

15.99.06 Use of Biohazards in Research, Teaching and Testing

Approved June 11, 2015
Next Scheduled Review: June 11, 2020



Regulation Statement

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 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.

Reason for Regulation

This regulation provides guidance in complying with federal and state laws, regulations and guidelines relating to research, teaching and testing with biohazardous materials including, but not limited to, infectious agents, biological toxins, select agents, recombinant and synthetic nucleic acid molecules and cells, organisms, and viruses containing such molecules.

Procedures and Responsibilities

1. BIOHAZARDOUS MATERIAL

1.1 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)*;
- (c) Human and non-human primate blood, tissue, cells and cell lines; and
- (d) Toxins of biological origin as defined in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* document.

1.2 Recombinant and Synthetic Nucleic Acid Molecules – In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

- (a) Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- (b) 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
- (c) Molecules that result from the replication of those described in 1.2(a) or 1.2(b) above.

2. ADMINISTRATIVE REQUIREMENTS

- 2.1 Each member involved with research teaching, testing, or utilizing biohazardous material shall establish a rule for carrying out this regulation.
- 2.2 Procedures for the use and storage of biohazardous material shall be consistent regardless of the sources of funding.
- 2.3 The chief executive officer or designee of each member that conducts research, teaching or testing with biohazards shall develop an Institutional Biological Safety Committee (IBC) or enter into an agreement with another member with a registered IBC. Each IBC shall meet the requirements set out in the *NIH Guidelines* and register with the Office of Biotechnology Activities (OBA) of the NIH, U.S. Department of Health and Human Services.
- 2.4 Each member with an IBC shall develop written IBC procedures, including procedures relating to the review of biohazard protocols and reporting guidelines. Activities involving the use of biohazards and/or recombinant DNA shall be reviewed and approved in a manner consistent with the *NIH Guidelines* before initiation.

3. GENERAL GUIDELINES

- 3.1 All faculty, staff and students must be aware of and are responsible for the safe and compliant use, storage, and disposal of biohazards used in their research, teaching or testing. Prior approval must be obtained for the possession or use of biohazards.
- 3.2 Principal investigators (PIs) and department heads (or equivalent) are responsible for ensuring that all research, teaching or testing involving biohazards (including protocols which may be exempt, as defined in the *NIH Guidelines*) is submitted to the member's respective IBC for review and approval.
- 3.3 PIs shall submit continuing reviews to their respective IBCs not less than annually at a minimum.
- 3.4 Activities involving biohazards must meet the criteria articulated in the most current versions of federal or state documents, requirements, and laws including:
 - (a) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*;

- (b) The Public Health Service/Centers for Disease Control and Prevention/National Institutes of Health's *Biosafety in Microbiological and Biomedical Laboratories* (BMBL);
 - (c) Select Agents Regulations (7 CFR Part 331, 9 CFR Part 121 and 42 CFR Part 73);
 - (d) U.S. Department of Agriculture (USDA) regulations and permits as applicable;
 - (e) Centers for Disease Control and Prevention's (CDC) Etiologic Agent Import Permit Program (EAIPP) import permit requirements; and
 - (f) State of Texas Health and Safety Code §§ 81.301 – 81.306.
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Related Statutes, Policies or Requirements

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

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

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#)

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

[System Regulation 15.99.05, Research Compliance](#)

[System Policy 24.01, Risk Management](#)

[System Regulation 24.01.01, Risk Management Programs](#)

Member Rule Requirements

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

Contact Office

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