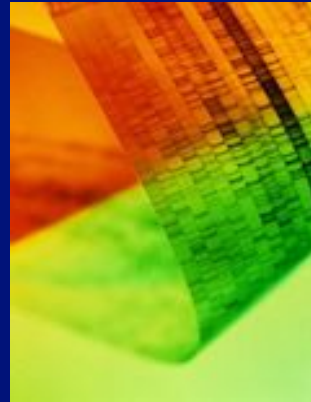


Guiding and Regulating

Dual Use Research of Concern

in the United States



Paul Keim, Ph.D.

The Translational Genomics Research Institute

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***

Anthrax Letter Attacks October 2001

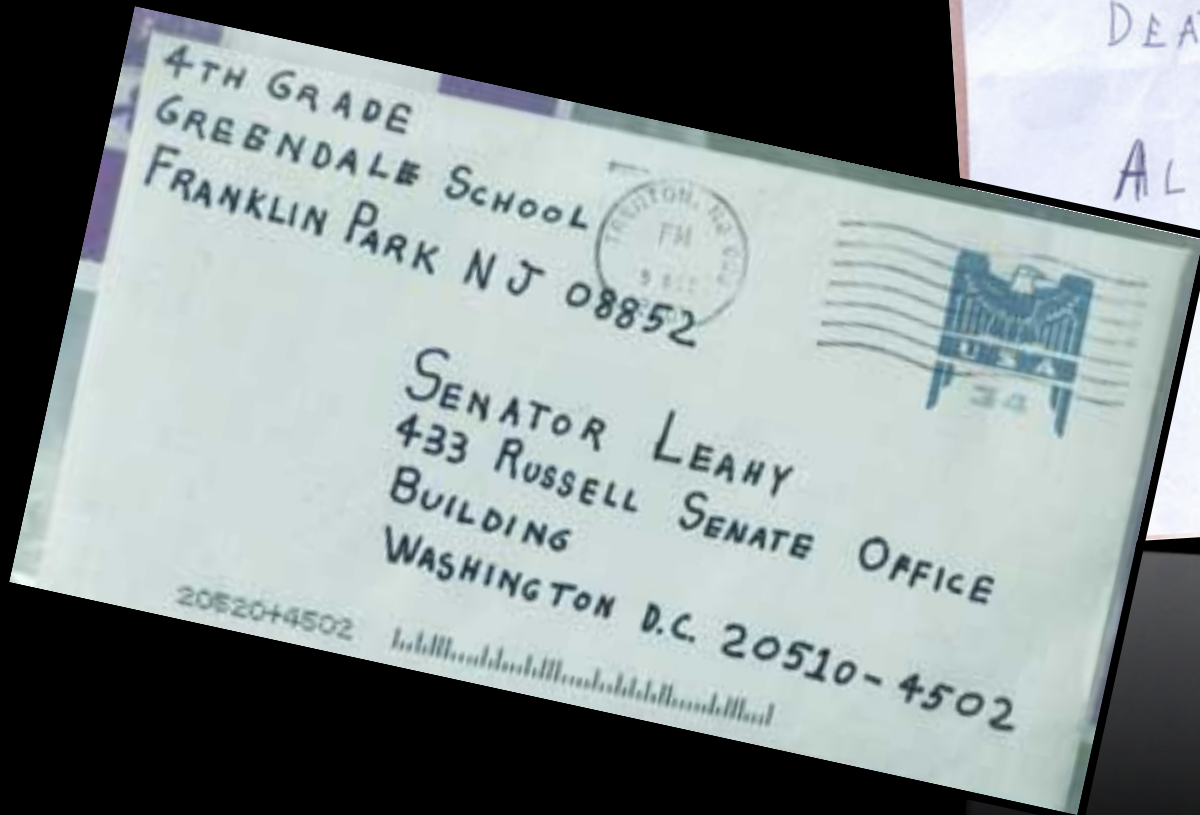
THIS IS NEXT

TAKE PENACILIN Now

DEATH TO AMERICA

DEATH TO ISRAEL

ALLAH IS GREAT

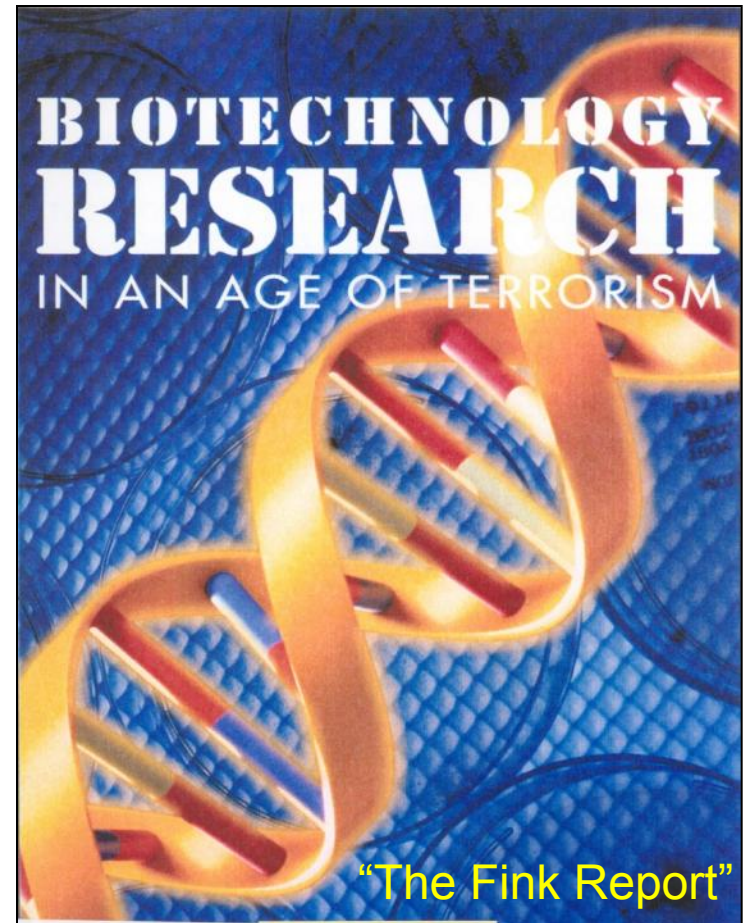


+205

The Concept of “Dual Use” Research



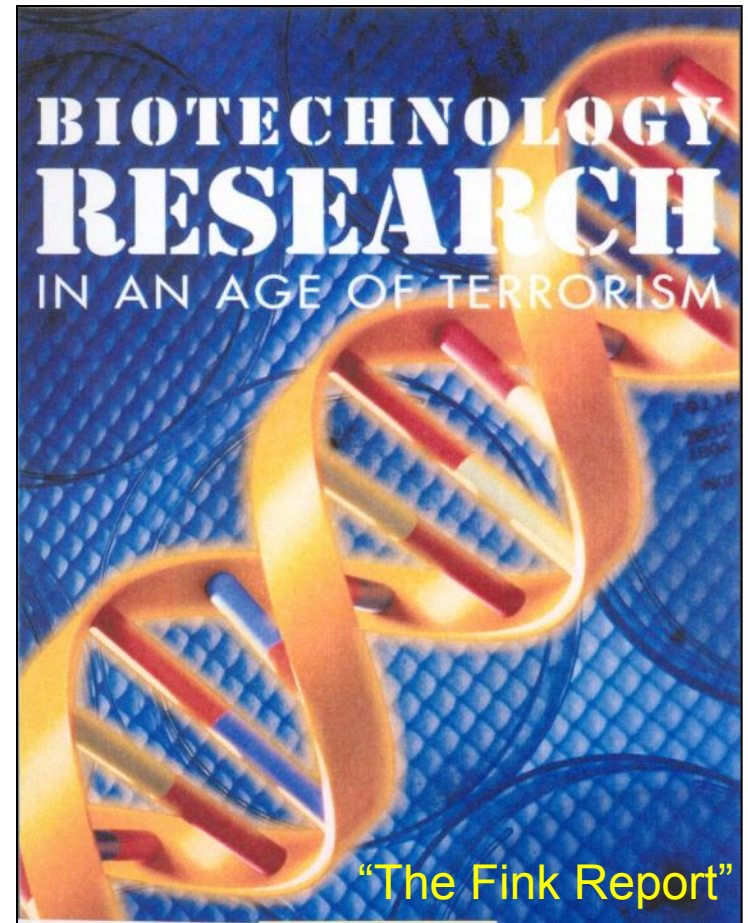
- **Report of the USA National Research Council of the National Academies (2004)**
- **“...the same technologies can be used legitimately for human betterment and misused for bioterrorism.”**



The NSABB



- **National
Science
Advisory
Board for
Biosecurity**



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 Reports

NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY

ADDRESSING BIOSECURITY CONCERNS RELATED TO THE SYNTHESIS OF SELECT AGENTS

NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY

Strategic Plan for Outreach and Education On Dual Use Research Issues



NATIONAL
SCIENCE
ADVISORY
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BIOSECURITY

ADDRESSING BIOSECURITY CONCERNS RELATED TO SYNTHETIC BIOLOGY



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NATIONAL
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ADVISORY
BOARD FOR
BIOSECURITY

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)

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)



<http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb>

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**

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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

How to Regulate?

