- The USG should include advances in synthetic biology in “tech-watch” endeavors



Personnel Reliability



Charge: Recommend strategies for enhancing personnel reliability among individuals with access to biological select agents and toxins

NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY

Enhancing Personnel Reliability among
Individuals with Access to Select Agents



Report of the
National Science Advisory Board for Biosecurity
(NSABB)

May 2009

- **NSABB recommended:**
 - A formal, national PRP is unnecessary at this time
 - Strengthening the current Security Risk Assessment
 - Enhancing the culture of responsibility and accountability
 - Professional societies should engage in dialogue with their communities regarding biosecurity, DURC, and PR
 - Shortening or stratifying the list of select agents

Latest NSABB Tasks



- **Recommend specific strategies and guidance for **enhancing the culture of responsibility** among individuals with access to biological select agents and toxins (BSATs)**
 - Develop specific guidance on how best to implement practices such as self- and peer-reporting, including how to “de-stigmatize” such reporting
 - Delineate the good hiring practices that will help to optimize personnel reliability
 - Recommend ways for local institutional leadership to communicate that security and personnel reliability is valued and a priority

CRWG Aims



- **Identify strategies and develop specific guidance for enhancing the culture of responsibility (CR) among individuals with access to BSATs**
 - **Implementation should be at the local level**
 - **Assist institutional and laboratory leadership in developing and implementing practices that promote a culture of responsibility**
 - **Broadly engage the scientific community**

Latest NSABB Tasks



- Recommend outreach strategies for the **amateur biologists** and **scientists in non-life science disciplines** who participate in life science research and collaborations (span such fields as engineering, chemistry, computer science, mathematics, and physics)

Latest NSABB Tasks



- **Develop strategies for promoting codes of conduct to research institutions, professional societies and other relevant professional groups**
 - **Develop strategies to promote the development of codes of conduct for life sciences research with dual use potential**
 - **Engage scientific societies, research institutions, and other relevant professional organizations to identify strategies for refining and promoting the wider adoption of codes of conduct throughout the organization**
 - **Can be a valuable educational tool, one that can be integrated into responsible conduct of research education modules**

Latest NSABB Tasks



- **Engage *journal editors* on lessons learned and future directions regarding review of dual use research of concern**
 - Engage science journal editors on policies for review of potentially sensitive material and specifically, on review for and of DURC
 - Solicit input on whether journal editors have utilized the NSABB guidance and on ways the existing NSABB guidance might be improved.
 - Continue raising awareness within the scientific editorial and publishing community about dual use research of concern
 - Encourage the adoption of policies and procedures for authors, manuscript reviewers, and editors to follow on identifying and managing DURC

Latest NSABB Task: Continued International Engagement



- **November 1, 2010: *Strengthening the Culture of Responsibility with Respect to Dual Use Research and Biosecurity***
 - Bilateral video-teleconference (Bethesda, MD and Beijing, China)
 - Satellite session of the *International Workshop to Assess Implications of Scientific and Technological Developments for Biosecurity*, in Beijing, China
 - Purpose: to raise awareness of DUR, to engage participants in a discussion on fostering a culture of responsibility, and to inform the NSABB on the views of these international scientists and policy experts from over 30 countries on this issue

- **March 16, 2011: RCR panel at the AAAS *International Engagement Meeting: Responsible Bioscience for a Safe and Secure Society***
 - Bilateral video-teleconference (Washington D.C. and Kuwait City, Kuwait)
 - Purpose: to address DUR within the framework of RCR, which also includes biosafety and bioethics

- **Planning the next international webcast series**
 - Fall 2011
 - South East Asia



Office of Biotechnology Activities



- Home
- Recombinant DNA
- Genetics, Health, Society
- Dual Use Research**
- Clinical Research Policy

Dual Use Research

About NSABB

News and Events

NSABB Meetings

Frequently Asked Questions

NSABB Documents

Participating Agencies

Educational Materials

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 national security.

OBA's activities to address such "dual use" research include convening and managing the [National Science Advisory Board for Biosecurity](#) (NSABB).

International Discussion on Dual Use Research and Biosecurity Now Available on OBA's Web Site

- On November 1, 2010 the National Institutes of Health (NIH) National Science Advisory Board for Biosecurity (NSABB) and the Chinese Academy of Sciences organized a bilateral video-teleconference (VTC) entitled ***Strengthening the Culture of Responsibility with Respect to Dual Use Research and Biosecurity***. This event was a satellite session of the *International Workshop to Assess Implications of Scientific and Technological Developments for Biosecurity* in Beijing, China. The VTC was held in cooperation with the InterAcademy Panel, the International Union of Microbiology Society, the International Union of Biochemistry and Molecular Biology, and the National Academies of Science. The aim of the VTC was to raise awareness of the dual use issue among workshop participants, to engage participants in a discussion on fostering a culture of responsibility, and to inform the NSABB on the views of these international scientists and policy experts from over 30 countries.

The one-hour VTC linked participants at the workshop site in Beijing with key experts in Bethesda, MD. Issues discussed included the principal features or attributes of a culture of responsibility and strategies for promoting, creating, and sustaining a culture of responsibility. The agenda and panelists/moderators biographies from the video-teleconference are available separately at this [site](#).

To go directly to the archived version of the video: [Videocast](#)

To learn more about the issue of dual use research in the life sciences, please watch the following educational video produced by the NIH:

www.biosecurityboard.gov