US GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

Kathryn Harris, PhD., RBP
Senior Outreach and Education Specialist (contractor)

National Institutes of Health
Program on Biosecurity and Biosafety Policy

Overview

- What is Dual Use Research in the Life Sciences?
- Oversight of Dual Use Research of Concern
- Key Responsibilities of Institutions, Investigators, the U.S. Government, and Others under the Institutional DURC Oversight Policy
- Resources and Educational Materials

DUAL USE RESEARCH IN THE LIFE SCIENCES

Importance of Life Sciences Research

- ***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**

Dual Use Research In The Life Sciences

Good science can be put to bad uses

Dual use research (DUR) is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized both for benevolent and harmful purposes

Dual Use Research of Concern (DURC)

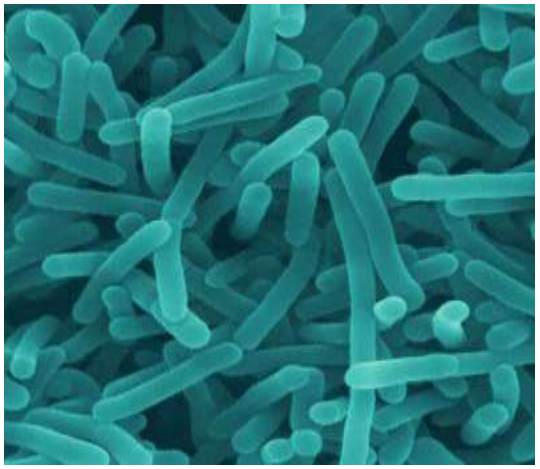
- **Most life sciences research conceivably could be considered DUR in that it has *some* potential to generate information that could be misused**

- **There is a subset of research that has the greatest potential for generating information that could be readily misused in ways that threaten public health and national security. Such research has been termed Dual Use Research of Concern (DURC) and is the focus of the US Government oversight policies**

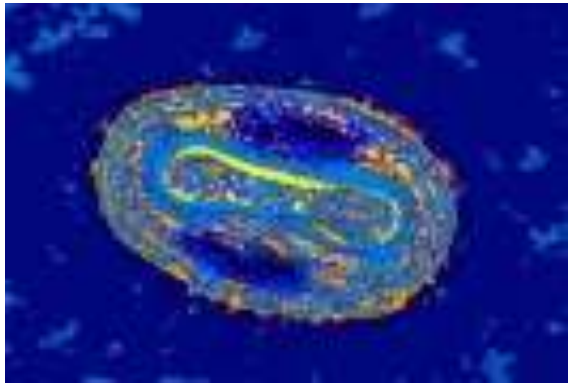
US Government Definition of DURC

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.

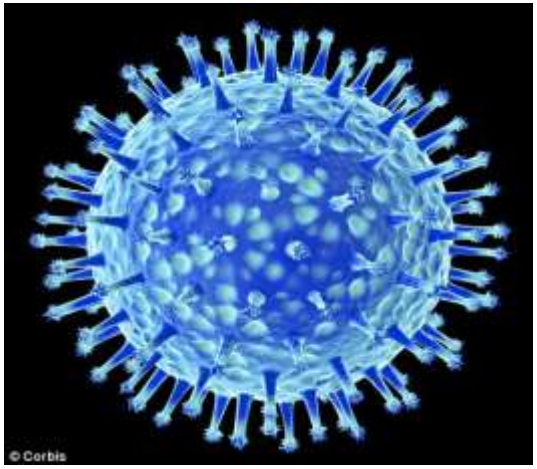
Examples



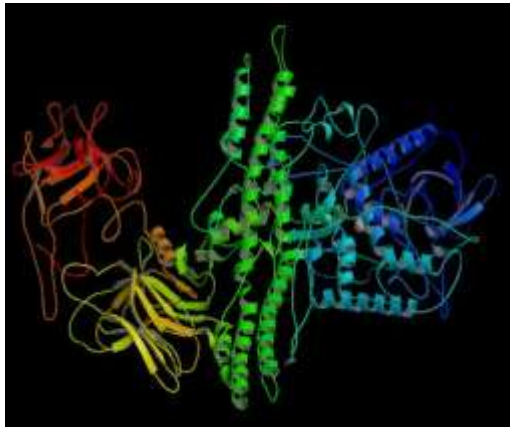
Expanded Host Range of *Listeria monocytogenes* (2007)



