Dual Use Research of Concern: Policy Update

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Dual Use Overview

- What is “dual use” research?
- USG Federal policy for oversight of life sciences dual use research of concern (March 2012)
- Issuance of a proposed policy for institutional oversight of dual use research
- Educational materials for institutions and investigators

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

DUR vs. DURC

- **Dual use research (DUR) = legitimate research that yields information or technologies that could be misused for malevolent purposes**
  - **NOTE: Most life sciences research conceivably could be considered DUR in that it has *some* potential to generate information that could be eventually misused**
- **Need to identify the subset that has highest potential for generating information that could be readily misused = DUR *of concern* (DURC)**

DURC 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.

Oversight of DURC

- All levels of the research continuum must be involved (e.g. Funding agencies, institutions, investigators)
- Goal of oversight
- Federal and Institutional oversight of DURC
  - Complimentary Process
- USG Policy (March 29, 2012)
- Proposed Institutional Policy

“It takes a village”

- To deal with the issue of dual use effectively:
  - Responsibility must be shared among researchers, publishers, institutional officials, local oversight bodies, and the Federal government

USG Policy on Oversight of DURC

- Issued by the USG on March 29, 2012

- Purpose: To establish regular review of USG funded or conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to:

  - mitigate risks where appropriate; and
  - collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC

USG Policy on Oversight of DURC

- **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.**

- **Complements existing regulations and policies governing the possession and handling of pathogens and toxins.**

- **Will be updated, as needed, following domestic dialogue, engagement with international partners, and input from interested communities**

USG Responsibilities

- **Department and Agency Responsibilities**
  - **Conduct a review to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of the policy.**
  - **Determine which, if any, of the projects identified meet the definition of DURC.**
  - **Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.**
  - **Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures.**

USG Policy Scope

Covered Agents and Toxins:

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*

Note - These agents and toxins are a subset of those regulated by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73), and have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.

USG Policy Scope

Categories of Experiments:

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; or
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed

USG Policy Scope

DURC 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.

Step 1:
Apply the List of 15 Select Agents and Toxins

Step 2:
Apply 7 Listed Effects

Step 3:
Apply Dual Use of Concern Criteria

Federally Funded Life Sciences Research

Requires additional Federal and local oversight and risk mitigation strategies to address dual use concerns

Risk Assessment

- For projects that fall within the scope and that are determined to meet the definition of DURC, departments and agencies will:
  - Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk
  - Develop, in collaboration with the institution or researcher, a risk mitigation plan to apply any necessary and appropriate risk mitigation measures

Risk Mitigation Strategies

Management of DURC may entail a variety of possible strategies, for example:

- **Changes in the design or conduct of research**
- **Applying specific biosecurity and/or biosafety measures**
- **Monitoring of research for findings with additional DURC potential**
- **In some rare instances, it may be appropriate to restrict communication of experimental details or other specific information**

Proposed Institutional Policy on Oversight of DURC

- Published in *Federal Register* February 22, 2013

- Proposed Policy has seven elements
  - Introduction
  - Purpose
  - Guiding Principles
  - Definitions
  - Policy Statement
  - Applicability and Scope of the Policy
    - *scope is same as March 29, 2012 USG Policy*
  - Organizational Framework for Oversight

Responsibilities of Institutions Under Proposed Policy

- Establish and implement internal policies and practices for identification and oversight of DURC
- Establish an institutional oversight process that:
  - Ensures appropriate review of research with DURC potential
  - Assesses the potential risks and benefits associated with DURC
  - Develops and implements risk mitigation plan, as necessary
  - Ensures compliance with the institution's dual use research policies
- Establish a mechanism for PIs to refer a project for institutional review if, at any time, the work comes under the proposed scope.

Responsibilities of Institutions Under Proposed Policy

- Provide education and training on DURC
- Periodically assess the effectiveness and impact of institution's policies for DURC oversight.
- Establish a mechanism for PIs to appeal the assessment of DURC.
- Ensure periodic review and updating of any risk mitigation plans developed by the IRE.
- As necessary, assist the PIs when questions arise about whether the research requires further review or oversight.

Responsibilities of Institutions Under Proposed Policy

- Consult the Federal funding agency for guidance on assessing risks or developing a risk mitigation plan.
- Promptly inform Federal agencies funding the research of:
  - Research reviewed for DURC potential
  - Research determined to be DURC
  - Instances of noncompliance with the Policy
  - The risk mitigation plans for research determined to be DURC
- On an annual basis, provide a formal assurance to the Federal funding agencies that the institution is in compliance with all aspects of the Proposed Institutional Oversight Policy
  - Maintain records of formal assurances

Responsibilities of Principal Investigators Under Proposed Policy

- Assess work on an ongoing basis to identify whether it involves any of the 15 listed agents or toxins
- Work with the IRE to develop risk mitigation plans where appropriate
- Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC
- Ensure that lab personnel conducting DURC receive education and training.
- Conduct and communicate DURC responsibly

Responsibilities of Funding Agencies Under Proposed Policy

- Ensure the implementation of the Policy for all life sciences research funding by the agency.
- Respond to questions from institutions regarding DURC oversight and provide guidance to institutions regarding compliance.
- For funded and proposed life sciences research that involves one or more of the 15 listed agents and toxins:
  - Assess whether the research produces, aims to produce, or can be reasonably anticipated to produce one or more of the 7 listed experimental effects, and
  - Assess whether the research meets the definition of DURC.
- Respond to reports of non-compliance with the Policy.
- Serves as the review entity for low-resourced, USG-funded research taking place abroad.

