Updates on Federal Biosafety and Biosecurity Policy

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NIH National Institutes of Health
Office of Science Policy

National Science Advisory Board for Biosecurity Meeting
November 4, 2016

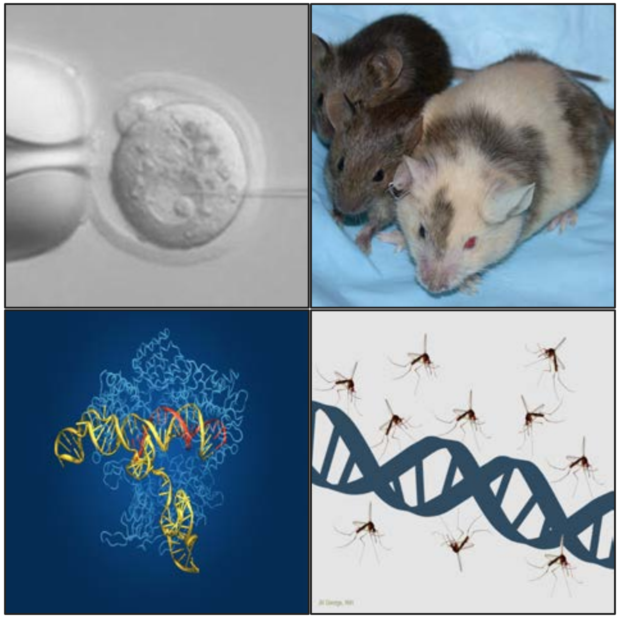
Emerging Biotechnologies: Opportunities and Challenges

An exciting and challenging time for science and policy

- Advances have dramatically altered the biotechnology landscape and hold great promise for innovation and discovery
- Some applications of new technologies are testing policies may raise questions about safety, security, and ethics

Areas of active policy discussion include:

- CRISPR/cas9 gene editing techniques
- Genome sequencing/synthesis
- Synthetic biology
- Gene drives
- Chimera research
- Human germline/mitochondrial modification
- Gain-of-function studies



Lab Incidents Prompt Renewed Safety and Security Efforts

The Washington Post

Health & Science

FDA found more than smallpox vials in storage room

The administrative building of the National Institutes of Health in Bethesda, Md. Hundreds of other potentially dangerous pathogens were in forgotten boxes on NIH campus. (J. Scott Applewhite/Associated Press)

By Brady Dennis and Lena H. Sun July 16, 2014

REUTERS

More: Reuters Health Reuters US

White House Orders U.S. Labs To Take Inventory Of Infectious Agents

REUTERS

BY JULIE STEENHUYSEN, REUTERS

AUG. 28, 2014, 7:20 PM | 26

GAO

United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

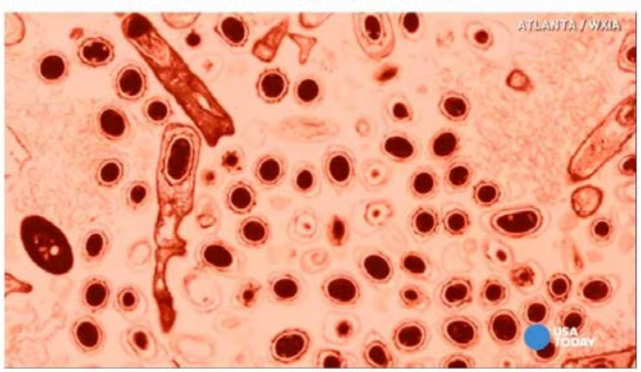
r Release on Delivery
pected 10:00 a.m. ET
Wednesday, July 16, 2014

HIGH-CONTAINMENT LABORATORIES

Recent Incidents of Biosafety Lapses

Statement of Nancy Kingsbury, Ph.D. Managing Director, Applied Research and Methods

Anthrax scare is latest safety lapse at CDC labs



The Center for Disease Control and Prevention in Atlanta says 75 workers may have been unintentionally exposed to anthrax. The CDC stressed that the public is not in any danger.

