

15.99.06.K1 Use of Biohazardous Material in Research, Teaching and Testing

Approved: July 05, 2016

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Revised: January 20, 2022

Next Scheduled Review: January 20, 2027

Rule Summary

Texas A&M University-Kingsville (TAMUK) 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.

Definition

- 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.

4. RESPONSIBILITIES OF THE BIOLOGICAL SAFETY OFFICER

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

Principal investigators (PIs) are primarily responsible for compliance with all federal and state laws and regulations involving activities covered by this Rule and are responsible for:

- (a) assuring all responsibilities of PIs as articulated in the most recent version of the *NIH Guidelines* are met;
- (b) that 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 BUP 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;
- (c) assuring 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) assuring 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) assuring 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.
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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 \(BMBL\)](#)

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

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