

Rule 15.99.06.O1 Use of Biohazardous Material in Research, Teaching and Testing



TEXAS A&M UNIVERSITY
SAN ANTONIO

Approved: 2/24/2023

Next Scheduled Review: 2/23/2028

Rule Summary

Texas A&M University-San Antonio (A&M-SA) is committed to protecting faculty, staff, students, visitors, the general public, and the environment from the risk of exposure to biohazardous materials, biological toxins, 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, and federal, state, local, system, and A&M-SA regulations and guidelines.

Reason for Rule

The Texas A&M University System (System) Regulation 15.99.06 [Use of Biohazardous Materials in Research, Testing, and Teaching](#) requires A&M-San Antonio to establish campus procedures and administrative responsibilities regarding the use of biohazardous materials in all research, teaching, or testing activities.

Procedures and Responsibilities

1. BIOHAZARDOUS MATERIALS

1.1 A biohazardous material is any material that contains:

- (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). Recombinant and Synthetic Nucleic Acid Molecules are
 - 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
- (c) Human and non-human primate blood or other fluid, tissue, cells, cell lines, and
- (d) Toxins of biological origin as defined in the [Biosafety in Microbiological and Biomedical Laboratories](#) document and select agents.

2. ADMINISTRATIVE REQUIREMENTS

- 2.1 The A&M-SA President 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 activities involving biohazardous materials. The IO has been delegated authority by the President to appoint and remove members of the A&M-SA Institutional Biosafety Committee (IBC).
- 2.2 The Vice Provost for Research and Graduate Studies has been appointed as the IO by the President.
- 2.3 Procedures for the use and storage of biohazardous materials must be consistent, regardless of the sources of funding.
- 2.4 Activities involving biohazardous materials must meet the criteria articulated in the most current versions of federal and state laws, and federal, state, local, system, and A&M-SA regulations and guidelines including:
 - a) *NIH Guidelines*;
 - b) The Public Health Service/Centers for Disease Control and Prevention (CDC)/NIH's
 - c) *Biosafety in Microbiological and Biomedical Laboratories*;
 - d) Select Agents Regulations (7 CFR Part 331, 9 CFR Part 121 and 42 CFR Part 73);
 - e) United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern;
 - f) USDA regulations and permits as applicable;
 - g) CDC's Etiologic Agent Import Permit Program import permit requirements; and
 - h) State of Texas Health and Safety Code §§ 81.301 – 81.306 and Texas Administrative Code §§ 96.101-301.
- 2.5 The use of biohazardous materials, whether for research, teaching, and/or testing purposes, shall be described in an IBC registration. The registration will contain relevant information regarding the appropriate use, transportation, and disposal of biohazardous materials and strategies to minimize exposure of personnel and the environment to biohazardous materials for research, teaching, and/or testing activities.
 - a) For each research, teaching, or testing project using biohazardous materials, IBC approval must be obtained before any activities begin.
 - b) An approved and current IBC registration for all research, teaching, or testing activities using biohazardous materials must be in place at all times during the activity.
 - c) All modifications to previously approved IBC registrations must be approved prior to initiation of the changes.

3. INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE

- 3.1 As an institution that uses biohazardous materials in research, teaching, and testing, A&M-SA is required by the NIH to have an IBC registered with the NIH. The A&M-SA IBC shall be structured and perform the duties and functions according to NIH guidelines.
- 3.2 Members of the A&M-SA IBC shall be appointed by the IO or designee.

- 3.3 All members shall receive appropriate training and orientation to discharge their duties.
- 3.4 IBC may choose to appoint expert reviewers as required to conduct risk analysis of the protocols.
- 3.5 Following review of applications for registration, the A&M-SA IBC may:
 - a) approve as is,
 - b) approve with administrative corrections,
 - c) approve with modifications,
 - d) defer, or
 - e) determine an application is un-approvable.
- 3.6 A decision by the IBC is final and may not be overridden by the IO or other University official.
- 3.7 The A&M-SA IBC may also terminate a previously approved registration for noncompliance.
- 3.8 The IBC Chair, Vice Chair, Biosafety Officer, and/or Director of Research Compliance shall have full authority to enter any areas where biohazardous materials are used or stored for research, teaching or testing to ensure compliance.

4. RESPONSIBILITIES

- 4.1 All faculty, staff, students, and other approved personnel are responsible for the safe and compliant transport, use, storage, and disposal of biohazardous materials used in their research, teaching or testing activities.
- 4.2 IBC approval must be obtained prior to the possession or use of biohazardous materials.
- 4.3 Principal investigators (PIs) 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 A&M-SA IBC for review and approval.
- 4.4 PIs must submit annual continuing reviews of their approved registrations to the A&M-SA IBC before the expiration of their anniversary dates.
- 4.5 PIs must notify the A&M-SA IBC in writing using appropriate forms of an adverse event within 24 hours.

5. REPORTING

- 5.1 The IO or designee is responsible notifying the NIH of any significant problems, violations of the NIH Guidelines, or any significant research-related accidents within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BSL-2 laboratories resulting in an overt exposure must be immediately reported to NIH.
- 5.2 Anyone who is aware of potential non-compliance to federal and state laws, and federal, state, local, system, and A&M-SA regulations and guidelines may report their concerns to the IBC Chair, Vice Chair, the Office of Research Compliance, or the IO through 'Ethics Point'.

- 5.3 All allegations of non-compliance will be investigated by the A&M-SA IBC. Confidentiality will be maintained to the extent possible and appropriate and permissible under the law. No university employee or student shall be discriminated against or subject to any reprisal for good faith reporting of actual or potential violations.

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](#)

Contact Office

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