Michael Winter and Alison Young, USA TODAY 3:21 p.m. EDT August 8, 2014

GAO

United States Government Accountability Office

Report to Congressional Requesters

March 2016

HIGH-CONTAINMENT LABORATORIES

Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety

Initiatives to Strengthen Biosafety and Biosecurity

The U.S. Government has undertaken a series of complementary, short- and long-term policy activities aimed at reinforcing commitments to biosafety, biosecurity, and responsible conduct of research.

- **Biosafety and Biosecurity Stewardship**
- **Research Involving Select Agents and Toxins**
  - Federal Experts Security Advisory Panel (FESAP)
  - Fast-Track Action Committee on Select Agent Regulations (FTAC-SAR)
- **Dual Use Research of Concern (DURC)**
  - National Science Advisory Board for Biosecurity (NSABB)

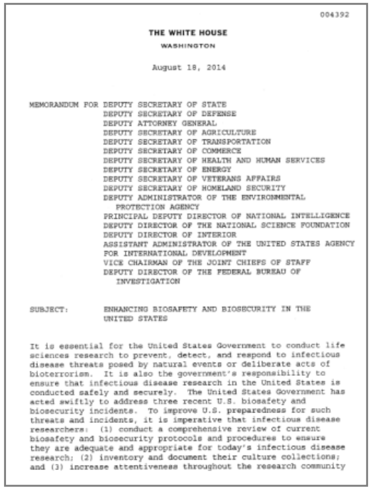
Initiatives to Strengthen Biosafety and Biosecurity

Holdren-Monaco memo (Aug. 2014) called on Federal agencies to:

1. Conduct a comprehensive review of current biosafety and biosecurity protocols to ensure adequacy and appropriateness for today's infectious disease research

2. Inventory and document culture collections

3. Increase attentiveness throughout research community to ensure the safety of laboratory workers and the American public



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THE WHITE HOUSE

WASHINGTON

August 18, 2014

MEMORANDUM FOR DEPUTY SECRETARY OF STATE
DEPUTY SECRETARY OF DEFENSE
DEPUTY ATTORNEY GENERAL
DEPUTY SECRETARY OF AGRICULTURE
DEPUTY SECRETARY OF TRANSPORTATION
DEPUTY SECRETARY OF COMMERCE
DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
DEPUTY SECRETARY OF ENERGY
DEPUTY SECRETARY OF VETERANS AFFAIRS
DEPUTY SECRETARY OF HOMELAND SECURITY
DEPUTY ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
PRINCIPAL DEPUTY DIRECTOR OF NATIONAL INTELLIGENCE
DEPUTY DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION
DEPUTY DIRECTOR OF INTERIOR
ASSISTANT ADMINISTRATOR OF THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT
VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF
DEPUTY DIRECTOR OF THE FEDERAL BUREAU OF INVESTIGATION

SUBJECT: ENHANCING BIOSAFETY AND BIOSECURITY IN THE UNITED STATES

It is essential for the United States Government to conduct life sciences research to prevent, detect, and respond to infectious disease threats posed by natural events or deliberate acts of bioterrorism. It is also the government's responsibility to ensure that infectious disease research in the United States is conducted safely and securely. The United States Government has acted swiftly to address three recent U.S. biosafety and biosecurity incidents. To improve U.S. preparedness for such threats and incidents, it is imperative that infectious disease researchers: (1) conduct a comprehensive review of current biosafety and biosecurity protocols and procedures to ensure they are adequate and appropriate for today's infectious disease research; (2) inventory and document their culture collections; and (3) increase attentiveness throughout the research community

National Biosafety Month

National Biosafety Month 2014

- Review policies, procedures/practice, and training
- Conduct inventories to ensure proper storage, containment, and documentation of infectious agents and toxins

National Biosafety Month 2015

- Enhance a top-down/bottom-up culture of safety and responsibility
- Promote training and transparency regarding institutional oversight

