

# Dual Use Research of Concern Program

## University of Wyoming

### September 2015

The University of Wyoming developed this Program to comply with the *United States Government Policy for Institutional Dual Use Research of Concern Oversight* of September 2014 (*Policy for Institutional DURC Oversight*). This policy compliments *The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012 DURC Policy)*.

Dual Use Research of Concern (DURC) is 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.

#### Scope of Research Requiring Oversight

Consistent with the *March 2012 DURC Policy*, under this Policy, research will be evaluated for DURC potential if it uses one or more of the fifteen listed agents or toxins and produces, and aims to produce, or can be reasonably anticipated to produce one or more of the seven listed effects (see below).

#### Agents and Toxins

The 15 agents and toxins listed in this Program are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products.

- Avian influenza virus (highly pathogenic)
- Bacillus anthracis*
- Botulinum neurotoxin (no exempt quantities)
- 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*

#### 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
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

The Biosafety Specialist will serve as the Institutional Contact for Dual Use Research.

Key Responsibilities:

1. Serve as institutional point of contact for questions regarding compliance with and implementation of the requirements for the DURC oversight policies
2. Serve as liaison between the institution and the relevant USG funding agency
3. Consult with the relevant USG funding agency when the institution seeks advice on matters related to DURC.
4. Maintain records as required by the *Policy for Institutional DURC Oversight*.

The UW Institutional Biosafety Committee (IBC) will serve as the Institutional Review Entity (IRE) for DURC oversight. The IBC will follow the requirements of an IRE as described in *The Policy for Institutional DURC Oversight*.

Key Responsibilities:

1. Verify and review research identified by the PI research for DURC potential.
2. Conduct risk assessments, develop risk mitigation plans, and notify U.S. Government funding agencies as required.
3. Monitor DURC research and review at least annually risk mitigation plans.

Principle Investigator (PI) Responsibilities:

1. Identify and refer to the IBC 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.
2. Work with the IBC to assess the dual use risks and benefits of the research in question and develop risk mitigation measures.
3. Conduct DURC in accordance with the risk mitigation plan.
4. Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC.
5. Continue to assess research to determine if, at any time, the research becomes subject to the policy.
6. 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.
7. Communicate DURC in a responsible manner, throughout the research process, not only at the point of publication.
8. Ensure that communication is in compliance with the risk mitigation plan approved by the appropriate Federal Funding agency.

## Responsibilities and Review Process for the UW Institutional Biosafety Committee:

### 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. Make a determination of whether 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 DURC definition.

### For research determined to be DURC, the IBC will

1. Consider the risks and benefits of conducting the research
2. Works with the appropriate Federal funding agency to develop a risk mitigation plan
3. Reviews the risk mitigation plan at least annually and modifies the plan, as warranted.

### Risk Assessment and Risk Mitigation

For projects that are determined to meet the definition of DURC, the IBC 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:

1. Changing the design or conduct of the research or not conducting certain aspects of DURC.
2. Applying specific biosecurity and/or biosafety measures.
3. Developing a plan for monitoring the research for findings with additional DURC potential.
4. Developing plan for responsibly communicating the results of DURC.
5. In rare instances, when appropriate, restricting communication of experimental details or other specific information.

### Process Overview

The PI notifies the IBC of planned research with potential DURC. Once the IBC makes the determination whether or not the research warrants DURC oversight, UW will notify the United States Government (USG) funding agency within 30 days. If DURC is verified, the IBC will work with the funding agency to develop the draft risk mitigation plan. UW will then have 90 days from the time of the IBC's determination to complete the draft mitigation plan. Once submitted, the funding agency will have 60 days to finalize the draft mitigation plan. After being finalized, UW will implement the approved risk mitigation plan. The PI may conduct and or communicate research according to the risk mitigation plan. The IBC will review the risk mitigation plan at least annually and modify it as warranted.

## Process Steps for DURC Review (Instructions)

Use templates and guidance located in this document's appendix from *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern. A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern*. September 2014.

1. PI notifies the IBC as soon as (use "Template for Notifying the IRE of Research That Requires Institutional Review"):
  - a. PI's research involves any of the agents listed, and/or
  - b. PI's research with one or more of the above agents also produces or can be reasonably anticipated to produce one or more of the effects listed, and/or
  - c. PI's research that may meet the definition of DURC.
2. Institution identifies whether USG funding agency has notified the institution that the research is DURC under the *March 2012 DURC Policy*.
  - a. If so, Institution implements approved risk mitigation plan and provides ongoing oversight of DURC (proceed to 4.d.).
  - b. If not proceed to 3.
3. IBC verifies that the research involves any of the listed agents, reviews PI's assessment, and makes final determination of the applicability of the list of experimental effects. (Use "Template for Assessment by the IRE of Research for DURC Potential").
  - a. If not verified, IBC notifies PI.
  - b. If verified, then IRE conducts a risk assessment to determine whether the research meets the definition of DURC.
  - c. Institution notifies appropriate USG funding agency of outcome within 30 calendar days (use Template for 30-Day Reporting).
4. If the research requires DURC oversight,
  - a. IBC considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan. (Use the *Companion Guide*, Section D for guidance.)
  - b. Institution works with the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE's determination that the research is DURC
  - c. USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan.
  - d. Institution implements approved risk mitigation plan and provides ongoing oversight of DURC. (Use section E of the *Companion Guide* for guidance.)
  - e. PI conducts and or communicates research according to risk mitigation plan.

## References

*United States Government Policy for Institutional Dual Use Research of Concern Oversight of September 2014 (Policy for Institutional DURC Oversight).*

<http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

*The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012 DURC Policy).*

<http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>

*Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern. A Companion Guide to the United States Government Policies for Oversight of Life Science Dual Research of Concern.* September 2014.

<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>

## Appendix

*Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern. A Companion Guide to the United States Government Policies for Oversight of Life Science Dual Research of Concern.* September 2014.

Templates in the *Companion Guide* have fillable form fields.

<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>