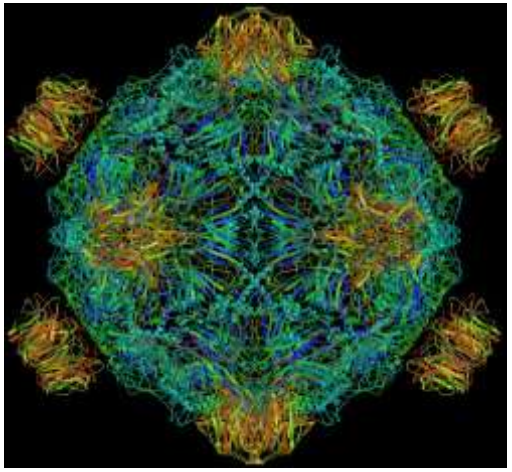
A More Lethal Mousepox (2003)



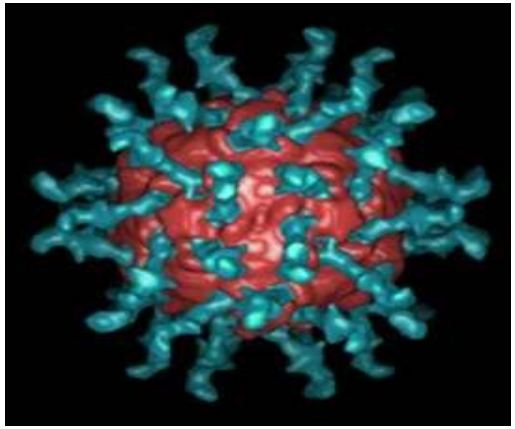
Synthetic Polio Virus from Mail-Order Kits (2002)



Modeling potential effects of Botulinum neurotoxin in the milk supply (2005)



Virus Built from Scratch in 2 Weeks (2003)



Highly pathogenic Avian Influenza Virus (2011)

OVERSIGHT OF DUAL USE RESEARCH OF CONCERN

Oversight of DURC

- **The dual use potential of certain life sciences research has been recognized as an important biosecurity issue for a number of years**
- **Managing the risks associated with DURC is a responsibility shared by:**
  - **Researchers**
  - **Journal editors and publishers**
  - **Institutional officials**
  - **Local oversight bodies**
  - **The Federal government**

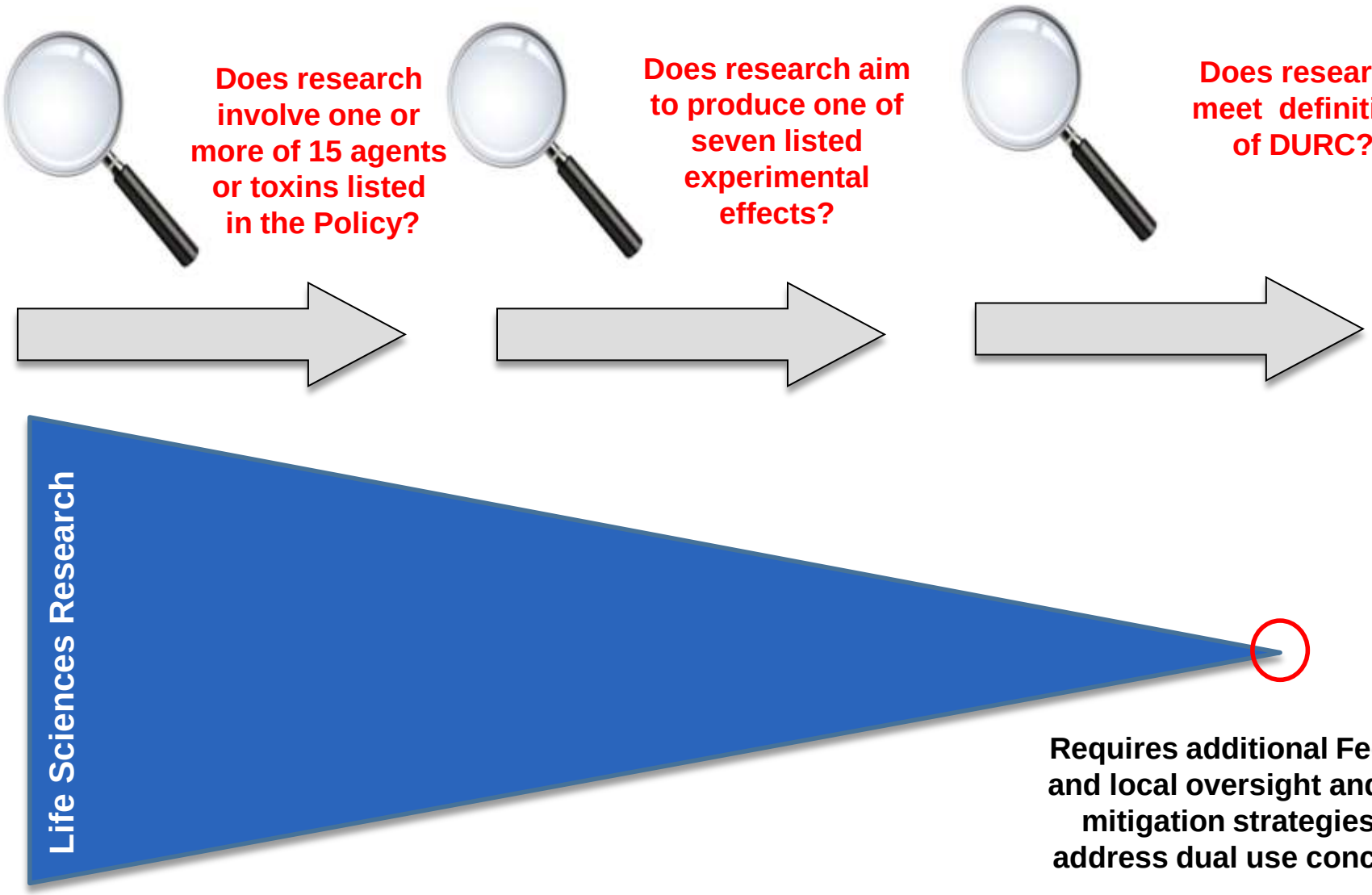
US Government Policies for DURC Oversight