- **Need for balance**



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**

Personnel Reliability



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

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Enhancing Personnel Reliability among
Individuals with Access to Select Agents

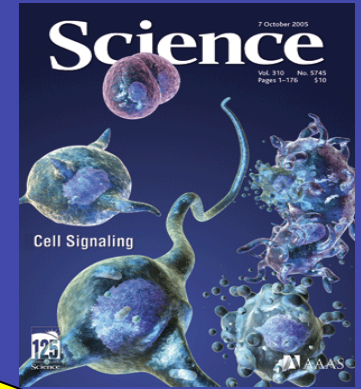
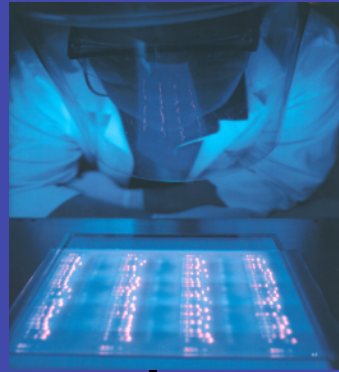


Report of the
National Science Advisory Board for Biosecurity
(NSABB)

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**

Culture of Awareness and Responsibility Throughout the Research Life Cycle



International Engagement



Charge: Promote international dialogue on dual use issues

- **International Roundtables on Dual Use Life Sciences Research**
- **Regional Webinars/Video-conferences**
 - 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

1

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

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Gain of Function Experiments

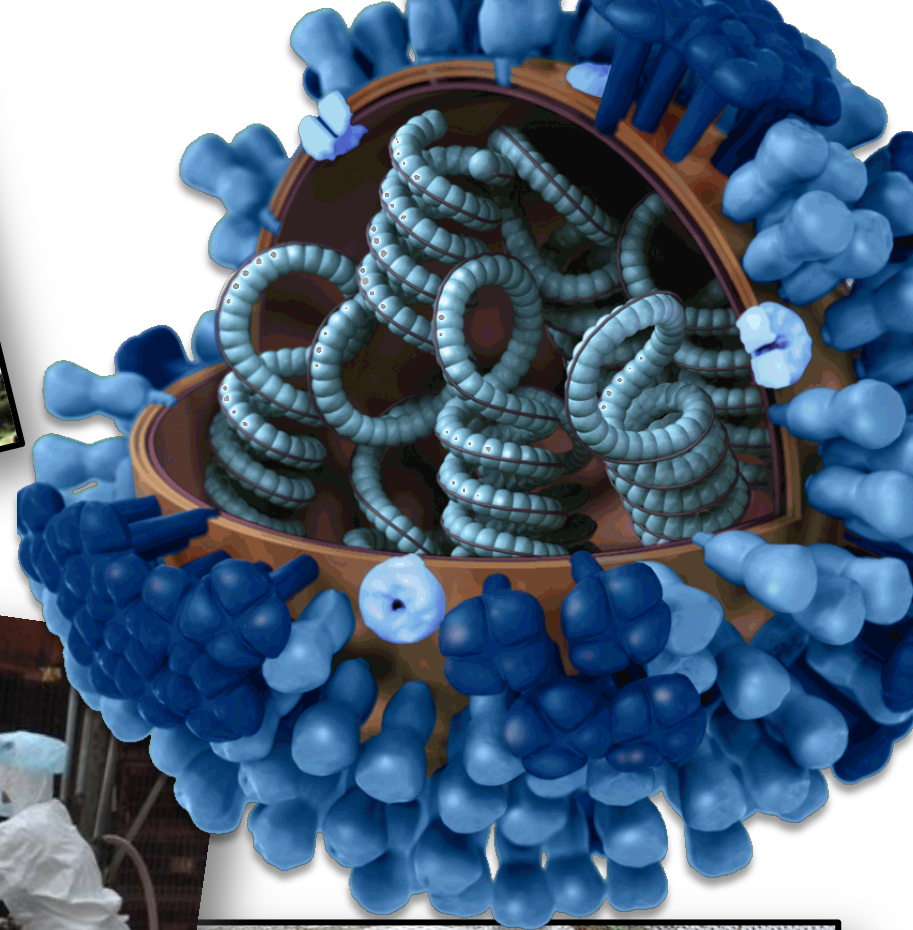


Definition

A pathogen gains a novel biological property through traditional or advanced genetic engineering methods

