15.99.06.E1 Use of Biohazardous Materials in Research, Teaching and Testing and Dual Use Research of Concern

Approved May 4, 2016
Reviewed March 17, 2022
Next Scheduled Review: March 17, 2027

Supplements System Regulation 15.99.06

Rule Summary

In accordance with System Regulation 15.99.06, *Use of Biohazardous Materials in Research, Teaching and Testing*, Texas A&M Engineering Experiment Station (TEES) will comply with all applicable laws and regulations relating to activities involving biohazardous materials and will ensure the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations and guidelines. Additionally, TEES is committed to the shared responsibility of upholding the integrity of science and to reducing the risk of its misuse.

This rule is required by A&M System Regulation 15.99.06, and describes the review and approval process for activities involving the use of biohazardous material and research which may constitute Dual Use Research of Concern (DURC).

Procedures and Responsibilities

1. GENERAL

1.1 In accordance with A&M System Regulation 15.99.06, *Use of Biohazardous Materials in Research, Teaching and Testing,* TEES will comply with all applicable standards including the Select Agent 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) and Biosafety in Microbiological and Biomedical Laboratories (BMBL).

1.2 Life science research is essential to the scientific advances that underpin improvements in the health and safety to the public and national security. Despite its value and benefits, however, certain types of research conducted for legitimate purposes can be utilized for benevolent or harmful purposes. The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research

of Concern (IODURC) addresses institutional oversight of Dual Use Research of Concern and identifies the criteria for what qualifies as DURC by listing specific agents and toxins and descriptions of the types of experiments, which when combined, define the parameters for research considered DURC.

1.3 TEES Research Compliance is the responsible office for compliance associated with TEES awards, and will closely coordinate with the Texas A&M University (TAMU) Office of Research Compliance and Biosafety, TAMU Sponsored Research Services (SRS), the principal investigator (PI), and other appropriate parties in the coordination of Institutional Biosafety Committee (IBC) and Institutional Review Entity (IRE) review and approval.

1.3.1 TEES has an intrasystem agreement in place with TAMU to utilize their IBC and IRE as necessary. TEES will comply with all the rights, duties and responsibilities as outlined in this agreement as it pertains to such research.

1.4 The TEES Deputy Director is the Institutional Official (IO). The IO ensures compliance with applicable state and federal law any may collaborate with appropriate institutional officials to place sanctions on researchers failing to comply with these laws, or failing to comply with System regulations, policies, procedures and guidelines.

2. PROCEDURES FOR REVIEW AND APPROVAL

2.1 All research conducted under TEES, including cooperative research in which biohazardous materials are utilized must be both reviewed and approved by the TAMU IBC. For more information regarding the approval process, please refer to the TAMU Office of Research Compliance and Biosafety Web site.

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2.2 Sponsored research administrators will notify TEES Research Compliance of all compliance issues for TEES involving the use of biohazardous materials in research.

2.3 Responsibility for ensuring that all research involving biohazardous materials or recombinant DNA is submitted to the TAMU IBC for review and approval lies with both the PI and division/department head, in coordination with research administrators, and TEES Research Compliance.

2.4 Policies and procedures for criteria, review, and approval by the TAMU IBC for research involving biohazardous materials will be conducted in accordance with TAMU Rule 15.99.06.M1, *Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern*.

2.5 TAMU Vice President of Research Staff will meet with the IO, at least annually, to provide a report of services covered under the intrasystem agreement.

3. COMPLIANCE

Reports and allegations of noncompliance with applicable laws, policies, regulations, rules, and procedures may be submitted to the Chief Operating Officer at TEES, the TAMU Office of Research Compliance and Biosafety, or via the TAMUS Risk, Fraud, and Misconduct Hotline.

4. EXPORT CONTROLS

Procedures and responsibilities related to export controls compliance associated with biohazards materials, biological toxins, recombinant DNA, and DURC can be found in the TEES *Export Controls Compliance Manual.*

5. RECORDKEEPING

Records will be kept in accordance with System Regulation 15.99.06 and TEES procedure 61.99.01.E0.01, *Records Management*.

Related Statutes, Policies, or Requirements

Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121)

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

Regulation 15.99.06, Use of Biohazards in Research, Teaching and Testing

Regulation 61.99.01, Retention of State Records

TAMU Rule 15.99.06.M1, Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern

TEES SAP 61.99.01.E0.01, Records Management

Contact Office

Office of Research Compliance
researchcompliance@tees.tamus.edu