

UNIVERSITY RULE

15.99.06.M1 Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern

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Standard Administrative Procedure Statement

Texas A&M University is committed to protecting faculty, staff, students, visitors, the general public and the environment from the risk of potential occupational exposure to biohazardous materials and recombinant DNA, and to ensuring that all activities involving biohazardous materials and recombinant DNA and the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations and guidelines. Additionally, the University is committed to the shared responsibility of upholding the integrity of science and to reducing the risk of its misuse.

Reason for Rule

This rule describes the review and approval process for activities involving the use of biohazardous materials and/or recombinant DNA and research which may constitute Dual Use Research of Concern.

Definitions

Biohazardous material has the meaning set forth in System Regulation 15.99.06 *Use of Biohazards in Research, Teaching and Testing*. **Dual Use Research** is research 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 reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural

crops and other plants, animals, the environment, materiel or national security. Research within the scope articulated in Section 6.2 of *The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (“IODURC”), and as amended from time, is considered DURC.

Laboratory Supervisor –individual with primary responsibility for the use of biological agents in the University’s teaching laboratories.

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 a level of ecosystems, populations, organisms, organs, tissues, cells and molecules.

Institutional Official – the individual appointed by the president to oversee and the University’s biosafety program. The President has designated the Vice President for Research (“VPR”) as the University’s Institutional Official.

Institutional Contact for Dual Use Research (“ICDUR”) – the VPR, or designee, who serves as the University’s internal resource for issues regarding compliance with and implementation of the requirements for oversight of DURC as well as the liaison (as necessary) between the university and the relevant Federal funding agency.

Institutional Review Entity (“IRE”) is established by and reports to the VPR. Its function is to execute the requirements in *The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (“IODURC”). Unless otherwise designated by the VPR, the IBC shall serve as the IRE.

Recombinant DNA (“rDNA”) and Synthetic Nucleic Acid Molecules – have the meaning set forth in System Regulation 15.99.06 *Use of Biohazards in Research, Teaching and Testing*.

Official Rule

1. USE OF BIOHAZARDS, BIOLOGICAL TOXINS AND RECOMBINANT DNA

1.1 GENERAL

This rule applies to all University employees, students and visitors who utilize rDNA and/or biohazardous agents or materials in the context of their research, teaching and/or testing activities. The rule applies to these activities when they occur in University facilities, other locations if the projects are funded or sponsored by the University, and/or if University faculty, staff or students are participating in

activities utilizing biohazardous materials or rDNA. These requirements are also applicable to all activities involving the use of biohazards and/or recombinant DNA for which the University is responsible, regardless of source of funding or whether the activity is funded.

To ensure that biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA are used safely and in compliance with federal and state laws, regulations and guidelines, the University adheres to the following: The Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) *Biosafety in Microbiological and Biomedical Laboratories*, the *NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules*, USDA regulations controlling the use of biohazardous materials and/or rDNA and the latest Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121). In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.

1.2 INSTITUTIONAL BIOSAFETY COMMITTEE (“IBC”)

Members of the Institutional Biosafety Committee (“IBC”) shall be appointed by the Institutional Official, and the committee shall be structured according to the “*NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules*”. The TAMU IBC will provide review and oversight of research, teaching, and experimental activities utilizing rDNA and other biohazardous agents, materials and biological toxins. Such activities performed under the auspices of Texas A&M University, including cooperative research conducted with one or more public or private entities, must be reviewed and approved by the IBC prior to initiation.

1.3 INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW AND APPROVAL

The requirement for IBC review and approval applies to all activities involving the use of biohazards and/or recombinant DNA in all locations, whether conducted by faculty, students, or staff of the University. The requirement for IBC review and approval also applies to persons unaffiliated with the University who wish to coordinate activities through the University involving the use of biohazards and/or recombinant DNA.

1.3.1 The IBC is responsible for the review of all activities involving the use of biohazards and/or recombinant DNA, including research, teaching and testing activities, to assess and set containment levels for activities utilizing rDNA or biohazardous materials, and to notify faculty of the outcome of this review. Activities involving the use of biohazards and/or rDNA may not be initiated prior to IBC review and approval.

