USG DURC Policy: Past and Present

Carrie D. Wolinetz, Ph.D.
Associate Director for Science Policy
National Institutes of Health

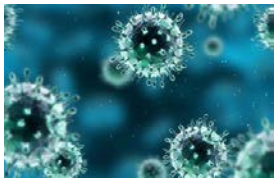
Striking the balance

- Benefits of life science research
  - Biomedical and public health advances
  - Improvements in agriculture
  - Safety and quality of food supply
  - Environmental quality
  - Strong national security and economy
- Recognition of risks
- Shared responsibility

Mitigating the risk: Biosafety and Biosecurity

- Distinct but complementary concepts

- Policy and implementation needs to consider both



Federal Policies and Guidelines

- Occupational Health and Safety Regulations & Standards
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

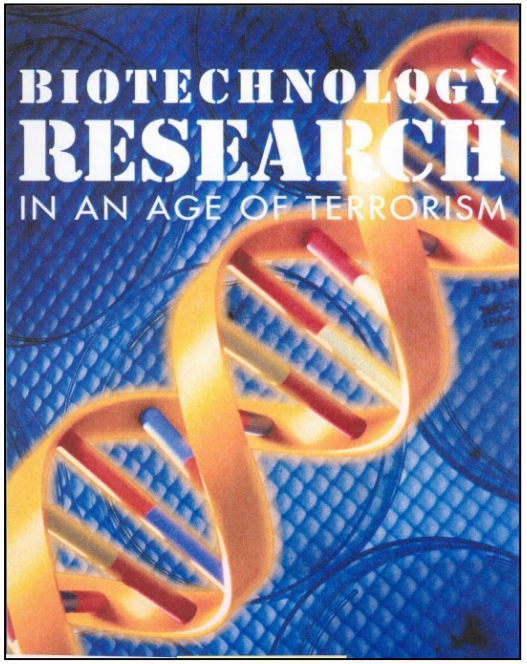
Select Agent Regulations

Dual Use Research of Concern (DURC) Policies

Recognition of Dual Use Nature of Life Sciences Research

Biotechnology Research in the Age of Terrorism
(National Research Council, 2004)

Biotechnology represents a "dual use" dilemma in which the same technologies can be used legitimately for human betterment and misused for bioterrorism



Recommendations included:

- A role for the life sciences in efforts to prevent bioterrorism
- Creation of a national science advisory board to provide advice, guidance, and leadership

National Science Advisory Board for Biosecurity (NSABB)

- Federal **Advisory** Committee established in 2004

"…to provide, as requested, advice, guidance and leadership regarding biosecurity oversight of dual-use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security."

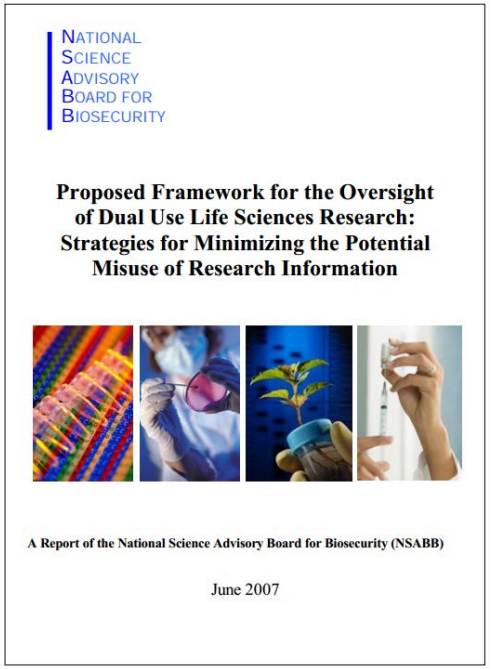
- Up to 25 voting members with broad scientific expertise as well as expertise in biosafety, biosecurity, risk communication, law, ethics, and more
- Non-voting *ex officio* members from federal agencies

NSABB– Proposed Framework for the Oversight of Dual Use Research

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

Proposed framework addressed:

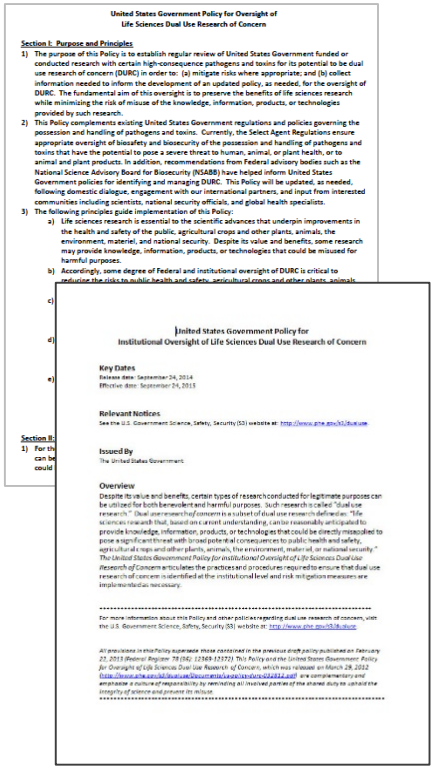
- Steps in the local oversight of dual use research
- Criteria and guidance for identifying subset of dual use research of concern (DURC)
- Tools to assess and manage dual use risk associated with certain research
- Tools for the responsible communication of research
- Code of conduct for dual use research



U.S. Government DURC Policies

USG has issued two policies for the oversight of dual use research of concern (DURC)

- ***USG Policy for Oversight of Life Sciences DURC* (March 2012)** – Requires federal funding agencies to identify DURC in their research portfolios and work to mitigate risks as needed
- ***USG Policy for Institutional Oversight of Life Sciences DURC* (issued 2014; effective 2015) –** Requires federally-funded research institutions to establish a system to identify DURC and work with funding agencies to mitigate risks as needed


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 the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel, and national security. Despite its value and benefits, some research may provide knowledge, information, products, or technologies that could be misused for harmful purposes.

b) Accordingly, some degree of Federal and institutional oversight of DURC is critical to