Examples

- mammalian transmissibility
- Increased virulence
- Drug Resistance
- Evade immunity



Avian H5N1 influenza

“1918 Flu and Responsible Science”



“The 1918 flu genome: Recipe for Destruction”

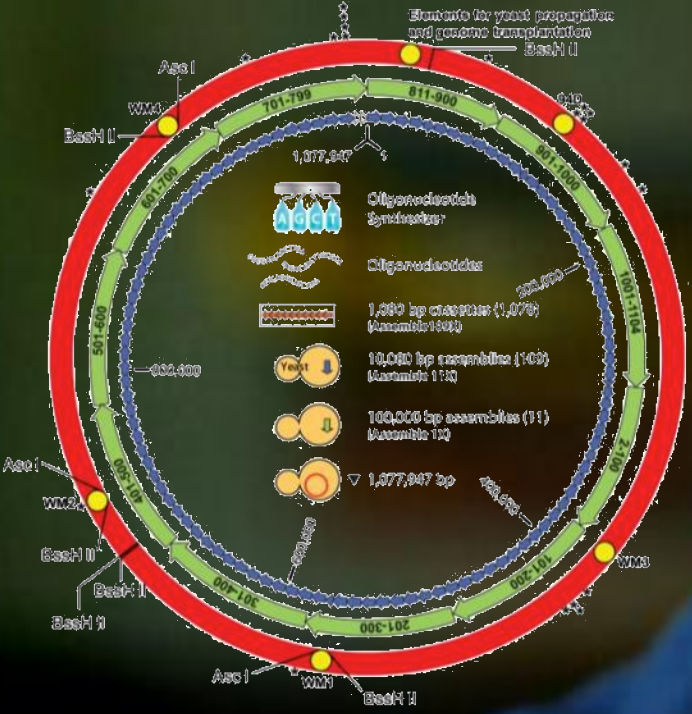


“This is extremely foolish. The genome is essentially the design of a weapon of mass destruction.”

New York Times Op-Ed
October 17, 2005

Ray Kurzweil and Bill Joy
contributors

Synthetic Biology



Dr. Craig Venter

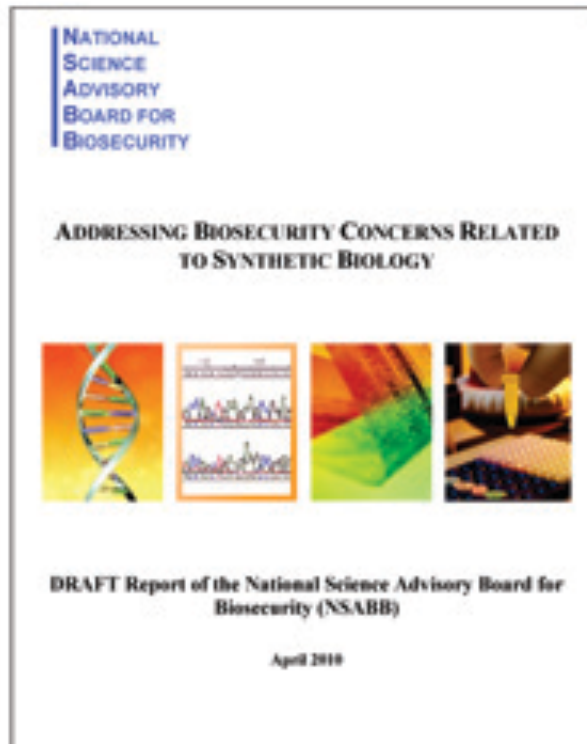
Synthetic Biology



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**



Office of Biotechnology Activities

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

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 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

About NSABB

News and Events

NSABB Meetings

Frequently Asked Questions

NSABB Documents

Participating Agencies

Educational Materials