- 1.3.2 The IBC will regularly review approved research, teaching, and other activities at intervals appropriate to the degree of risk, but no less than once per year.
- 1.3.3 The IBC will review activities involving the use of biohazards and/or recombinant DNA in accordance with the criteria outlined in the most current versions of either the *NIH Guidelines*, select agent regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121), the *Biosafety in Microbiological and Biomedical Laboratories (“BMBL”)* manual, and other federal, state, System regulations and university rules and procedures.
- 1.3.4 The IBC may suspend or terminate approval for use of biohazardous materials or rDNA if such use poses a risk to personnel, public health and safety, or for issues of non-compliance.

1.4 RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS AND LABORATORY SUPERVISORS

- 1.4.1 Principal Investigators and Laboratory Supervisors are responsible for submitting complete and accurate applications involving the use or possession of biohazards and/or recombinant DNA to the IBC prior to the initiation of any work. Regardless of funding sources, research and/or teaching protocols involving the use of biohazards and/or recombinant DNA must be prepared by the faculty member and submitted to the IBC for review. Any proposed modification or amendment must be approved in writing by the IBC. If the research or teaching activity involves the use of biohazards and/or recombinant DNA in animals or humans, the applicable research oversight committees (for example, IACUC, IRB, etc.) must approve the proposed project. (See 15.01.01.M3: *University Councils, Committees, and Boards Governing Research*).
- 1.4.2 Principal Investigators and Laboratory Supervisors must complete training, as required by the IBC or any other oversight agency, as applicable; ensure that all staff and students participating in biohazard related activities have completed appropriate training; and maintain documentation of training. Agent and laboratory specific training must be provided by the Principal Investigator/Laboratory Supervisor or the Principal Investigator/Laboratory Supervisor’s designee to all staff and students engaged in research, teaching or other activities using biohazardous materials and/or rDNA.
- 1.4.3 Principal Investigators and Laboratory Supervisors must communicate to staff and students the signs and symptoms compatible with disease caused by the infectious agents or materials in use, as appropriate.
- 1.4.4 Principal Investigators and Laboratory Supervisors should correct and must report conditions that may lead to exposure to or release of biohazardous

materials and/or recombinant DNA and must report any significant problems or research related illness or accident to the Biological Safety Officer (“BSO”), Responsible Official (“RO”) and/or the IBC.

- 1.4.5 Principal Investigators and Laboratory Supervisors must accept primary responsibility for compliance with all Federal laws and regulations involving handling, storage, disposal, inventory, security, transportation, and access to biological and/or recombinant agents. The Biosafety Office shall assist in this process.

1.5 RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER (“BSO”):

- 1.5.1 To the extent the University engages in activities involving research with recombinant DNA materials requiring BSL3 or BSL4 containment, the Institutional Official is responsible for the appointment of a BSO. The BSO shall be a member of the IBC.
- 1.5.2 The BSO implements the decisions of the IBC, conducts periodic inspections of facilities where biohazardous materials and/or rDNA are being used or stored to ensure that appropriate laboratory practices and procedures are followed, and reports any significant problems, violations of the *NIH Guidelines* or significant research or teaching related accidents or illnesses to the IBC and the Institution and/or the RO.
- 1.5.3 The BSO shall assist Principal Investigators, Laboratory Supervisors, research staff and teaching faculty with the development of exposure control plans and provide technical advice to the IBC, investigators, faculty and staff on laboratory safety to facilitate safe handling, storage and use of biohazardous materials.
- 1.5.4 The BSO shall develop emergency plans for handling accidental spills and personnel contamination and investigate laboratory accidents involving recombinant DNA activities.

1.6 RESPONSIBILITIES OF THE RESPONSIBLE OFFICIAL (“RO”):

- 1.6.1 To the extent the University manages and/or controls facilities where select agents are present and/or used, the University is responsible for acquiring and maintaining a certificate of registration from the U.S. Department of Health and Human Services (“HHS”) and United States Department of Agriculture and for designating a RO with both authority and responsibility for compliance with federal laws and regulations governing select agents. The Institutional Official shall appoint the RO, who shall provide routine updates and compliance concerns to the VPR. The appointment of the RO must be approved by CDC and/or APHIS.