Responsibilities of USG Under Proposed Policy

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

Public Comment

- All stakeholders are encouraged to comment on this proposal
- Comments must be received by April 23, 2103
- FR Notice contains 16 specific questions that the USG is seeking input on

Federal Register (February 22, 2013)
https://federalregister.gov/a/2013-04127

Public Comment - Specific Questions

- *Question 1*: What is the feasibility and anticipated burden of proposed policy?
- *Question 2:* Are there alternatives to the administrative requirements of the proposed policy that could be more easily implemented yet still meet the intent of the Federal and proposed institutional policy?
- *Question 3*: How would oversight be integrated with other existing institutional oversight processes in order to reduce duplication or administrative burden?
- *Question 4*: What are the benefits and limitations of an IBC conducting the DURC review?

Public Comment - Specific Questions

- *Question 5*: Should research reviewed and found not to be DURC be monitored for emerging DURC issues? If so, who often?
- *Question 6*: Is it feasible for a single institutional official to be the point of contact for all Dual Use Research related questions to and from funding agencies? If not, who could help fill this role?
- *Question 7*: Should a PI make the determination for only the first part of the DURC analysis or the first two parts of the DURC analysis?
- *Question 8*: Is additional guidance needed for interpreting the seven effects/categories listed in the policy?

Public Comment - Specific Questions

- *Question 9*: What additional tools or guidance would be useful in implementing and complying with the proposed policy?
- *Question 10*: Are there any potential conflicts or challenges posed by implementing both the March 29 Federal policy and the proposed institutional policy?
- *Question 11*: Should the policy include attenuated forms of the 15 listed agents? The use of any genes from the 15 listed agents? *In silico experiments involving the 15 agents (bioinformatics, etc.)? Research related to public, animal, and agricultural health impact of any of the 15 listed agents* (i.e. modelling effects of a toxin, vaccine delivery, etc.)?

Public Comment - Specific Questions

- *Question 12*: Is the scope of the proposed policy appropriate?
- *Question 13*: For institutions that review experiments beyond the scope of the proposed policy (i.e. more than the 15 agents or 7 effects listed), what other agents or toxins or other categories of experiments would be considered by the institution
- *Question 14*: For an investigator conducting potential DURC at multiple institutions, which institution should have oversight? One institution? Each institution?
- *Question 15*: Is the approach listed in the proposed policy regarding oversight for non-Federally funded research appropriate?
- *Question 16*: What is the appropriate amount of time institutions should be required to maintain their DURC records?

Next Steps

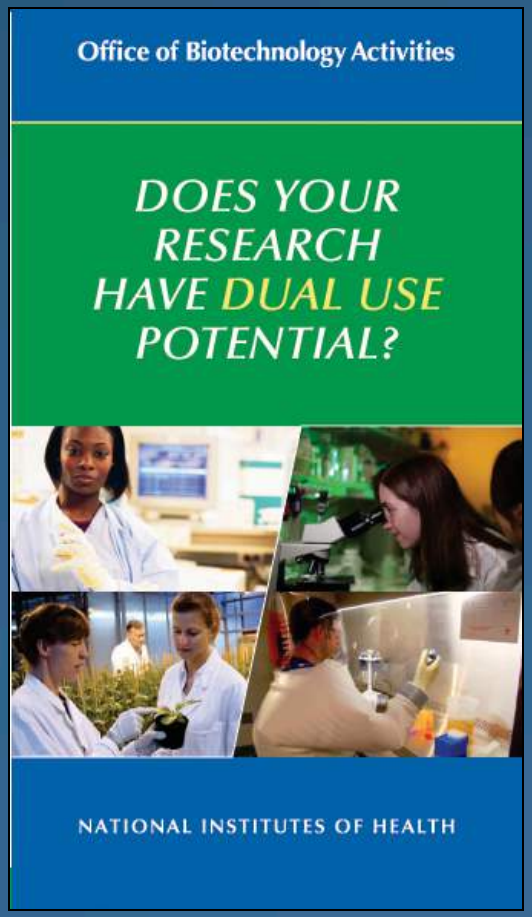
- Collect and assess public comments received on the proposed institutional policy
- Modify the proposal as necessary
- Issue final policy

