

15.99.06 Use of Biohazardous Material in Research, Teaching and Testing



Revised [August 9, 2021](#)

Next Scheduled Review: August 9, 2026

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Regulation Summary

The Texas A&M University System (system) is committed to protecting faculty, staff, students, visitors, the general public and the environment from the risk of exposure to Biohazardous Material and to ensuring that all activities involving Biohazardous Material and the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations and guidelines.

Regulation

1. BIOHAZARDOUS MATERIAL

1.1 Biohazardous Material is any material containing:

- (a) Biological agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites, and prions) that may cause disease in humans, animals or plants;
- (b) Recombinant or Synthetic Nucleic Acid Molecules as defined in the National Institutes of Health (NIH) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, 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*;
- (c) Human and non-human primate blood, tissue, cells, and cell lines;
- (d) Toxins of biological origin as defined in the *Biosafety in Microbiological and Biomedical Laboratories* document; and
- (e) Recombinant and Synthetic Nucleic Acid Molecules, as defined in the *NIH Guidelines*:
 1. Molecules that (a) are constructed by joining nucleic acid molecules and (b) can replicate in a living cell; i.e., recombinant nucleic acids;
 2. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules; i.e., synthetic nucleic acids;
or
 3. Molecules that result from the replication of those described in 1.1(e)(1) or 1.1(e)(2).

2. ADMINISTRATIVE REQUIREMENTS

- 2.1 Each member involved with research, teaching, testing, or utilizing Biohazardous Material must establish a rule for carrying out this regulation.
- 2.2 The chief executive officer (CEO), or designee, must name an Institutional Officer (IO) who is responsible for ensuring institutional compliance with relevant policies and procedures in all research, teaching or testing involving Biohazardous Material.
- 2.3 Procedures for the use and storage of Biohazardous Material must be consistent, regardless of the sources of funding.
- 2.4 Activities involving Biohazardous Material must meet the criteria articulated in the most current versions of federal or state documents, requirements and laws including:
 - (a) *NIH Guidelines*;
 - (b) The Public Health Service/Centers for Disease Control and Prevention (CDC)/NIH's *Biosafety in Microbiological and Biomedical Laboratories*;
 - (c) Select Agents Regulations (7 CFR Part 331, 9 CFR Part 121 and 42 CFR Part 73);
 - (d) United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern;
 - (e) USDA regulations and permits as applicable;
 - (f) CDC's Etiologic Agent Import Permit Program import permit requirements; and
 - (g) State of Texas Health and Safety Code §§ 81.301 – 81.306 and Texas Administrative Code §§ 96.101-301.

3. INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE

- 3.1 The CEO, or designee, of each member that conducts research, teaching or testing with Biohazardous Material must develop an Institutional Biological Safety Committee (IBC) or enter into an agreement with another member with a registered IBC. Each IBC must meet the requirements specified in the *NIH Guidelines* and register with the Office of Science Policy of the NIH, U.S. Department of Health and Human Services.
- 3.2 Each member with an IBC must develop written IBC procedures, including procedures relating to the review of Biohazardous Material protocols and reporting guidelines. Activities involving the use of Biohazardous Material must be reviewed and approved in a manner consistent with the *NIH Guidelines* before initiation.

4. RESPONSIBILITIES

- 4.1 All faculty, staff and students are responsible for the safe and compliant use, storage, and disposal of Biohazardous Material used in their research, teaching or testing. IBC approval must be obtained prior to the possession or use of Biohazardous Material.

- 4.2 Principal investigators (PIs) and department heads (or equivalent) are responsible for ensuring that all research, teaching or testing activities involving Biohazardous Material (including protocols that may be exempt from the *NIH Guidelines*) are submitted to the member's respective IBC for review and approval.
- 4.3 PIs must submit continuing reviews to their respective IBC at least annually.
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Related Statutes, Policies or Requirements

[Select Agents Regulations \(7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73\)](#)

USDA Permit Requirements ([9 CFR Subchapter E](#))

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)

[Biosafety in Microbiological and Biomedical Laboratories](#)

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

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

Tex. Health & Safety Code §§ [81.301 – 81.306](#)

[Texas Administrative Code §§ 96.101-301](#)

[System Regulation 15.99.05, Research Compliance](#)

[System Policy 24.01, Risk Management](#)

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

Member Rule Requirements

A rule is required to supplement this regulation. See Section 2.1.

Contact Office

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