MONTANA STATE UNIVERSITY Office of Research Compliance

Dual Use of Research of Concern Policy

Introduction

Life science research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. This type of research is defined as dual use research. The United States Government (USG) has adopted a policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC). This policy defines DURC as:

"Life science 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.

This policy is designed to effectively capture the requirements of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The effective oversight of DURC is based on identifying research that involves dual use and its associated risks, then devising ways to mitigate these risks. Under the USG's policy, DURC oversight is the responsibility of Montana State University (MSU), which includes the principal investigators (PIs) and the Institutional Biosafety Committee (IBC). The IBC acts as MSU's Institutional Review Entity (IRE). The DURC policy covers research involving 1 (or more) of the 15 listed agents (see below). Research involving these agents must be assessed for whether the activity produces one or more of seven listed experimental effects (see below) thereby classifying it as DURC.

Research activities requiring DURC oversight

Research that involves any of the 15 listed agents and one or more of the seven categories of experiments listed below require DURC oversight.

DURC Listed Agents and Toxins

a. Avian influenza virus (highly pathogenic)
b. Bacillus anthracis
c. Botulinum neurotoxin
d. Burkholderia mallei
e. Burkholderia pseudomallei
f. Ebola virus
g. Foot-and-mouth disease virus
h. Francisella tularensis
i. Marburg virus
j. Reconstructed 1918 influenza virus
k. Rinderpest virus
l. Toxin-producing strains of *Clostridium botulinum*
m. Variola major virus
n. Variola minor virus
o. Yersinia pestis

Categories of experimental effects

a. Enhances the harmful consequences of the agent or toxin

b. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
c. 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
d. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
e. Alters the host range or tropism of the agent or toxin
f. Enhances the susceptibility of a host population to the agent or toxin
g. Generates or reconstitutes an eradicated or extinct agent or toxin listed above

Responsibilities of PIs

- Notify the IBC when the research involves one or more of the listed agents or toxins.
- Work with Biosafety Officer and IBC to determine if research produces one or more of the seven listed effects USG's risk assessment PI template (Institutional Policy Companion Guide Appendix 2).
- Work with the IBC to assess the dual use risks and develop risk mitigation measures.
- Conduct DURC in accordance with the provisions in the risk mitigation plan.
- Be knowledgeable of, and comply with, all institutional and USG policies and requirements for DURC oversight.
- Ensure that laboratory personnel conducting DURC have received education and training.
- Communicate DURC in compliance with the approved risk mitigation plan.

Responsibilities and Review Process of the IBC

During the initial IBC protocol review/assessment process, the IBC will determine if any of the PI's proposed work meets the criteria for DURC. If the IBC deems any research to fall under DURC oversight, the following steps will be implemented:

- Notify the PI that the proposed work meets the criteria for DURC.
- Conduct a risk assessment on the proposed research using USG's risk assessment template (Institutional Policy Companion Guide Appendix 3).
- Develop a risk mitigation plan for the identified DURC using USG's risk mitigation template.
- Provide education and training for individuals conducting DURC, as needed.
- Review all active risk mitigation plans at least annually. If the research still constitutes
- DURC, the IBC should modify the plan as needed.
- Act as the Institutional Contact for Dual Use Research (ICDUR) and point of contact for questions regarding compliance with, and implementation of the requirements.
- Maintain records of the institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years.

Strategies for Mitigating DURC Associated Risks

The IBC will determine whether existing biosafety and biosecurity measures are adequate or warrant additional biosafety and security measures.

Risk Mitigation Measures

- Consider changing the timing, mode, or venue of communication for DURC to outside entities.
- Establish a mechanism for pre-publication or pre-communication review by the institution and/or appropriate USG funding.

- Consider the need to redact specific information in light of security concerns.
- When communicating the DURC, emphasize the biosafety and biosecurity measures that were in place throughout the course of the research.
- Emphasize the public health or broader significance of the DURC. For example, describe specifically how the findings inform the development of countermeasures, disease surveillance, preparedness, and response efforts.
- Provide additional training that addresses risks or concerns that are unique to the DURC in question.
- Require that research staff receive refresher training on a more frequent basis rather than the required annual refresher training.
- Review the DURC in question at more frequent time intervals.

DURC Risk Mitigation Plan

Once the IBC makes the determination that research DURC oversight is warranted, MSU will notify the USG funding agency within 30 days using USG's template for reporting (Institutional Policy Companion Guide Appendix 4). The IBC will work with the funding agency to develop the draft risk mitigation plan. MSU will then have 90 days, from the time of the IBCs 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 MSU will implement the approved risk mitigation plan.