Mississippi State University
Institutional Review Entity Policy
On
Institutional Oversight of Life Sciences Dual Use Research of Concern

Overview

Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research *of concern* is a subset of dual use research 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, material, or national security." *The United States Government Policy (USG) for Institutional Oversight of Life Sciences Dual Use Research of Concern* articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

The USG has limited the scope of the policy to a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments (See Appendix).

Purpose

The purpose of this policy is to strengthen Mississippi State University's (MSU) ongoing institutional review and oversight of certain life sciences research with high-consequence pathogens and toxins in order to identify potential DURC and mitigate risks where appropriate. This policy describes the roles and responsibilities of the institution and performance standards for review of life sciences research, identification of potential DURC, and development and implementation of risk mitigation measures for DURC, where applicable.

Definitions

For the purpose of this policy the following terms are defined:

A. "Dual use research" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

B. "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.

C. "Institutional Contact for Dual Use Research" (ICDUR) is an individual designated by MSU to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant USG funding agency.

D. "Institutional Review Entity" (IRE) is a committee established by the institution as described by the MSU IRE Charter and empowered to execute the requirements stated in the USG policy.

E. "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 aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular 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.

F. "Principal Investigator" (PI) is an individual who is designated by the research institution to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within a single or between multiple institutions.

Policy Statement

It is the policy of MSU that:

A. Life sciences research that meets the scope specified in the Appendix of this policy is subject to the USG DURC policy as well as institutional oversight. The purpose of this oversight is to preserve the benefits of DURC while minimizing the risk that the knowledge, information, products, or technologies generated by this research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security; and

B. Oversight includes the identification of life sciences research that raises dual use concerns as well as the implementation of measures to mitigate the risk that DURC may be used in a manner that results in harm.

Applicability: This policy applies to the following types of research at MSU: Any institutional research project that receives both funding from the USG and involves one or more of the agents or toxins listed in the Appendix even if the research is not supported by USG funds.

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

Compliance: Non-compliance with this policy may result in suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at MSU.

Responsibilities of Principal Investigators

In accordance with this policy, PIs are to:

A. Notify the Institutional Review Entity (IRE) as soon as:

i. The PI's research involves one or more of the agents or toxins listed in the Appendix;

ii. The PI's research with one or more of the listed agents or toxins also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven effects listed in the Appendix. The notification must include the PI's assessment of whether any research involving these agents or toxins produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in the Appendix.

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

C. Conduct DURC in accordance with the provisions in the risk mitigation plan.

D.Be knowledgeable about and comply with all MSU and USG policies and requirements for oversight of DURC.

E.Ensure that laboratory personnel conducting life sciences research with one or more of the agents listed in the Appendix have received education and training on DURC.

F. Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of

publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan.

Responsibilities of Mississippi State University

In accordance with the USG Policy, research conducted under the auspices of MSU that receive USG funds for life sciences research and conduct or sponsor research with any of the 15 agents or toxins listed in the Appendix are to:

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

B. When research is identified by a PI as utilizing one of the agents or toxins listed in the Appendix, initiate an institutional review and oversight process.

C. Designate an Institutional Contact for Dual Use Research (ICDUR) to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of research.

D. Establish an IRE to review potential DURC.

E. Maintain records of 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, unless a shorter period is required by law or regulation.

F. Provide education and training on DURC for individuals conducting life sciences research with one or more of the agents listed in the Appendix and maintain records of such education and training for the term of the research grant or contract plus three years after its completion. Institutions may also wish to address dual use topics in existing courses on research ethics or the responsible conduct of research. Institutions may require additional record keeping and should designate an individual responsible for maintaining documentation.

G. Ensure compliance with this Policy and with approved risk mitigation plans.

Appendix

Agents and toxins

a) Avian influenza virus (highly pathogenic)
b) *Bacillus anthracis*
c) Botulinum neurotoxin (**all quantities**)
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 experiments

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