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/dual-use

Issued By

The United States Government

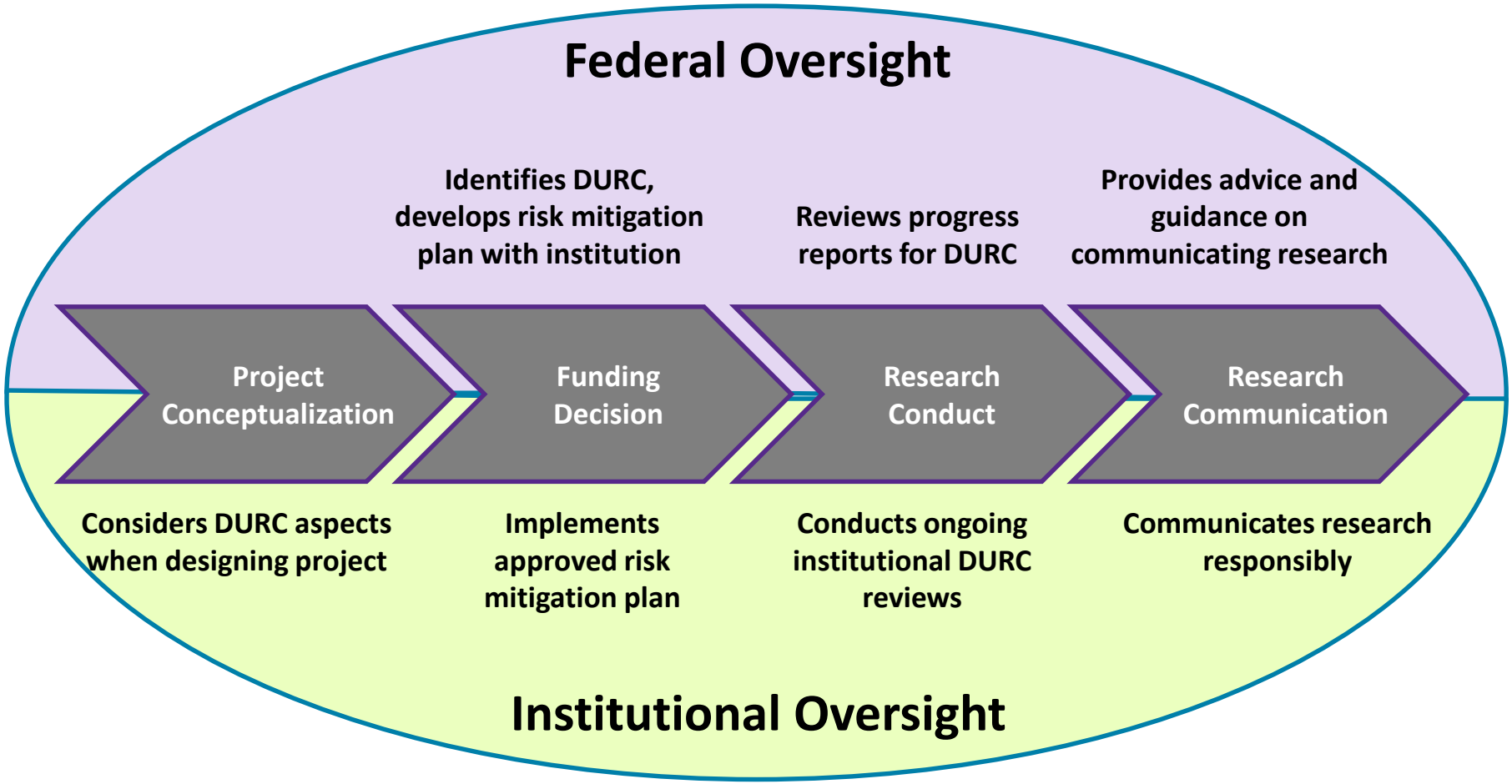
Overview

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/dual-use

All provisions in this Policy supersede those contained in the previous draft policy published on February 22, 2013 (Federal Register 78 (36): 12369-12372) This Policy and the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, which was released on March 29, 2012 (http://www.phe.gov/s3/dualuse/Documents/powg-publication-032912.pdf) are complementary and emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.

U.S. Government DURC Policies and the Research Continuum



U.S. Government DURC Policies- Purpose and Principles

Aim to **preserve the benefits** of life sciences research while **minimizing the risk of misuse** of the information, products, or technologies generated by such research.

- The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise
- Promoting a culture of responsibility relies on the education of the scientific community about the dual use potential of life sciences research
- Institutions and investigators are most familiar with the research conducted in their facilities and are best positioned to promote and strengthen responsible conduct and communication of results
- Effective oversight helps build and maintain public trust in the life sciences research enterprise

Institutional DURC Policy

Institutional oversight of DURC is a critical component of a comprehensive oversight system.

The institutional DURC policy outlines roles and responsibilities of:

- Institution
- Institutional Review Entity (IRE)
- Institutional Contact for Dual Use Research (ICDUR)
- Principal Investigators
- United States Government (USG)

Institutional DURC Policy

The institutional DURC policy applies to:

- Institutions within the United States that both:
  i. Receive federal funds to conduct or sponsor life sciences research; and
  ii. Conduct or sponsor research subject to the policy, regardless of the source of funding
- Institutions outside of the United States that receive U.S. federal funds to conduct or sponsor research subject to the policy
- Federal departments and agencies that fund or conduct life sciences research

❖ *Institutions that do not receive federal funds for life sciences research are not subject to oversight under the policy but are strongly encouraged to implement internal oversight procedures consistent with the culture of shared responsibility underpinning the policy*

Institutional DURC Policy Scope – 15 Agents & Toxin

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

- *Attenuated strains of the agents that are excluded from the Select Agent Regulations and inactive forms of botulinum neurotoxin are excluded from the scope of the DURC policy*

Institutional DURC Policy Scope – 7 Experimental Effects

1. Enhances the harmful consequences of the agent or toxin;
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5. Alters the host range or tropism of the agent or toxin;
6. Enhances the susceptibility of a host population to the agent or toxin;
7. Generates or reconstitutes an eradicated or extinct agent or toxin

