UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

INSTITUTIONAL OVERSIGHT POLICY FOR DUAL USE RESEARCH OF CONCERN

I. BACKGROUND

On September 24, 2014 the United States Government (USG) issued the USG Policy for Institutional Oversight of Life Sciences Dual Use research of Concern (DURC), http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf. This policy is complementary to the USG Policy for Oversight of Life Sciences DURC which was released on March 29, 2012, http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf. The institutional policy requires that institutions strengthen their review and oversight of life sciences research project that could meet the current definition of DURC.

Dual use research is defined by the USG as "research conducted for legitimate purposes that generate knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes". Dual use research of concern is a subset of this broader category. DURC is 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".

II. PURPOSE

The purpose of this plan is to strengthen the institutional review and oversight by the University of Colorado Denver ("University") of certain research to identify potential DURC and to develop and implement risk mitigation where appropriate. This Policy seeks to preserve the benefits of life sciences DURC research while minimizing the risk that the output of such research would be used for harmful purposes.

III. SCOPE

All research conducted at the University involving DURC agents is subject to this Policy regardless of the source of funding. Principal investigators (PI) are ultimately responsible for ensuring that all research involving these agents is submitted to the Institutional Review Entity (IRE) for review.

Specific instructions for individuals and committees at the University are responsible for the implementation of the University's requirements with respect to DURC.

IV. DEFINITIONS

Dual Use Research is research that is conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonable 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, material or national security.

DURC Agents and Toxins *(as noted in the 2014 USG Policy)*

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. **Botulinum neurotoxin** (in any amount, exempt quantities from 42 CFR Part 73 are not recognized by this policy)
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*

Experimental Effects of Concern *(as noted in the 2014 USG Policy)*

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

Institutional Contact for Dual Use Research (ICDUR) is the individual designated by the University to be the institutional point of contact for questions relating to compliance with this plan and the liaison with the relevant USG funding agencies. The University has designated the Vice Chancellor for Research as the ICDUR.

Institution is any government agency (Federal, State or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity involved in funding, conducting, or sponsoring research.

Institutional Review Entity (IRE) is the review committee created by the University for the sole purpose of conducting review of research for dual use potential.

Life Sciences pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs tissues, cells, and molecules.

Principal Investigator (PI): An individual who is designated by OSU to direct a project or program and who is responsible for the scientific and technical direction of that project or program.

US Funding Agency: The USG agency that is funding the subject research or, if the research is not USG-funded, the USG agency designated by the NIH, based on the nature of the research. If a federal department or agency simply passes through funding from another federal department or agency to support life sciences research involving one or more the DURC Agents, the agency originally providing the funding shall be considered the US Funding Agency.

V. RESPONSIBILITIES

Institution:

1. Establish and implement policies and practices for identification and oversight of DURC that include:

    a. Establishing an IRE
    b. Ensuring appropriate review of research with DURC potential
    c. Assessing the potential risks and benefits associated with DURC
    d. Developing and implementing risk mitigation plans, as necessary
    e. Ensuring compliance with the Policy and approved risk mitigation plans
    f. Ensuring periodic review and updating of risk mitigation plans
    g. Providing education and training on DURC
    h. Assisting investigators when questions arise regarding research that may be subject to the Policy

2. Notify USG funding agencies of:

    a. Research reviewed by the IRE that involves one of the seven experimental effects, including whether the research is determined to be DURC
    b. Instances of noncompliance with the Policy
    c. Proposed risk mitigation plans for research determined to be DURC
    d. Changes in status of DURC or modification to risk mitigation plans

Institutional Contact for Dual Use Research (ICDUR)

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. Ensure that any Research Risk Mitigation Plans are reviewed annually.
5. Ensure education and training on DURC is provided to individuals conducting research with one or more of the DURC agents and that records are maintained of such education; that training (and records) is conducted for the term of the research grant or contract plus three years after its completion.
6. Ensure records of institutional DURC reviews and completed Risk Mitigation Plans are maintained for no less than eight years.

7. Ensure the applicable US Funding Agency is notified within 30 calendar days of any change in the status of any DURC, including whether such research has been determined to no longer meet the definition of DURC. The notification should include details of any changes to an approved Risk Mitigation Plan, which must be approved by the US Funding Agency.
8. Ensure reporting of any noncompliance within 30 calendar days to the applicable US Funding Agency. This reporting would include the mitigation measures undertaken by the University to prevent recurrences of similar noncompliance.

Principal Investigators (PIs)

1. Notify the IRE as soon as:

    a. The PI's research involves non-attenuated forms of one or more of the listed agents;
    b. The PI's research with non-attenuated forms of one or more of the listed agents also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects; or
    c. The PI concludes that his/her research with non-attenuated forms of one or more of the listed agents that also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects may meet the definition of DURC and should be considered or reconsidered by the IBC for its DURC potential.

2. Work with the IBC to assess the dual use risks and benefits of the DURC and develop risk mitigation measures.

3. Conduct DURC in accordance with the approved risk mitigation plan.

4. Be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC.

5. Ensure that laboratory personnel conducting life sciences research with one or more of the listed agents have received education and training regarding DURC. Documentation of this training to be retained for a minimum of eight years.

6. Communicate DURC in a responsible manner.

Institutional Review Entity (IRE)

1. Establish and implement internal policies and practices that provide for the identification and oversight of DURC.

2. Consist of at least five member including at least two members of the Institutional Biosafety Committee (IBC), the Biosafety Officer (or designee), a representative of the Office of Regulatory Compliance and the Office of University Counsel.

3. When research is identified by a PI **or** the IBC as utilizing one of the listed agents or toxins, initiate an institutional review and oversight process that includes the following steps, as applicable:

   a. Verification that the research identified by the PI or IBC utilizes one or more of the listed agents or toxins.
   b. Review of the PI's assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the listed experimental effects.
   c. If the research has been assessed to meet the scope of the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, determine whether the research meets the DURC definition.
   d. Within 30 calendar days of the institutional review of the research for DURC potential, notify the funding agency of any research that involves one or more of the 15 listed agents AND one or more of the seven listed experimental effects, including whether it meets or does not meet the definition of DURC. *Note: For non-USG funded research, notification will be made to the National Institutes of Health.*
   e. Review and update annually all active Risk Mitigation Plans at the University.
   f. Meet at least quarterly and as needed when research is identified as potentially being DURC.