- There are two US Government policies that address the oversight of life sciences DURC.
  - The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012)
  - The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research Of Concern (September 2014)
- Available at www.phe.gov/s3/dualuse

US Government Policies for DURC Oversight

- **These policies:**
  - **Aim 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; and**
  - **Complement existing regulations and policies governing the safe and secure use of pathogens and toxins**
- **Whereas the March 2012 policy describes the responsibilities of Federal agencies, the September 2014 policy primarily describes the responsibilities of institutions**

Research Subject to the Policies



The US Government Policy for Oversight of Life Sciences DURC (March 2012)

- **Requires Federal departments and agencies to review their research portfolios, both intramural and extramural, to:**
  - **Identify all research under the policy with DURC potential**
  - **Mitigate the risks posed by any DURC identified**

The USG Policy for Institutional DURC Oversight (September 2014)

- **Institutional oversight of DURC is a critical component of a comprehensive oversight system that involves:**
  - **Principal Investigators (PIs)**
  - **Institutional Review Entity (IRE)**
  - **Institutional Contact for Dual Use Research (ICDUR)**
  - **Institution**
  - **United States Government (USG)**

The USG Policy for Institutional DURC Oversight

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, 2018

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

All provisions in this Policy supersede those contained in the previous draft policy published on February 22, 2013 (Federal Register 78 (36): 12383-12372). 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/oversight-policy-032812.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.

Federal Register / Vol. 79, No. 186 / Thursday, September 25, 2014 / Notices 57589

The Establishment Information Form, the Wage Data Collection Form, and the Wage Data Collection Continuation Form are wage survey forms developed by OPM based on recommendations of the Federal Prevailing Rate Advisory Committee for use by the Department of Defense to establish prevailing wage rates for FWS employees Governmentwide.

Analysis

Agency: Employee Services, Pay and Leave Policy, U.S. Office of Personnel Management

Title: Establishment Information Form (ID 10H1E, Wage Data Collection Form (ID 10H1F, and Wage Data Collection Continuation Form (ID 10H1C)

OMB Number: 3206-0036

Frequency: Annually

Affected Public: Private Sector Establishments

Number of Respondents: 21,708

Estimated Time per Respondent: 1.5 hours

Total Burden Hours: 32,648

U.S. Office of Personnel Management.
Katherine Archuleta,
Director.

