15.99.06.C1 Use of Biohazards in Research, Teaching, and Testing

Revised: February 7, 2022
Next Scheduled Review: February 7, 2027
Revision History

Rule Summary

Texas A&M University-Corpus Christi (TAMU-CC) 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.

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 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 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)*, the 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 must prevail, as appropriate.

1.3. The university will maintain its Institutional Biosafety Committee (IBC) registration with the National Institutes of Health at all times, even if not required by federal requirements.

1.4. The storage and use of biohazardous materials within the university, whether for research, teaching, or testing purposes, must be described in a Biohazardous Use Protocol (BUP). The BUP is a form designed to capture relevant information regarding the appropriate use of biohazardous materials in research, teaching, or testing activities.

1.5. IBC approval is required prior to possession or use of biohazardous materials.

1.6. All modifications to approved storage and use of biohazardous materials must be approved prior to initiating the changes.

1.7. TAMU-CC 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 the 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 of any select agent or toxin, including receipt of select agents and toxins from outside the United States.

2. INSTITUTIONAL OFFICIAL

2.1. The President has appointed the Vice President for Research and Innovation to serve as the Institutional Official (IO) with administrative authority to commit institutional resources to ensure that the oversight of 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 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 policies and regulations or university rules, procedures, and guidelines.

3. INSTITUTIONAL BIOSAFETY COMMITTEE

3.1. The IBC shall meet 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 the use of biohazardous materials if such use poses a risk to personnel, public health and safety, or for issues of non-compliance.

4. APPLICABILITY OF AND RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER

4.1. The IO must appoint a Biological Safety Officer if TAMU-CC becomes engaged in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules.

4.2. When appointed, the Biological Safety Officer's duties will 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 are primarily responsible for compliance with all federal and state laws and regulations involving activities covered by this rule and are responsible for:

(a) ensuring all responsibilities of principal investigators as articulated in the most recent version of the *NIH Guidelines*.

(b) ensuring that all activities with biohazardous materials are appropriately reviewed and approved prior to initiation of any activities or changes to approved activities.

a. Regardless of funding sources, a BUP must be prepared and signed by the principal investigator and must be reviewed and approved by the IBC.

b. If research is collaborative or involves other institutions, approval must

be obtained and a copy of the same provided from each institution.

(c) ensuring that conduct of research, teaching, or testing activities involving biohazardous materials is restricted to that described in the approved BUP or approved amendments, and is in congruence with funding grants, if applicable.

(d) ensuring that all participants in activities with biohazardous materials are appropriately qualified through training and education to perform their responsibilities as listed in the BUP.

(e) ensuring that all participants in activities with biohazardous materials are enrolled in an Occupational Health and Safety program if required by their approved BUP.

(f) abiding by all determinations of the IBC, including, but not limited to, directives to terminate participation in designated research, teaching, or testing activities.

(g) notifying the IBC as soon as possible after the discovery of any reportable incident or noncompliance that involves biohazardous materials.

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 Policy *15.99.05, Research Compliance*
System Regulation *15.99.06, Use of Biohazardous Material in Research, Teaching and Testing*
System Policy *24.01, Risk Management*
System Regulation *24.01.01, Health and Safety*

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