IBC Dual Use Research of Concern Policy

(Adopted 09/17/2015)

1.0 Purpose

This policy strengthens life science research oversight by identifying potential Dual Use Research of Concern (DURC) and provides instructions on risk mitigation where appropriate. This policy sets forth explicit instructions for individuals and committees at MU who are responsible for the implementation of the University's requirements with respect to DURC.

2.0 Scope

This policy applies to all University of Missouri faculty, staff and students involved in life science research.

3.0 Related Documents

- University of Missouri Institutional Biosafety Committee (IBC) Resource Book
- U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines
- U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

4.0 General Policy

All MU Principal Investigators will disclose to the MU Institutional Biosafety Committee (IBC), which is serving as the Institutional Review Entity (IRE), use of Select Agents and Toxins as identified under the CDC/USDA Federal Select Agent Program, via the MU IBC protocol application Risk Assessment Section. Investigators working with select

agents and toxins must identify any research conducted for legitimate purposes which could be utilized for both benevolent and harmful purposes. This is dual use research of concern and 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."

5.0 Listing of Agents or Toxins requiring Dual Use Research of Concern Oversight

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing straings of *Clostridium botulinum*
    - NOTE: There are no exempt quantities of Botulinum neurotoxin. Research involving any quantity of Botulinum neurotoxin should be evaluated for DURC potential.
- Variola minor virus
- *Yersinia pestis*

6.0 Categories of Experiments

Research that uses one or more of the agents or toxins listed above and produces, aims to produce, or can be reasonably anticipated to produce one or more of the following experimental effects will be evaluated for DURC potential.

6.1 Enhance the harmful consequences of the agent or toxin

6.2 Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification

6.3 Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies

6.4 Increase the stability, transmissibility, or the ability to disseminate the biolgical agent or toxin

6.5 Alter the host range or tropism of a biological agent or toxin

6.6 Enhance the susceptibility of a host population

6.7 Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent

7.0. When research is determined to be DURC:

7.1 Responsibilities of the Principal investigator:

7.1.1. Develop a laboratory specific risk mitigation plan.

7.1.2. Conduct research in compliance with the risk mitigation plan.

7.1.3. Be knowledgeable and comply with institutional and US government policies and requirements for oversight of DURC.

7.1.4. Ensure laboratory personnel received education and training on DURC.

7.1.5. Communicate research findings in compliance with the risk mitigation plan.

7.2. Responsibilities of the University of Missouri:

7.2.1. Establish and implement internal polices and practices that provide for identification and effective oversight of DURC

7.2.2. Initiate and maintain an institutional review and oversight process for DURC research

7.2.2.1. Notify the United States Goverment (USG) funding agency or NIH (for non US Government funded experiments) of the committee's findings.

7.2.2.2. Assure research does not begin until a risk mitigation plan is in place, and has been provided to the USG funding agency or NIH within 90 days of the committee's determination.

7.2.2.3. Upon approval of the risk mitigation plan, ensure DURC is conducted in accordance with that plan.

7.2.2.4. The committee must review the risk mitigation plan annually, determine if the research is still DURC, and modify the plan as needed.

7.2.2.5. Notify USG or NIH within 30 days of any change in the status of the DURC project and details of changes to the risk mitigation plan.

7.2.3. Ensure the internal policies establish a mechanism for the PI to immediately refer a project to the MU IBC.

7.2.4. Designate an Institutional Contact for Dual Use Research.

7.2.5. Establish a review committee (at the University of Missouri the MU Institutional Biosafety Committee has been designated).

7.2.6. Maintain records of DURC reviews and and complete risk mitigation plans.

7.2.7. Provide education and training on DURC for individuals and maintain records of trainings.

7.2.8. Ensure compliance with this policy and with approved risk mitigation plans, and report instances of noncompliance with this policy.

7.2.9. Assist Principal Investigator with questions if their research may require further review or oversight.

7.2.10.Establish an internal mechanism for Principal Investigators to appeal DURC decisions made by the MU IBC.

7.2.11.Make information about the process for review of research subject to the policy available upon request, as consistent with applicable state, local and federal laws.

7.2.12.Certify that the institution will be or is in compliance with all aspects of the MU IBC DURC policy.

7.3. Responsibilities of the USG Funding Agencies (or NIH):

7.3.1. Require all funded institutions meet applicability criteria.

7.3.2. Respond to institutions questions regarding DURC oversight and provide instruction on policy compliance.

7.3.3. Notify an institution when the funding agency determines that research does or does not meet the definition of DURC based upon a risk assessment and progress reports. Risk mitigation plans will be reviewed, and any concerns or disagreements will include consultation with the institution.

7.3.4. Respond to an institution within 30 days from receipt of material or an inquiry.

7.3.5. Respond to reports of non-compliance and work with the institution to address the issue.

7.4. Responsibilities of USG:

7.4.1. Develop training tools and materials for use by the USG agencies and institutions implementing this policy.

7.4.2. Provide education and outreach to stakeholders about dual use policies and issues.

7.4.3. Provide guidance to institutions on the sharing of DURC research products and on the communication of DURC.

7.4.4. Convene advisory bodies such as National Science Advisory Board for Biosecurity, as necessary, to develop recommendations on particularly complex cases of DURC.

7.4.5. Periodically assess the impact of this Policy on life sciences research programs and institutions, and update the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

7.5. Compliance:

7.5.1. Non-compliance with this policy may result in suspension, limitation, or termination of USG funding for the funded project and/or any future project at the institution, and may subject the institution to other potential penalties under applicable laws and regulations.