OFFICE OF PERSONNEL MANAGEMENT

Civil Service Retirement System and Federal Employees Retirement System; Notice to Surviving Same-Sex Spouses of Deceased Federal Annuitants, Employees, or Former Employees Who Died Prior to June 26, 2013

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: On August 2, 2013, the Office of Personnel Management (OPM) published notice in the **Federal Register** informing annuitants that they had an extended opportunity until June 26, 2015, to elect survivor annuity benefits for their same-sex spouses if they had been married prior to the U.S. Supreme Court's decision in *United States v. Windsor*, 133 S.Ct. 2675 (2013), on June 26, 2013, and were prevented by the Defense of Marriage Act (DOMA), 1 U.S.C. 7(3)(1996), from making a timely election. See 78 FR 47018 (Aug. 2, 2013). Similarly, because annuitants, employees, or former employees in same-sex marriages may have died prior to the *Windsor* decision (i.e. prior to June 26, 2013), and because the same-sex spouses of those deceased annuitants, employees, and former employees may not have applied for death benefits because of DOMA, or may have applied for death benefits but were denied benefits because of DOMA, OPM is publishing this notice to inform those surviving same-sex spouses that they may apply for (re-apply) for death benefits so that OPM can evaluate whether or not those same-sex spouses may now be entitled to survivor annuity or lump-sum death benefits.

FOR FURTHER INFORMATION CONTACT: Roxanne Johnson, (202) 606-0299.

SUPPLEMENTARY INFORMATION: On June 26, 2013, the United States Supreme Court (the Supreme Court) held in *United States v. Windsor*, 133 S.Ct. 2675 (2013), that Section 3 of the Defense of Marriage Act (DOMA), 1 U.S.C. 7(3)(1996), was unconstitutional. Section 3 of DOMA provided that, when used in a federal law, the term "marriage" would mean only a legal union between one man and one woman as husband and wife, and that the term "spouse" referred only to a person of the opposite sex who is a husband or a wife. Therefore, as a result of DOMA, OPM was not permitted to accept survivor annuity elections for same-sex spouses from retirees from September 27, 1996, until June 25, 2013. OPM also denied eligible same-sex surviving spouses monthly survivor annuity and/or lump-sum death benefits, and/or may have discouraged employees, annuitants, and/or surviving spouses from electing a survivor annuity benefit and/or applying for benefits during that period. After the U.S. Supreme Court held that DOMA was unconstitutional, however, OPM was able to extend benefits to surviving same-sex spouses of deceased federal annuitants, employees, and former employees under the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS), even if the annuitants, employees, and former employees had died before June 26, 2013.

Therefore, in order to ensure that surviving same-sex spouses of deceased federal annuitants, employees, or former employees who died prior to the *Windsor* decision on June 26, 2013, are able to exercise their rights and interests as "widows" and "widowers" under CSRS and FERS, OPM is providing this notice to inform those surviving same-sex spouses how they may apply for survivor annuities and/or lump-sum death benefits. OPM also wants to make clear that surviving same-sex spouses of deceased annuitants who died prior to June 26, 2013, may apply for benefits even if the annuitants did not attempt to elect survivor annuity benefits for their spouses prior to death, and/or even if OPM has previously denied applications for benefits from surviving spouses as a result of DOMA.

How To Apply For Benefits: If you are a same-sex spouse of a deceased federal employee or annuitant whose spouse died before June 26, 2013, you may submit an application for death benefits (Standard Form (SF) 2800 for CSRS and SF 3104 for FERS) to OPM at this address: Office of Personal Management, Survivor Benefits Window Decision, P.O. Box 45, Boyers, PA 16017–0045.

Surviving spouses may download these applications from OPM's Web site at http://www.opm.gov/forms/standard-forms/, or may call OPM's Retirement Information Office at 1–(888)–767–6738, or may send an email to retire@opm.gov to request an application for benefits. Please include "Survivor Benefits Window Decision" in the subject line of the email.

When a same-sex surviving spouse submits an application for death benefits or contacts OPM for information regarding eligibility for benefits, the surviving spouse should inform OPM that s/he is a same-sex spouse of a deceased annuitant, federal employee or former federal employee who died prior to June 26, 2013. The surviving spouse should also send OPM a copy of the couple's marriage certificate and a copy of the annuitant's death certificate if OPM has not already received these documents. Additionally, the surviving spouse should provide OPM with the deceased federal employee's name, date of birth, and the annuitant's CSA/CSF number or social security number to expedite processing of the claim.

Office of Personnel Management.
Katherine Archuleta,
Director.

