



Rule

15.99.06.L1 Use of Biohazards in Research, Teaching, and Testing

First Approved: July 11, 2017
Revised: July 11, 2017
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Rule Statement and Reason for Rule

Texas A&M International University (TAMIU) 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.

This rule describes the review and approval process for activities involving the use of biohazardous materials.

Procedures and Responsibilities

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 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.

- 1.2 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 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). In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.

2. INSTITUTIONAL OFFICIAL

- 2.1 The President has appointed the Provost and VP for Academic Affairs to serve as the Institutional Official (IO) with administrative authority to commit institutional resources to ensure that use of biohazardous materials will comply with system, state and federal requirements.
- 2.2 The IO has been delegated authority by the President to appoint member to and remove members from the Institutional Biosafety Committee (IBC).
- 2.3 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 policies, procedures, and guidelines.

3 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

- 3.1 The IO shall ensure the IBC meets the membership requirements articulated in the current version of the "*NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules.*"
- 3.2 The IBC is responsible for the review and approval of all activities involving the use of biohazardous materials, to assess and set containment levels for activities utilizing biohazardous materials, and to notify faculty of the outcome of this review.
- 3.3 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.
- 3.4 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.
- 3.5 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.
- 3.6 The IBC Chair in coordination with the Office of Research and Sponsored Projects will maintain its Institutional Biosafety Committee registration with the National Institutes of Health at all times, even if not required by federal requirements.

- 3.7 The storage and use of biohazardous materials within the University, whether for research, teaching, or testing purposes, shall be described in an IBC Protocol Application (Protocol). The Protocol is a form designed to capture relevant information regarding the appropriate use of the biohazardous materials in research, teaching, or testing activities.
- 3.8 IBC approval is required prior to possession or use of biohazardous materials.
- 3.9 All modifications to approved storage and use of biohazardous materials must be approved prior to initiation of the changes.
- 3.10 The IBC Chair shall be responsible for registering 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 any select agent or toxin, including receipt of select agents and toxins from outside the United States.

4 RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER

- 4.1 The IO shall appoint a Biological Safety Officer (BSO) if the University engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules.
- 4.2 The BSO's duties include, but are not limited to, those articulated in the most recent version of the *NIH Guidelines*.

5 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Principal investigators (PI's) 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 assuring all responsibilities of PI's as articulated in the most recent version of the *NIH Guidelines* are met;
- 5.2 assuring 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 Protocol must be prepared and signed by the PI and must be reviewed and approved by the IBC. If research is collaborative or involves other institutions, approval must be obtained from each institution;
- 5.3 assuring conduct of research, teaching, or testing activities involving biohazardous materials is restricted to that described in the approved protocol or approved amendments and is in congruence with funding grants, if applicable;
- 5.4 assuring all participants in activities with biohazardous materials are appropriately qualified through training and education to perform their responsibilities as listed in the Protocol;

- 5.5 assuring all participants in activities with biohazardous materials are enrolled in an Occupational Health and Safety program, if required by their approved Protocol;
 - 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 non-compliance that involves biohazardous materials.
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Related Statutes, Policies, Regulations, or SAP's

[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 \(BMBL\)](#)

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

[System Regulation 15.99.05, Research Compliance](#)

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

[System Policy 24.01, Risk Management](#)

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

Definitions

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.

Contact Office

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