

15.99.06.W1 Use of Biohazardous Material in Research, Teaching and Testing

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Rule Summary

West Texas A&M University (WTAMU) 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.

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 the 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 most recent versions of following:
 - 1.2.1 The Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*;
 - 1.2.2 *NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines)*;
 - 1.2.3 USDA regulations controlling the use of biohazardous materials
 - 1.2.4 Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121);
 - 1.2.5 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern;
 - 1.2.6 USDA regulations and permits as applicable;

- 1.2.7 CDC's Etiologic Agent Import Permit Program import permit requirements; and
 - 1.2.8 State of Texas Health and Safety Code §§81.301 – 81.306 and Texas Administrative Code §§96.101 – 96.301
 - 1.2.9 In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.
- 1.3 The storage and use of biohazardous materials within the University, whether for research, teaching or testing purposes, shall be described in an Institutional Biosafety Committee (IBC) Permit Application. The permit application is designed to capture relevant information regarding the appropriate use of the biohazardous materials in research, teaching or testing activities.
 - 1.3.1 IBC approval of the permit application and issuance of an IBC permit is required prior to possession or use of biohazardous materials.
 - 1.3.2 All modifications to approved storage and use of biohazardous materials must be approved prior to initiation of the changes.
 - 1.4 Laboratory principal investigators 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 any select agent or toxin, including receipt of select agents and toxins from outside the United States.

2. INSTITUTIONAL OFFICIAL

- 2.1 The WTAMU President/CEO has appointed the Vice President for Research and Compliance to serve as the Institutional Official (IO) with administrative authority to commit institutional resources to ensure that the use of biohazardous materials will comply with system, state and federal requirements.
- 2.2 The IO has been delegated authority by the WTAMU President/CEO to appoint and remove members of the 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 regulation, University policies, procedures and guidelines.

3. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

- 3.1 The IBC shall meet the membership requirements articulated in the current version of the *NIH Guidelines*.
- 3.2 The IBC is responsible for developing written procedures, including procedures relating to the review of Biohazardous Materials protocols and reporting guidelines.

- 3.3 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.
- 3.4 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.
- 3.5 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.
- 3.6 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.
- 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.

4. RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER

- 4.1 The Institutional Official shall appoint a Biological Safety Officer if:
 - 4.1.1 It engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules or
 - 4.1.2 It engages in recombinant or synthetic nucleic acid molecule research at BL3 or BL4.
- 4.2 Biological Safety Officer'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

- 5.1 Principal investigators are primarily responsible for compliance with all federal and state laws and regulations involving activities covered by this rule and are responsible for:
 - 5.1.1 Assuring all responsibilities of principal investigators articulated in the most recent version of the *NIH Guidelines* are met;
 - 5.1.2 Assuring all activities with biohazardous materials are appropriately reviewed and approved prior to initiating any activities or changes to approved activities. Regardless of funding sources, an IBC permit application must be prepared and

signed by the principal investigator and must be reviewed and approved by the IBC. If research is collaborative or involves other institutions, approval must be obtained from each institution;

- 5.1.3 Assuring that conduct of research, teaching or testing activities involving biohazardous materials is restricted to that described in the approved IBC permit or approved amendments and is in congruence with funding grants, if applicable;
- 5.1.4 Assuring that all participants in activities with biohazardous materials are appropriately qualified through training and education to perform their responsibilities as listed in the IBC permit application;
- 5.1.5 Assuring that all participants in activities with biohazardous materials are enrolled in an Occupational Health and Safety program, if required;
- 5.1.6 Abiding by all determinations of the IBC, including, but not limited to directives to terminate participation in designated research, teaching or testing activities;
- 5.1.7 Notifying the IBC as soon as possible after the discovery of any reportable incident or non-compliance that involves biohazardous materials.

Related Statutes, Policies, or Requirements

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

[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, *Health and Safety*](#)

Definitions

Biohazardous Material: 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) 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 or Biotechnology; (d) human and non-human primate blood, tissue, cells and cell lines;

and (e) toxins of biological origin as defined in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) document.

Recombinant and Synthetic Nucleic Acid Molecules: In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as (a) molecules that (1) are constructed by joining nucleic acid molecules and (2) 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 above in biohazardous materials.

Revision History

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Approval Signature



President/CEO

Date

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