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice Response to Comments and Notice of Final Action Regarding the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

SUMMARY: On February 22, 2013, the Office of Science and Technology Policy (OSTP) published a 60-day public notice in the **Federal Register** (**Federal Register** Volume 78, Number 36, Docket No. 2013–04127) to invite public

www.phe.gov/s3/dualuse

Overview of the Process for Institutional DURC Oversight

PI identifies research that involves any of the 15 listed agents

↓

Institutional Review Entity (IRE):

- **Determines whether the research involves any of the 7 experimental effects;**
- **If so, conducts a risk assessment to determine whether the research is DURC; and**
- **If so, weighs the risks and benefits and develops a draft risk mitigation plan**

↓

USG funding agency finalizes and approves risk mitigation plan

↓

Institution implements approved risk mitigation plan and provides ongoing oversight

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PI conducts and communicates research according to risk mitigation plan

Entities Subject to the Institutional DURC Oversight Policy

- **Federal departments and agencies that fund or conduct life sciences research**
- **Institutions within the United States that:**
  - **Receive Federal funds to conduct or sponsor life sciences research; and**
  - **Conduct or sponsor research that is subject to the Policy, regardless of source of funding**
- **Institutions outside of the United States that receive Federal funds to conduct or sponsor research subject to the Policy**

What Research is Subject to the Policy?

- **Research that uses one or more of the agents or toxins listed in the Policy to discern if it:**
  - **Produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects**

What Research is Subject to the Policy?

- **Research that directly involves any of the following 15 agents and toxins***
  - Avian influenza virus (highly pathogenic)
  - *Bacillus anthracis*
  - Botulinum neurotoxin (in any quantity)
  - *Burkholderia mallei*
  - *Burkholderia pseudomallei*
  - Ebola virus
  - Foot-and-mouth disease virus
  - *Francisella tularensis*
  - Marburg virus
  - Reconstructed 1918 Influenza virus
  - Rinderpest virus
  - Toxin-producing strains of *Clostridium botulinum*
  - Variola major virus
  - Variola minor virus
  - *Yersinia pestis*

* Except attenuated strains of the agents that are excluded from the Select Agent list and inactive forms of botulinum neurotoxin

What Research is Subject to the Policy?

- **Experimental effects**
  - **Enhances the harmful consequences of the agent or toxin**
  - **Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification**
  - **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**
  - **Increases the stability, transmissibility, or the ability to disseminate the agent or toxin**
  - **Alters the host range or tropism of the agent or toxin**
  - **Enhances the susceptibility of a host population to the agent or toxin**
  - **Generates or reconstitutes an eradicated or extinct agent or toxin listed in the policy**

Determine if the Research Meets the Definition of DURC

If the research with any of the 15 agents involves any of the 7 experimental effects, conduct a risk assessment to determine if it meets the following definition:

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.

Risk Assessment and Risk Mitigation

- For projects that are determined to meet the definition of DURC, the IRE must develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures

Management of DURC-Associated Risks

- **DURC risk mitigation strategies may include:**
  - **Changing the design or conduct of the research or not conducting certain aspects of DURC**
  - **Applying specific biosecurity and/or biosafety measures**
  - **Developing a plan for monitoring the research for findings with additional DURC potential**
  - **Developing plan for responsibly communicating the results of DURC**
  - **In rare instances, when appropriate, restricting communication of experimental details or other specific information**

KEY RESPONSIBILITIES OF INSTITUTIONS

Key Responsibilities of Institutions

- **Establish and implement policies and practices for identification and oversight of DURC that include:**
  - **Establishing an IRE**
  - **Ensuring appropriate review of research with DURC potential**
  - **Assessing the potential risks and benefits associated with DURC**
  - **Developing and implementing risk mitigation plans, as necessary**

Key Responsibilities of Institutions

… continued

- Ensuring compliance with the Policy and approved risk mitigation plans
- Ensuring periodic review and updating of risk mitigation plans
- Providing education and training on DURC
- Assisting investigators when questions arise regarding research that may be subject to the Policy

Key Responsibilities of Institutions

- **Notify USG funding agencies of:**
  - **Research reviewed by the IRE that involves one of the seven experimental effects, including whether the research is determined to be DURC**
  - **Instances of noncompliance with the Policy**
  - **Proposed risk mitigation plans for research determined to be DURC**
  - **Changes in status of DURC or modification to risk mitigation plans**