National Biosafety Month 2016

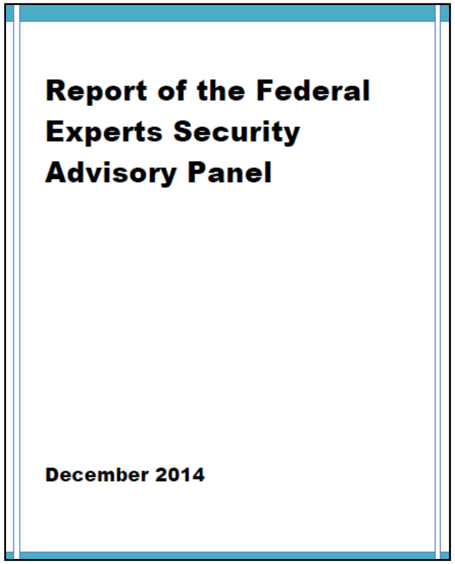
- Evaluate biosafety programs and related governance structures
- Collaborate to promote biosafety and share best practices
- Commit to providing appropriate resources to all elements of biosafety programs

Federal Experts Security Advisory Panel (FESAP)

FESAP examined policy issues relevant to the security of select agents and toxins to optimize biosafety, biosecurity, oversight, and inventories

FESAP Report (Dec. 2014)

- Concludes that, in general, the USG has a robust set of rules, regulations, and practices to inform safe, secure and responsible research with infectious agents and toxins
- Outlines recommendations to promote oversight and compliance for biosafety, biocontainment, and biosecurity; called for more applied biosafety research


Report of the Federal Experts Security Advisory Panel

December 2014

Fast Track Action Committee on Select Agent Regulations (FTAC-SAR)

FTAC-SAR engaged with a wide range of stakeholders on the impact of the Select Agent Regulations on science, technology, and national security

FTAC-SAR Report (Oct. 2015)

- Outlines findings and recommendations based on stakeholder feedback
- Calls for strengthening inventory control, material accountability, outreach and education, sharing of best practices

Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement

October 2015

National Science and Technology Council
Committee on Homeland and National Security
Subcommittee on Biological Defense Research and Development
Fast Track Action Committee on the Select Agents Regulations

Implementation of FESAP & FTAC-SAR Recommendations

USG is implementing FESAP and FTAC-SAR recommendations:

- Developing and optimizing biosafety and biosecurity policies and practices
- Strengthening oversight mechanisms
- Promoting outreach and education
- Enhancing the culture of responsibility

IMPLEMENTATION OF RECOMMENDATIONS OF THE FEDERAL EXPERTS SECURITY ADVISORY PANEL (FESAP) AND THE FAST TRACK ACTION COMMITTEE ON SELECT AGENT REGULATIONS (FTAC-SAR)

October 2015

Gain-of-Function Research

NSABB led the deliberative process; developed recommendations for the evaluation and oversight of gain-of-function research involving pathogens with pandemic potential.

NSABB Report (May 2016)

- <u>Central finding:</u> Studies anticipated to enhance pathogens with pandemic potential have potential public health benefits but also entail significant potential risks
- Recommended additional, multidisciplinary Department-level evaluation prior to funding decision, and appropriate ongoing oversight if funded

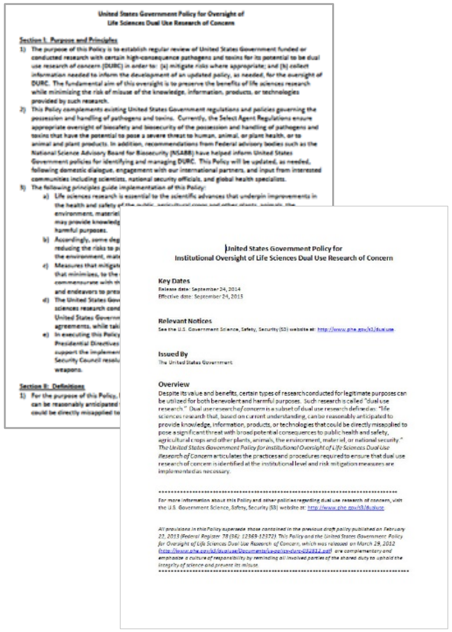
Looking Ahead: New Tasks for the NSABB

USG DURC Policies

USG has released two policies for the oversight of dual use research of concern:

- **USG Policy for Oversight of Life Sciences DURC (March 2012)** – Addresses roles and responsibilities of Federal funding agencies; requires identification and oversight of DURC in research portfolios

- **USG Policy for Institutional Oversight of Life Sciences DURC (issued 2014; effective Sept. 2015)** – Addresses roles and responsibilities of USG-funded research institutions; requires institutions to establish a system for the identification and oversight of DURC



United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern

Section I. Purpose and Principles

1) The purpose of this Policy is to establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. The fundamental aim of this oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.
2) This Policy complements existing United States Government regulations and policies governing the possession and handling of pathogens and toxins. Currently, the Select Agent Regulations ensure appropriate oversight of biosafety and biosecurity of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products. In addition, recommendations from Federal advisory bodies such as the National Science Advisory Board for Biosecurity (NSABB) have helped inform United States Government policies for identifying and managing DURC. This Policy will be updated, as needed, following domestic dialogue, engagement with our international partners, and input from interested communities including scientists, national security officials, and global health specialists.
3) The following principles guide implementation of this Policy:
   a) Life sciences research is essential to the scientific advances that underpin improvements in ...

Section II: Definitions

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Key Dates
Release date: September 24, 2014
Effective date: September 24, 2015

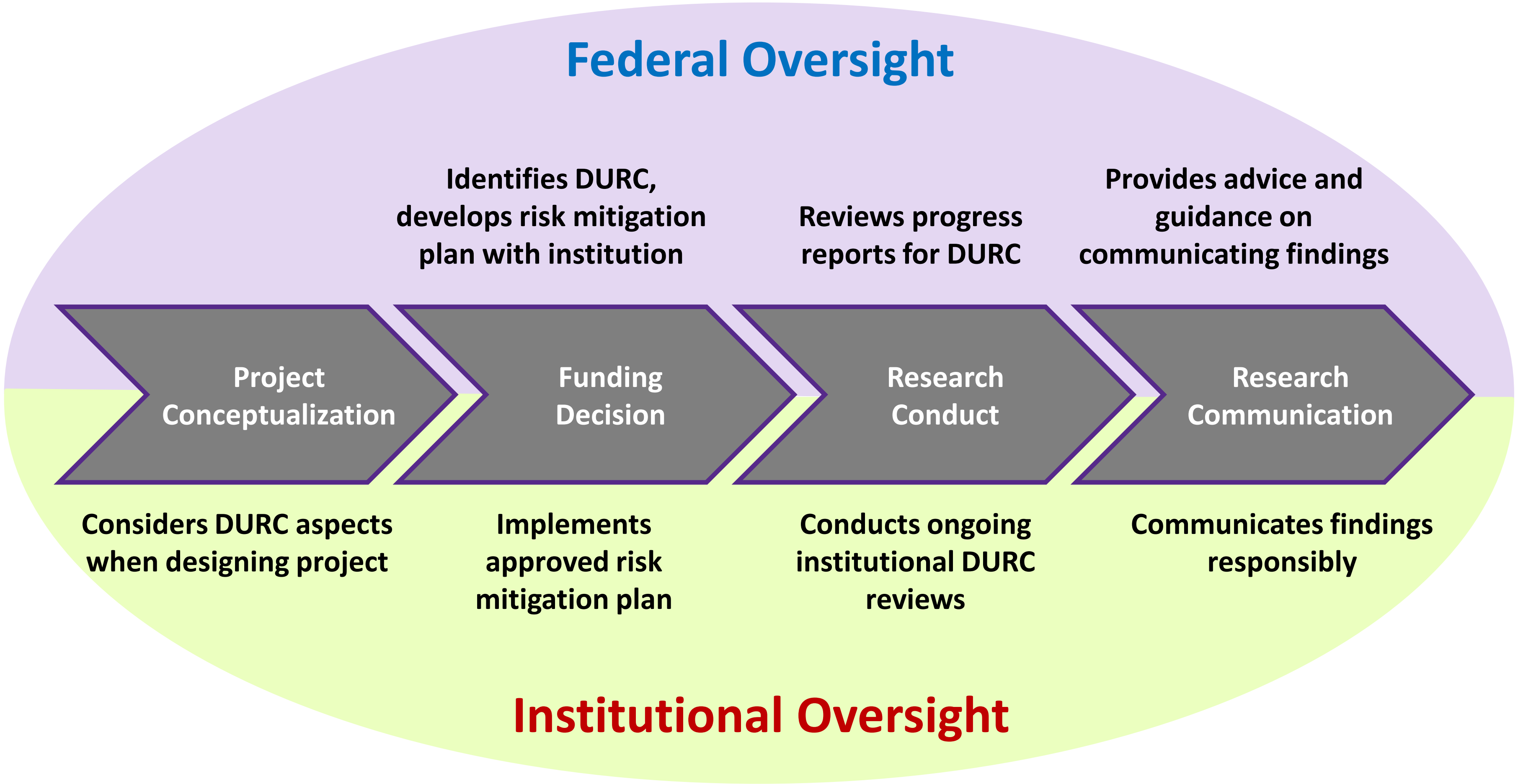
Relevant Notices
See the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse.