Dual Use Research Educational Resources

Educational DVD

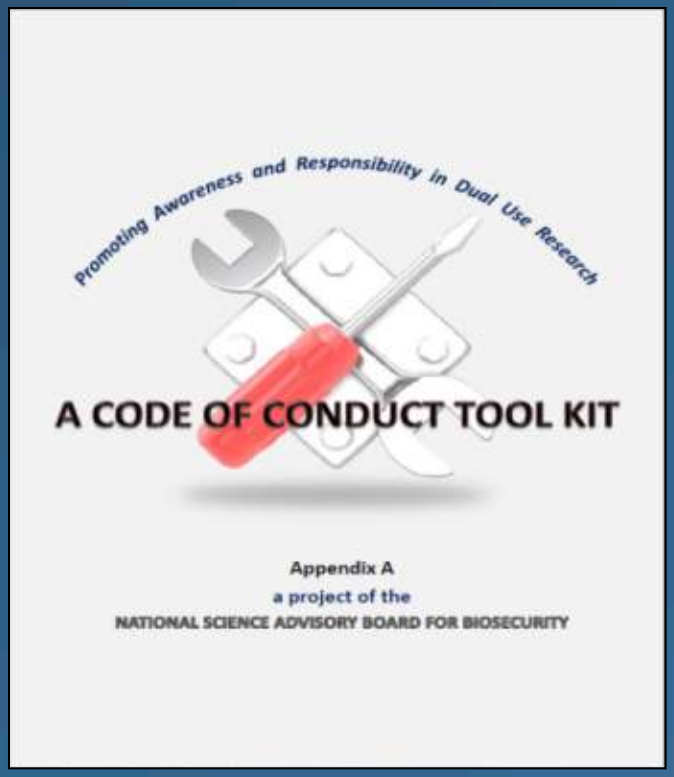
Available on YouTube and http://oba.od.nih.gov/ biosecurity/biosecurity.html

Dual Use Research Educational Resources

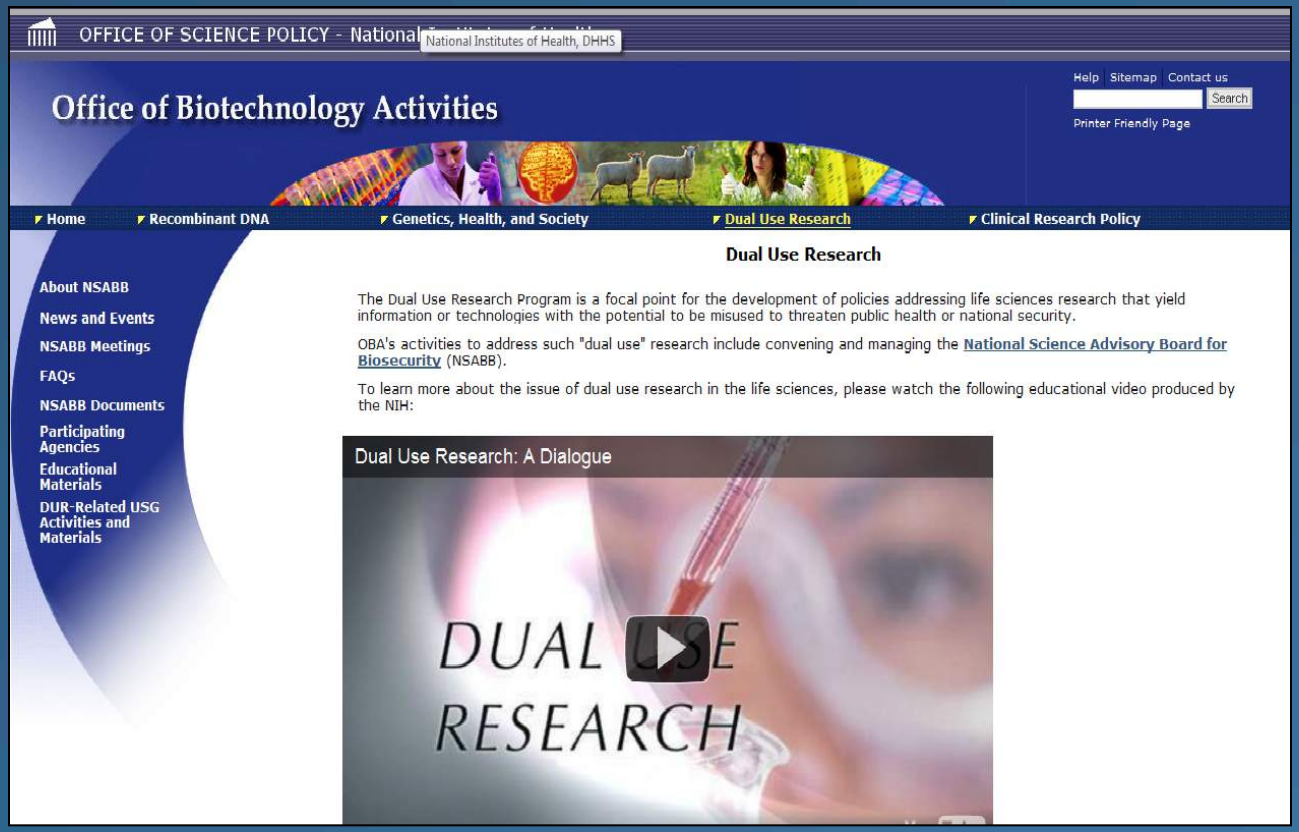


Investigator Brochure

Dual Use Research Educational Resources



Dual Use Research Educational Resources



http://oba.od.nih.gov/ biosecurity/biosecurity.html

Questions