KEY RESPONSIBILITIES OF INVESTIGATORS

Key Responsibilities of Investigators

- Identify and refer to the IRE all research involving one or more of the agents or toxins listed in the Policy, along with an assessment of whether the research involves any of the seven listed experimental effects
- Work with the IRE to assess the dual use risks and benefits of the research in question and develop risk mitigation measures

Key Responsibilities of Investigators

- Conduct DURC in accordance with the risk mitigation plan
- Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC
- Continue to assess research to determine if, at any time, the research becomes subject to the policy

Key Responsibilities of Investigators

- **Ensure that laboratory personnel (e.g. graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting research with any of the 15 listed agents have received education and training on DURC**

- **Communicate DURC in a responsible manner, throughout the research process, not only at the point of publication**
  - **Ensure that communication is in compliance with the risk mitigation plan approved by the appropriate Federal funding agency**

KEY RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW ENTITY (IRE)

Key Responsibilities of the IRE

- **Be composed of at least 5 members, including persons with knowledge of US government policies and sufficient range of expertise to assess the dual use potential of research conducted at that institution**
- **Review of research identified by PIs:**
  1. **Verification that the research involves one or more of the 15 listed agents**
  2. **Review of the PIs assessment and final determination of whether the research meets any of the seven experimental effects**
  3. **When appropriate, make a determination of whether the research meets the definition of DURC**

Key Responsibilities of the IRE

- **For research determined to be DURC, the IRE:**
  - **Consider the risks and benefits of conducting the research**
  - **Works with the appropriate Federal funding agency to develop a risk mitigation plan**
  - **Reviews the risk mitigation plan at least annually and modifies the plan, as warranted**

KEY RESPONSIBILITIES OF THE INSTITUTIONAL CONTACT FOR DUAL USE RESEARCH (ICDUR)

Key Responsibilities of the ICDUR

- **Serve as institutional point of contact for questions regarding compliance with and implementation of the requirements for the DURC oversight policies**
- **Serve as liaison between the institution and the relevant USG funding agency**
- **Consult with the relevant USG funding agency when the institution seeks advice on matters related to DURC**

KEY RESPONSIBILITIES OF US GOVERNMENT FUNDING AGENCIES

Key Responsibilities of US Government Funding Agencies

- Require policy implementation at all institutions subject to the Policy.
- When notified by an institution of research meeting the scope of the Policy:
  - Notify the institution when the USG funding agency disagrees with any part of the IRE's review outcome
  - For research determined to be DURC, work with the institution to finalize a risk mitigation plan
  - Respond to questions from institutions regarding DURC oversight and compliance with the Policy
- Respond to reports of non-compliance and work with the institution to address such non-compliance

KEY RESPONSIBILITIES OF THE US GOVERNMENT

Key Responsibilities of the US Government

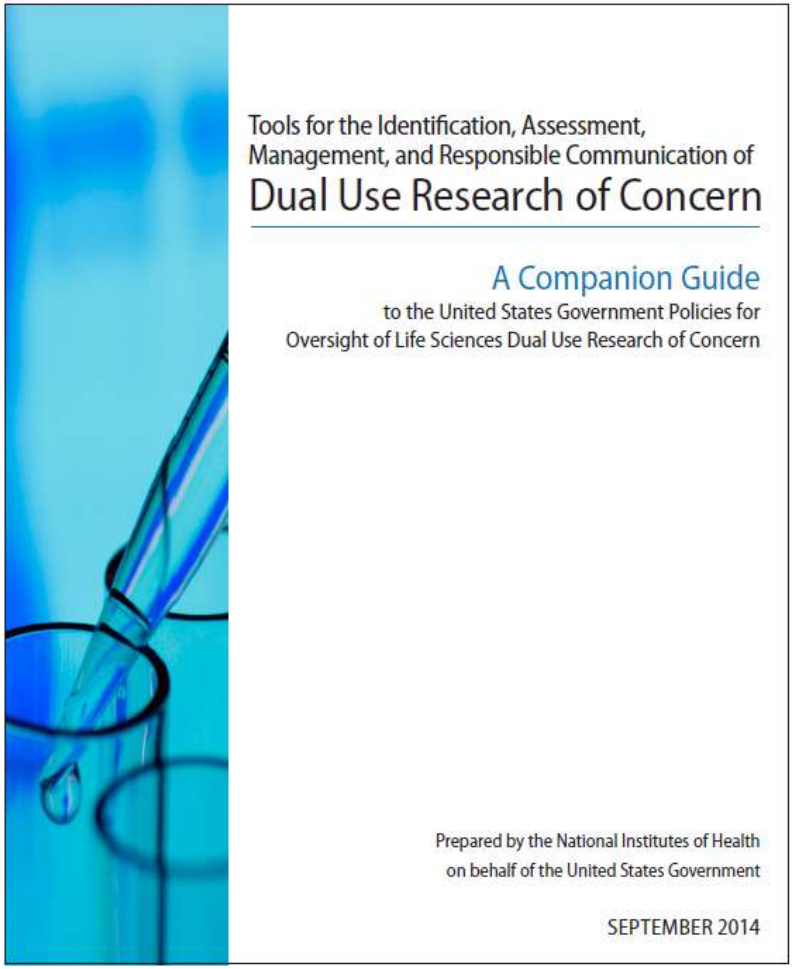
- Provide guidance to institutions regarding review, management, and responsible communication of DURC
- Develop training tools and materials for use by the USG agencies and institutions implementing the Policy
- Provide education and outreach to stakeholders about dual use policies and issues
- Assess periodically the impact of the Policy on life sciences research programs and, as appropriate, update the Federal and institutional dual use research oversight policies