1.6.2 The RO and the BSO are responsible for coordinating their respective responsibilities as described in this rule.

1.7 RESPONSIBILITIES OF THE INSTITUTIONAL OFFICIAL (“IO”):

1.7.1 The Texas A&M University President has designated the Vice President for Research as the University’s Institutional Official (“IO”). The IO ensures the safety of faculty, staff, and students engaged in research or teaching activities involving the use of rDNA and/or biohazardous agents, materials and toxins of biological origin.

1.7.2 The IO appoints all IBC members and grants the authority to the IBC to review and oversee research or teaching activities involving the use of rDNA, biohazardous materials, or toxins of biological origin.

1.7.3 The IO ensures that the IBC has sufficient resources to conduct its activities, and that the membership of the IBC is adequate with regards to numbers and expertise to appropriately review all types of submissions received, involving rDNA and biohazardous materials.

1.7.4 The IO ensures ongoing compliance with applicable state and federal law and may collaborate with appropriate institutional officials to place sanctions on faculty failing to comply with these laws, or failing to comply with University policies, procedures and guidelines.

2. DUAL USE RESEARCH OF CONCERN (“DURC”)

2.1 GENERAL

Life science research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materials (e.g. food, water, equipment and supplies), and national security. Despite its value and benefits, however, certain types of research conducted for legitimate purposes can be utilized for benevolent or harmful purposes.

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (“IODURC”) addresses institutional oversight of Dual Use Research of Concern and identifies the criteria for what qualifies as DURC by listing specific agents and toxins and descriptions of the types of experiments, which when combined, define the parameters for research considered DURC.

2.2 ROLES AND RESPONSIBILITIES

- 2.2.1 The VPR is responsible for oversight of DURC and for ensuring procedures and processes are in place to identify potential DURC and implement risk mitigation measures for DURC where applicable, with the aim of preserving the benefits of DURC while minimizing the risk that the knowledge, information, products, or technologies generated from such research could be used in a manner that results in harm to the public health and safety, agricultural crops and other plants, animals, the environment, material or national security.
- 2.2.2 Potential DURC is subject to review by the IRE, designated by the VPR
- 2.2.3 It is the responsibility of researchers to:
- a. identify if his or her research involves one or more of the agents or toxins listed in Section 6.2.1 of the IODURC and to notify the IBC so that the research may be reviewed for its DURC potential. This includes instances where the researcher is conducting research with potential DURC at multiple institutions;
 - b. work with the IRE to develop risk mitigation measures where appropriate;
 - c. conduct DURC in accordance with the provisions of the risk mitigation plan;
 - d. be knowledgeable about, and comply with, all institutional and Federal policies and requirements for oversight of DURC;
 - e. ensure that laboratory personnel conducting life sciences research that falls within the scope of IODURC (i.e., those under the supervision of laboratory leadership including graduate students, postdoctoral fellows, research technicians, laboratory staff and visiting scientists) have received education and training on DURC; and
 - f. communicate DURC in a responsible manner and in compliance with any risk mitigation plan stipulated by the IRE.

3. REPORTING

- 3.1 The ICDURC is responsible for notifying the Federal funding agency of an IRE determination that research falls within the scope of Section 6.2 of IODURC. This includes whether or not it meets the definition for DURC. The notice is required within 30 days of the determination. For non-federally funded research, notice will be given to the National Institutes of Health.

- 3.2 The ICDURC is responsible for providing a copy of the risk mitigation plan to the Federal funding agency or to NIH (as appropriate) for review within 90 days from the DURC determination by the IBC.
- 3.3 Instances of noncompliance with IODURC, as well as mitigation measures to prevent recurrences of similar noncompliance must be reported to the Federal funding agency or to NIH, as appropriate, within 30 calendar days.

Related Statutes, Policies, or Requirements

System Policy 24.01 Risk Management

System Regulation 15.99.06 Use of Biohazards in Research, Teaching and Testing

System Regulation 24.01.01 Supplemental Risk Management Standards

Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121)

NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines)

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC)

United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern (September 2014)

United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012)

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