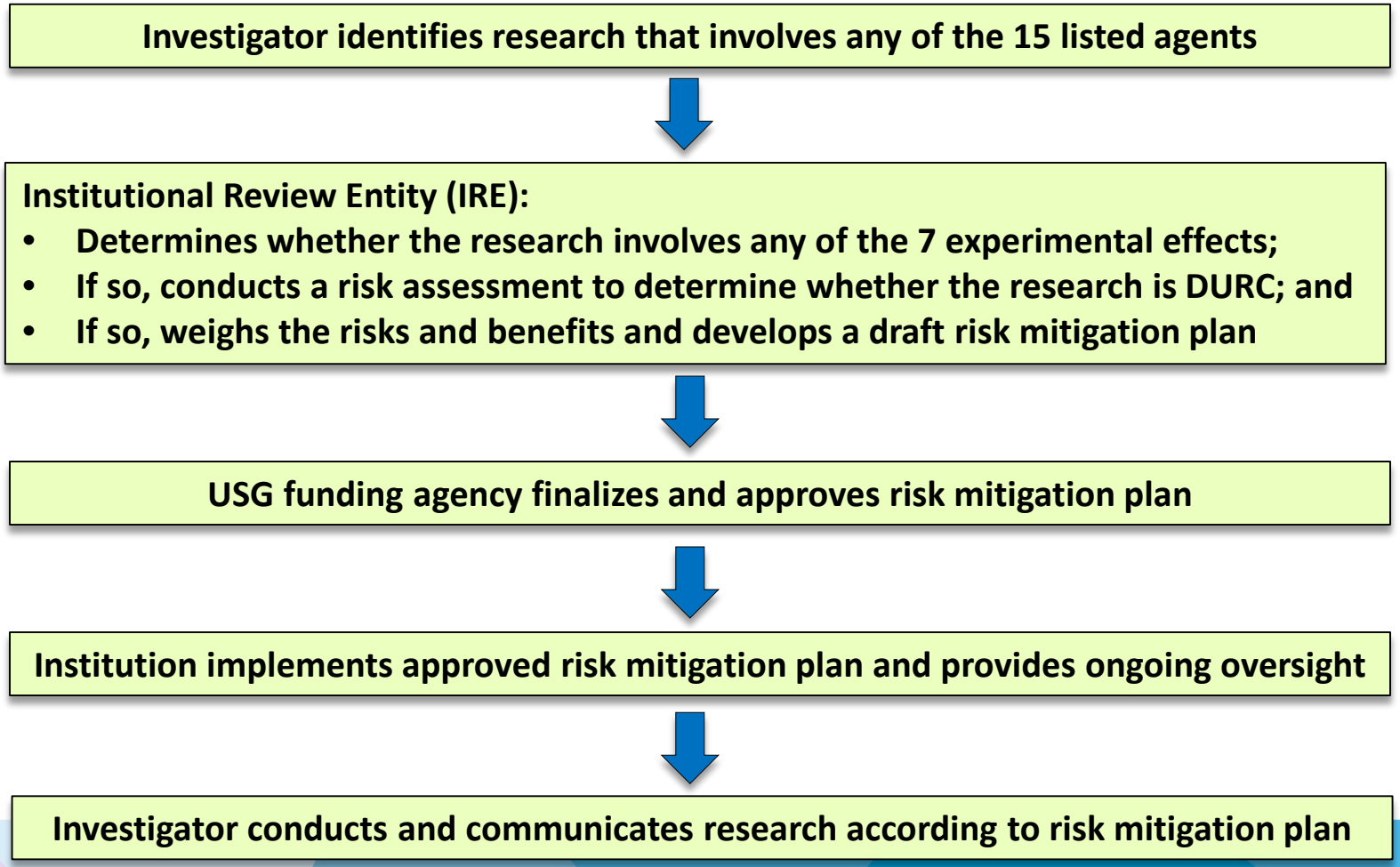
Identifying DURC

Research that directly utilizes one or more of 15 agents or toxins, and that produces, aims to produce, or can be reasonably anticipated to produce one or more of 7 experimental effects must be assessed for potential DURC

Is it Dual Use Research of Concern?

Based on current understanding, can the research 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?