RESOURCES AND EDUCATIONAL MATERIALS

Resources and Educational Materials

- **Companion Guide**
  - A compendium of tools to assist investigators and research institutions in the implementation of DURC oversight
- **Case Studies**
  - Provide a range of examples of research that is subject to the policy and demonstrate the type of analysis that should be brought to bear during institutional reviews
- **These tools promote the:**
  - understanding and identification of DURC
  - risk assessment and development of risk mitigation plans and risk management processes
  - responsible communication of DURC, and training and education on DURC

Companion Guide

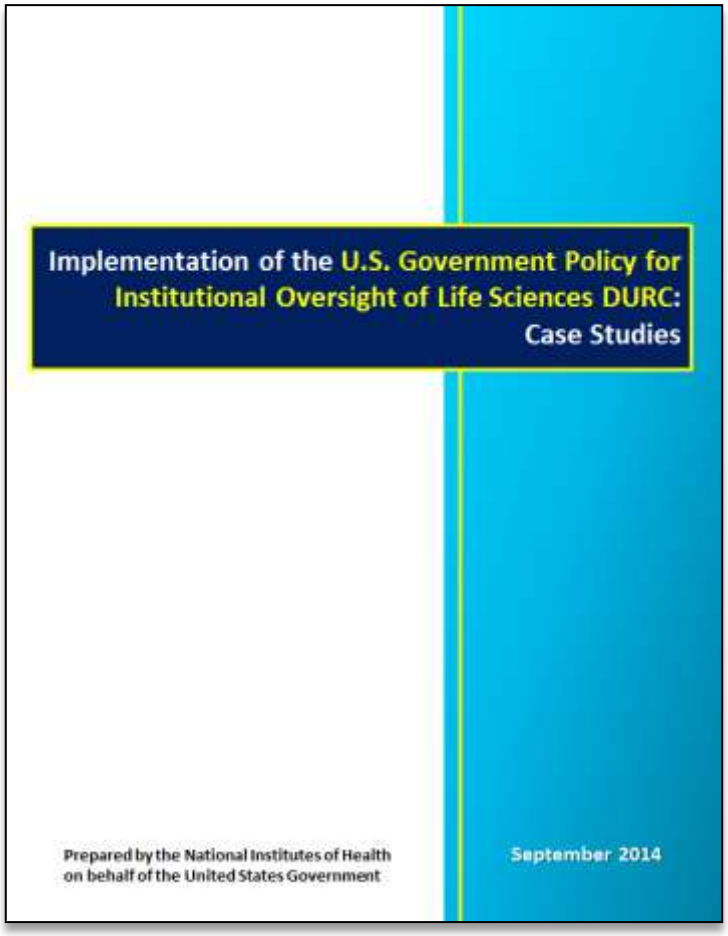


Available at: www.phe.gov/s3/dualuse

Companion Guide

- **The Companion Guide includes:**
  - **Frequently asked questions regarding US Government DURC oversight policies**
  - **Guidance for PIs on identification and assessment of research that requires institutional review**
  - **Guidance for IREs on conducting institutional review, including risk assessments and drafting and review of risk mitigation plans**
  - **Guidance to all audiences on responsible communication of DURC**
  - **Templates (optional) for institutions to use in fulfilling policy requirements**

