

15.99.06.D1

Use of Biohazardous Material in Research, Teaching and Testing



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Rule Summary

Texas A&M University-Central Texas (A&M-Central Texas) 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.

Definitions

See System Regulation [15.99.06, Use of Biohazardous Material in Research, Teaching and Testing](#)

Rule

1 ADMINISTRATIVE REQUIREMENTS

- 1.1 This rule applies to all university 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 biohazards and/or recombinant DNA for which the university is responsible, regardless of source of funding or whether the activity is funded.
- 1.2 To ensure that biologically hazardous 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 DNA Molecules (NIH Guidelines), USDA regulations controlling the use of biohazardous materials and the latest Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) and Texas Health and Safety Code §§ 81.301 –81.306, and plant pests as defined by the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)

and the Coordinated Framework for Regulation of Biotechnology.

- 1.3 In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.
- 1.4 The University will maintain its Institutional Biosafety Committee (IBC) registration with the National Institutes of Health at all times, even if not required by federal requirements.
- 1.5 The storage and use of biohazardous materials within the university, whether for research, teaching, or testing purposes, shall be described in a Biohazardous Use Protocol (BUP). The BUP is a form designed to capture relevant information regarding the appropriate use of the biohazardous materials in research, teaching, or testing activities.
- 1.6 IBC approval is required prior to possession or use of biohazardous materials.
- 1.7 All modifications to approved storage and use of biohazardous materials must be approved by IBC prior to initiation of the changes.
- 1.8 The University must register with either the Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT) or U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)/ Agriculture Select Agent Services (AgSAS) (collectively known as the Federal Select Agent Program) prior to possession, use, or transfer of any select agent or toxin, including receipt of select agents and toxins from outside the United States.

2 INSTITUTIONAL OFFICIAL

- 2.1 The President has appointed the Vice President for Research, Economic Development, and Innovation to serve as the Institutional Official (IO) with administrative authority to commit institutional resources to ensure that the oversight of all research, teaching or testing involving biohazardous materials will comply with system, state, and federal requirements.
- 2.2 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 System regulations, university rules, procedures, and guidelines.

3 INSTITUTIONAL BIOSAFETY COMMITTEE

- 3.1 The Vice President for Research, Economic Development, and Innovation will appoint members to staggered three-year terms to the Institutional Biosafety Committee (IBC).
- 3.2 All members of the IBC will complete all appropriate training applicable to biosafety.
- 3.3 The IBC shall meet the membership requirements articulated in the current version of the NIH Guidelines and register with the Office of Science Policy of the NIH, U.S. Department of Health and Human Services.

- 3.4 The IBC is responsible for the review and approval of all research, teaching, and testing activities involving the use of biohazardous materials, assessing and setting containment levels for activities utilizing biohazardous materials, and for notifying faculty of the outcome of this review.
 - 3.5 The IBC will regularly review approved research, teaching, and other activities at intervals appropriate to the degree of risk, but no less frequently than once per year.
 - 3.6 The IBC will review activities involving the use of biohazardous materials in accordance with the criteria outlined in the most current versions of the NIH Guidelines, select agent regulations, the BMBL, and other federal, state, and university rules and procedures.
 - 3.7 The IBC may suspend or terminate approval for the use of biohazardous materials if such use poses a risk to personnel, public health and safety, or for issues of non-compliance.
- 4 APPLICABILITY OF AND RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER

The Biological Safety Officer is the designated administrative officer who assists in assuring compliance and biosafety of recombinant DNA research conducted at A&M-Central Texas. The Biological Safety Officer is designated by the Vice President for Research and Economic Development to provide services and assistance as required by federal guidelines and regulations and Institutional requirements.

- 4.1 The institution shall appoint a Biological Safety Officer if it engages in substantial research or production activities involving biohazardous materials, agents or containing viable organisms. Substantial research or production activities are defined as any research that involves procedures at level BL-3 or higher, or research that is funded by federal or state agencies; once such work is planned, a BSO must be appointed prior to the start of work.
- 4.2 The institution shall appoint a Biological Safety Officer if it engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules at levels BL-3 or BL-4. The Biological Safety Officer shall be a member of the Institutional Biosafety Committee.
- 4.3 The Biological Safety Officer's duties include, but are not limited to:
 - 4.3.1 Periodic inspections to ensure that laboratory standards are rigorously followed;
 - 4.3.2 Reporting to the Institutional Biosafety Committee and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator;
 - 4.3.3 Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research;

- 4.3.4 Providing advice on laboratory security;
- 4.3.5 Providing technical advice to Principal Investigators and the Institutional Biosafety Committee on research safety procedures.
- 4.3.6 Developing and providing periodic biosafety training.

5 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Principal investigators (PIs) are primarily responsible for compliance with all federal and state laws and regulations involving activities covered by this rule and are responsible for:

- 5.1 Ensuring all responsibilities of PIs as articulated in the most recent version of the NIH Guidelines are met;
- 5.2 Ensuring that all activities with biohazardous materials are appropriately reviewed and approved prior to initiation of any activities or changes to approved activities. Regardless of funding sources, a BUP must be prepared and signed by the PI and must be reviewed and approved by the IBC. PIs must also submit continuing reviews to their respective IBC at least annually. If research is collaborative or involves other institutions, approval must be obtained and a copy of the that approval provided from each institution;
- 5.3 Ensuring that conduct of research, teaching, or testing activities involving biohazardous materials is restricted to that described in the approved BUP or approved amendments, and is in congruence with funding grants, if applicable;
- 5.4 Ensuring that all participants in activities with biohazardous materials are appropriately qualified through training and education to perform their responsibilities as listed in the BUP;
- 5.5 Ensuring that all participants in activities with biohazardous materials are enrolled in an Occupational Health and Safety program if required by their approved BUP;
- 5.6 Abiding by all determinations of the IBC, including, but not limited to, directives to terminate participation in designated research, teaching, or testing activities;
- 5.7 Notifying the IBC as soon as possible after the discovery of any reportable incident or noncompliance that involves biohazardous materials.

6 OTHER

All documentation associated with IBC reviews will be maintained within the Office of Research. Sufficient resources will be provided to support the IBC in all phases of its work, help track and monitor submissions, and maintain records related to all research involving biohazardous materials. The Office of Research will be responsible for determining that applicable theses and dissertations have received approval by the IBC.

7 TRAINING

- 7.1 All individuals involved with biohazardous materials in research, teaching, and testing will complete all appropriate training, including all university prescribed training modules applicable to biosafety.
- 7.2 Employees are responsible for completing the training prior to being permitted to enter and work in the BL-2 Lab, and prior to initiating any activity relating to research, teaching, and testing with biohazardous materials.

Related Statutes, Policies, or Requirements

System Regulation [*15.99.05, Research Compliance*](#)

System Regulation [*15.99.06, Use of Biohazardous Material in Research, Teaching, and Testing*](#)

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

[*NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)*](#)

University Procedure [*24.01.01.D1.04 Bloodborne Pathogens*](#)

[*Texas A&M University Central Texas Bloodborne Pathogens Exposure Control Plan*](#)

Code of Federal Regulation [*Title 42 Part 73*](#)

Code of Federal Regulation [*Title 7 Part 331*](#)

Code of Federal Regulation [*Title 9 Part 121*](#)

[*Texas Health and Safety Code §§ 81.301 –81.306*](#)

Contact Office

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