

## UNIVERSITY RULE

### 15.99.06.M1 Use of Biohazardous Materials and Dual Use Research of Concern

*Approved July 8, 2003*

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*Revised March 17, 2022*

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#### Rule Statement

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Texas A&M University is committed to protecting faculty, staff, students, visitors, the general public and the environment from the risk of exposure to biohazardous materials and to ensuring that all activities involving biohazardous materials 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.

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#### Reason for Rule

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

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#### Definitions

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**Biohazardous Material** has the meaning set forth in System Regulation 15.99.06 *Use of Biohazardous Material 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 is considered DURC.

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## Official Rule

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### 1. USE OF BIOHAZARDOUS MATERIAL

#### 1.1. GENERAL

This rule applies to all employees, students and visitors who utilize biohazardous 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. These requirements are also applicable to all activities involving the use of biohazardous materials for which the University is responsible, regardless of source of funding or whether the activity is funded.

To ensure that biohazardous materials, 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 (BMBL), the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Services (APHIS) 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.

The Office of Biosafety has developed a Biosafety Manual to provide information on how to work safely with biohazards and recombinant or synthetic nucleic acid molecules, and to maintain compliance with university rules (see <https://vpr.tamu.edu/biohazards-in-research-teaching-or-testing/>).

#### 1.2. RESPONSIBILITIES OF THE INSTITUTIONAL OFFICIAL (IO):

- 1.2.1. The Texas A&M University President has appointed the Vice President for Research (VPR) as the Institutional Official. The IO oversees the biosafety program and ensures the safety of faculty, staff, and students engaged in activities involving the use of biohazardous materials.
- 1.2.2. The IO appoints all Institutional Biosafety Committee (IBC) members and grants the authority to the IBC to review and oversee activities involving the use of biohazardous materials.
- 1.2.3. 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 involving biohazardous materials.

- 1.2.4. 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.

### 1.3. RESPONSIBILITIES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

- 1.3.1. The IBC is responsible for the review, approval and oversight of activities that involve biohazardous materials, to set containment levels, and to notify faculty of the outcome of this review. Activities involving the use of biohazardous materials may not be initiated prior to IBC review and approval.
- 1.3.2. The IBC will regularly review approved activities involving the use of biohazardous materials 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 biohazardous materials in accordance with the criteria outlined in the most current versions of either the BMBL, the *NIH Guidelines*, the Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121), 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 if such use poses a risk to personnel, public health and safety, or for issues of non-compliance.

### 1.4. RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER (BSO):

- 1.4.1. To the extent the university engages in activities involving large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules, or in activities involving recombinant or synthetic nucleic acid molecules at BSL-3 or BSL-4 containment, the IO is responsible for the appointment of a BSO. The BSO shall be a member of the IBC.
- 1.4.2. The BSO implements the decisions of the IBC; conducts periodic inspections of facilities where biohazardous materials 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, the Institution, and/or the RO.
- 1.4.3. The BSO shall assist Principal Investigators, 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.

1.4.4. The BSO shall ensure that the University Biosafety Manual is available, accessible, and periodically reviewed and updated, as necessary.

1.4.5. The BSO shall investigate incidents involving biohazardous materials.

#### 1.5. RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

1.5.1. Principal Investigators are responsible for submitting complete and accurate applications describing the use or possession of biohazardous materials to the IBC for review and approval prior to the initiation of any work. Any proposed modification or amendment also must be reviewed and approved by the IBC prior to initiation. If the activities involve the use of biohazardous materials in animals or humans, the applicable research oversight committees (e.g., IACUC, IRB, etc.) must approve the proposed project.

1.5.2. Principal Investigators must complete training, as required by the IBC or any other oversight agency, as applicable; ensure that all personnel participating in activities involving biohazardous material have completed appropriate training; and maintain documentation of training.

1.5.3. Agent and laboratory specific training must be provided by the Principal Investigator or their designee to all personnel engaged in activities involving biohazardous materials.

1.5.4. Principal Investigators must communicate to personnel the signs and symptoms associated with disease caused by the biohazardous materials in use, as appropriate.

1.5.5. Principal Investigators must mitigate work errors and conditions that may lead to exposure to or release of biohazardous materials report any significant problems or research related illness or accident to the BSO, Responsible Official (RO), and/or the IBC.

1.5.6. Principal Investigators must accept primary responsibility for compliance with all state and federal laws and regulations involving handling, storage, disposal, inventory, security, transportation, and access to biohazardous materials. The Biosafety Office shall assist in this process.

#### 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 the USDA and for designating an RO with both authority and responsibility for

compliance with federal laws and regulations governing select agents. The IO 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.

## 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, materiel (i.e., military 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 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, materiel or national security.
- 2.2.2. Potential DURC is subject to review by the Institutional Review Entity (IRE), which is established by and reports to the VPR. Its function is to execute the requirements in the IODURC. Unless otherwise designated by the VPR, the IBC shall serve as the IRE.
- 2.2.3. It is the responsibility of researchers to:
  - a. identify if their 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 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.

### 2.3. REPORTING

- 2.3.1. The Institutional Contact for Dual Use Research of Concern (ICDUR) is appointed by the VPR to serve 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. Unless otherwise designated by the VPR, the RO serves as the ICDUR.
- 2.3.2. The ICDUR 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.
- 2.3.3. The ICDUR 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.
- 2.3.4. 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.

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### **Related Statutes, Policies, or Requirements**

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**System Policy 24.01, Risk Management**

**System Regulation 15.99.06, Use of Biohazardous Material in Research, Teaching and Testing**

**[System Regulation 24.01.01, Health and Safety](#)**

***Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 21)***

***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)***

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**Contact Office**

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Division of Research  
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