Issued By
The United States Government

Overview
Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research *of concern* is a subset of dual use research defined as: "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." *The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse.

USG DURC Policies: Collaborative Oversight Throughout the Research Life Cycle



Evaluating the Institutional DURC Policy

Questions to Address

- What are the strengths and limitations of the institutional DURC policy?
- What challenges are institutions facing as they implement the policy?
- Are there best practices for identifying DURC, managing risks, training researchers, etc?
- What are the effects of the policy on scientific research and publishing?

NSABB New Task: DURC Policy Stakeholder Engagement

NSABB Task

To host a series of regional meetings to gather feedback from stakeholders implementing the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Anticipated deliverables

- A series of regional stakeholder meetings, video archived
- Meeting summaries describing stakeholder feedback

NSABB Working Group

- Chair: Joseph McDade, Ph.D.

NSABB New Task: DURC Policy Stakeholder Engagement

Objective

To obtain feedback from those involved in the implementation of the institutional DURC policy to inform USG policy review and development efforts.

<u>Topic areas include:</u>

- Experiences implementing the policy at the institutional level
- Challenges (and any steps taken to address them)
- Best practices and novel strategies for managing DURC
- Effective strategies for training investigators and laboratory staff
- Impact of the policy on researchers and institutions

NIH Conducting an External Review of 2014 Smallpox Incident

- **July 2014:** 327 sealed vials of pathogens and biological materials were discovered on a cold room on the NIH main campus; 6 vials contained variola virus
- Samples were promptly secured, transported to CDC; smallpox samples were tested and destroyed, witnessed by officials from WHO
- Incident has resulted in a number of reports/investigations and generated considerable interest from members of Congress
- NIH is conducting a review of this incident

Blue Ribbon Panel Reviewing 2014 Smallpox Incident

- NIH Director has appointed a Blue Ribbon Panel to review the incident and to report its findings to the NSABB
- **Blue Ribbon Panel is to:**
  - Review the incident and the immediate response
  - Consider whether systemic issues may have contributed to the presence of variola virus and to the delay in its discovery
  - Determine whether NIH policies have been appropriately strengthened, if necessary, in response to the incident
- **NSABB is to:**
  - Provide additional subject matter expertise and input to the Blue Ribbon Panel and a forum for public discussion of the issue

Resources

- **NSABB**
  - **Submit public comments to NSABB**: nsabb@od.nih.gov
  - Website: http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb

National Science Advisory Board for Biosecurity

- **Science, Safety, Security (S3)**
  - http://www.phe.gov/s3/Pages/default.aspx

Science Safety Security
Finding the Balance Together

- **NIH Office of Science Policy**
  - Website: http://osp.od.nih.gov/
  - Blog: http://osp.od.nih.gov/under-the-poliscope
  - Twitter: https://twitter.com/cwolinetznih
  - **Subscribe to the OSP listserv** by sending an email to LISTSERV@list.nih.gov with "Subscribe OSP_News" in the message body

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Bringing Science Policy Into Focus