Office/Contact: Office of Research and Sponsored Programs
Source: *US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (USG Policy)
Link: https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/

SOUTH DAKOTA STATE UNIVERSITY
Policy and Procedure Manual

SUBJECT: Dual Use Research of Concern
NUMBER: 8:11

1. Purpose

   The purpose of this policy is to provide the framework for the University's review and oversight of certain life sciences research with high-consequence pathogens and toxins to preserve the benefits of such research while ensuring safe practices and mitigating risks. This policy has been developed to comply with the *US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (USG Policy).

2. Definitions

   a. Dual Use Research of Concern (DURC): 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.

   b. Life Sciences: 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.

3. Policy

   a. The University will identify life sciences research that raises dual use concerns and implement measures to mitigate the risk that it is used in a manner that results in harm. These measures will be applied in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.

   b. Research that directly involves nonattenuated forms of one or more of the agents or toxins listed below, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed below will be evaluated for DURC potential.

i. DURC Agents
    1. Avian influenza virus (highly pathogenic)
    2. Bacillus anthracis
    3. Botulinum neurotoxin
    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

ii. Experimental Effects
    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

c. The following need **not** be reviewed under this policy:

i. The use of any of the DURC Agents in attenuated forms (unless the experiment will reconstitute a virulent agent);

ii. The use of the genes from any of the DURC Agents;

iii. In silico experiments (e.g., modeling experiments, bioinformatics approaches) involving the biology of the DURC Agents; or

iv. Research relating to the public, animal and agricultural health impact of any of the DURC Agents (e.g., modeling the effects of a toxin, developing new methods to deliver a vaccine, developing surveillance mechanisms for a DURC Agent).

4. Procedures

a. A principal investigator (PI) must register with the Institutional Biosafety Committee (IBC) any research that involves any nonattenuated form of a DURC Agent.

b. The IBC will promptly notify the DURC Institutional Review Entity (IRE) of any

i. registration in which the research involves one or more of the DURC Agents; and

ii. other research protocol which the IBC believes should be reviewed by the IRE.

The notification will include the PI's assessment of whether the research aims to produce, or is reasonably anticipated to produce one or more of the Experimental Effects.

c. Upon notification of research of potential concern, the IRE will:

i. Verify that the research uses a nonattenuated form of a DURC Agent.

ii. Determine whether the research involves one of the Experimental Effects. If not, the research is not subject to additional review or oversight, but will continue to be assessed by the PI.

iii. If one of the Experimental Effects is possible, determine whether the research meets the DURC definition. If not, the research is not subject to additional DURC oversight, but the University will provide the appropriate USG agency of the review findings within 30 calendar days. If the research meets the definition of DURC, the IRE will:
   1. Assess the risks and benefits of the research in consultation with the PI.
   2. Develop a draft risk mitigation plan to guide the conduct and communication of the research, and provide the draft to the appropriate USG agency within 90 calendar days for final review and approval.
   3. Implement and annually review the risk mitigation plan.
   4. Notify the appropriate USG agency, within 30 calendar days, of any change in a project's status or risk mitigation plan, or any instances of noncompliance with the USG Policy.

d. The Vice President for Research and Economic Development will establish an IRE to execute the requirements above, composed of at least five members with:

i. Sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted; and

ii. Knowledge of relevant Federal policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity.

Members will be appointed to three (3) year terms, which can be renewed. Ad hoc members with relevant expertise will be recruited as necessary where specific expertise is needed to review a proposed protocol. Ad hoc members will not be counted towards a quorum, but will be counted in any vote regarding a protocol. A majority vote of a quorum will be sufficient to approve or disapprove any matter before the IRE. Any IRE member involved in or with a direct financial interest in the research in question will be recused except to provide specific information requested.

e. The University Research Integrity and Compliance Officer will serve as the institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC research, and will provide training on DURC for individuals conducting life sciences research with nonattenuated DURC Agents.

f. Administrative support for the IRE will reside in the Division of Research and Economic Development and will include:

   i. Scheduling IRE meetings and taking minutes.

   ii. Maintaining records of DURC training, reviews, and completed risk mitigation plans for no less than eight years after project completion, unless a shorter period is required by law or regulation.

   iii. Making information about the process for review of research subject to the USG Policy available upon request, as consistent with applicable law.

g. Disputes regarding decisions made by the IRE will be referred to the Vice President for Research and Economic Development, who may deny the appeal or request that parts of the decision be reconsidered. The IRE will reconsider the determination after soliciting input from the Vice President for Research and Economic Development, the relevant USG agency, the IBC, and/or other experts as needed. After this reconsideration, the subsequent decision of the IRE will be final.

5. Responsible Administrator

   The Vice President for Research and Economic Development, successor, or designee is responsible for annual and ad hoc review of this policy and procedures. The University President is responsible for approval of modifications to this policy.

SOURCE: Approved by President on 11/19/2019.