Case Studies

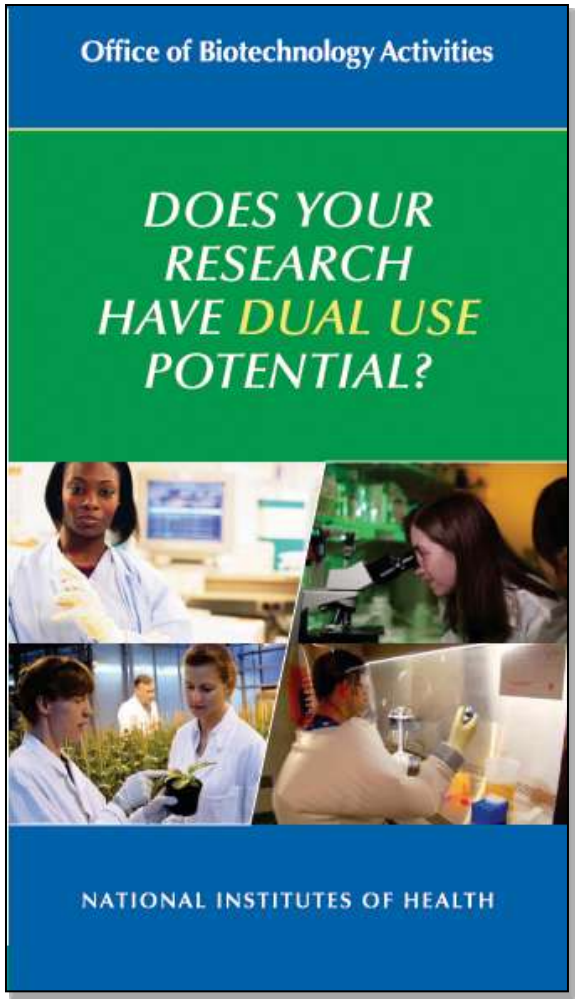


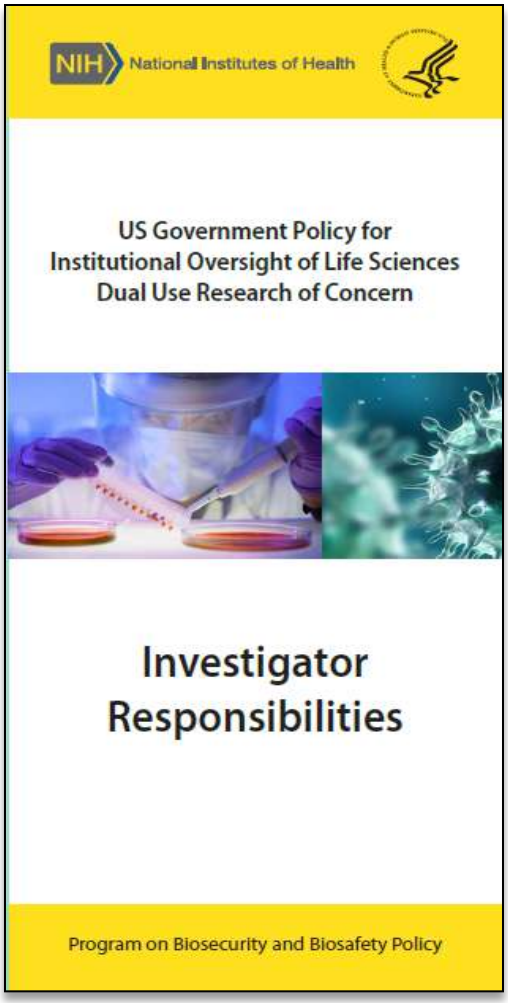
Available at www.phe.gov/s3/dualuse

Educational Video

Available on YouTube:
http://www.youtube.com/watch?v=0yS1ur24j40

Investigator Brochures





To request copies email: PBBP@od.nih.gov

Poster

To request copies email: PBBP@od.nih.gov

Additional Information

- **Information about dual use research in the life sciences as well as specific details on the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern can be found at:**

www.phe.gov/s3/dualuse

Implementation Questions

- **Questions about implementing the Policy may be sent to:**

DURC@ostp.gov

Contact PPBP

Program on Biosecurity and Biosafety Policy
Office of the Director
National Institutes of Health
Suite 750
6705 Rockledge Drive,
Bethesda, MD 20892-7985

Phone (301) 496-9838
Fax (301) 496-9839

PBBP@od.nih.gov

Questions