Overview of Institutional DURC Oversight



Roles and Responsibilities: Institutions

- Implement policies and practices for identification and oversight of DURC
- Establish an Institutional Review Entity (IRE)
- Designate an Institutional Contact for Dual Use Research (ICDUR)
- Educate and train employees
- Report to funding agency on DURC review outcomes as required
- Work with the PI and funding agency to develop and implement risk mitigation plans for DURC
- Provide ongoing oversight of DURC

Roles and Responsibilities

Institutional Review Entity (IRE)

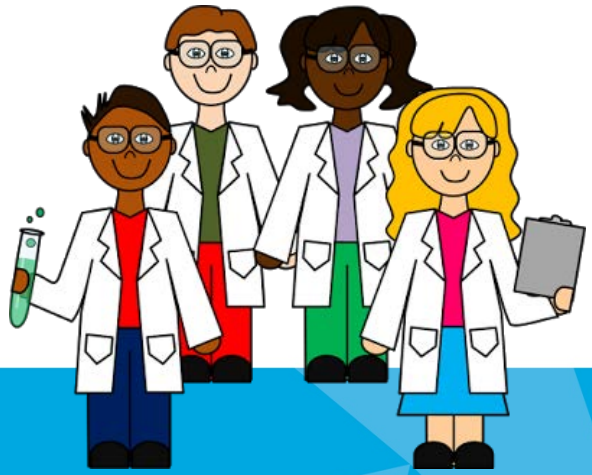
- Review research for potential to be DURC
- Conduct a risk assessment and determine whether the research meets the definition of DURC
- Develop a draft risk mitigation plan to guide the conduct and communication of DURC
- Review active risk mitigation plans

Institutional Contact for Dual Use Research (ICDUR)

- Serve as the point-of-contact for information about the policy
- Serve as the liaison between the institution and federal agencies

Roles and Responsibilities: Investigators

- Notify the IRE of research that is subject to review
- Aid in the assessment of dual use risks and development of risk mitigation plans for DURC
- Ensure that relevant laboratory personnel receive DURC education and training
- Conduct and communicate DURC responsibly and in accordance with necessary risk mitigation measures
- Continuously monitor their research



Risk Mitigation for DURC

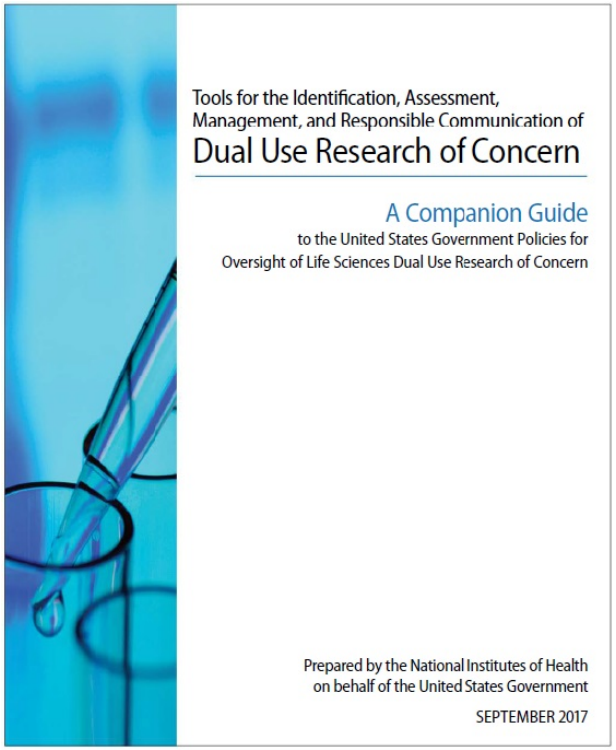
Federal agencies + Institutions

Risk mitigation may involve:

- Adding additional biosafety practices or containment features
- Evaluating the effectiveness of countermeasures
- Providing additional training or education to staff
- More frequent federal or institutional reviews
- Modifying the design of the experiment
- Developing a responsible communication plan

Tools and Resources for Institutions and Investigators

The Companion Guide: *Tools for the Identification, Assessment, Management, and Responsible Communication of DURC*



- Qs & As on the USG DURC policies
- Frameworks and guidance on risk/benefit assessment and risk mitigation
- Guidance for the responsible communication of research
- Resources for outreach and education on dual use research

More Resources on Dual Use Research

- **Science, Safety, Security (S3)**
  - **DURC Policies, Companion Guide, and other resources** https://www.phe.gov/s3/dualuse/Pages/default.aspx
- **Questions and submissions regarding DURC policy**
  - Email: DURC@od.nih.gov
- **National Science Advisory Board for Biosecurity (NSABB)**
  - https://osp.od.nih.gov/biotechnology/national-science-advisory-board-for-biosecurity-nsabb