Texas A&M Veterinary Medical Diagnostic Laboratory Rules

15.99.06.V1 | Use of Biohazardous Material in Research, Teaching, and Testing

Revised: March 31, 2022

Next Scheduled Review: March 31, 2027

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RULE SUMMARY

In accordance with The Texas A&M University System (A&M System) Regulation 15.99.06, *Use of Biohazards in Research, Teaching, and Testing*, Texas A&M Veterinary Medical Diagnostic Laboratory (TVMDL) will comply with all applicable laws and regulations relating to activities involving biohazardous materials and recombinant DNA (rDNA), and will ensure the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations, and guidelines. Additionally, TVMDL 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.

Click **here** for **Definitions**

PROCEDURES AND RESPONSIBILITIES

1.0 GENERAL

1.1 In accordance with A&M System Regulation 15.99.06, TVMDL will comply with all applicable standards including the Public Health Services/Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), the latest Select Agent Regulations (7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73), the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, United States Department of Agriculture (USDA) regulations and permits as applicable, CDC's Etiologic Agent Import Permit Program import permit requirements, and State of Texas Health and Safety Code §§ 81.301-81.306 and Texas Administrative Code §§ 96.101-301.

1.2 Life science research is essential to the scientific advances that underpin improvements in the health and safety to the public, agricultural crops and other plants, animals, the environment, material (e.g., food, water, equipment, and supplies), and national security. Despite its value and benefits, certain types of research conducted for legitimate purposes can be used 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 DURC 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.

2.0 INSTITUTIONAL BIOSAFETY COMMITTEE

2.1 Texas A&M AgriLife (AgriLife) Risk Ethics and Compliance is the responsible office for compliance associated with TVMDL awards, and will closely coordinate with the Texas A&M University (Texas A&M) Office of Research Compliance and Biosafety, Texas A&M 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.

2.2 TVMDL has an intrasystem agreement in place with Texas A&M to utilize their IBC and IRE as necessary. TVMDL will comply with all the rights, duties, and responsibilities as outlined in this agreement as it pertains to such research.

2.3 Per University Rule 15.99.06.M1, the IBC shall be structured according to the "NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules." The Texas A&M IBC will provide review and oversight of activities utilizing biohazardous materials. Such activities performed under the auspices of Texas A&M University, including cooperative research conducted with one or more public or private entities, must be reviewed and approved by the IBC prior to initiation. The IBC is responsible for the review of all activities involving the use of biohazardous materials including research, teaching and testing activities.

3.0 INSTITUTIONAL OFFICIAL

3.1 The director or designee is the Institutional Official (IO) for TVMDL. 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 A&M System regulations, Texas A&M policies, procedures, and guidelines

4.0 PROCEDURES FOR IBC PERMIT REVIEW AND APPROVAL

4.1 All activities involving biohazardous material conducted under TVMDL—including cooperative research — must be both reviewed and approved by the Texas A&M IBC. For more information regarding the approval process, please refer to the Texas A&M Office of Research Compliance and Biosafety website.

4.2 SRS is responsible for sponsored research administration for TVMDL, and will notify AgriLife Ethics and Compliance of all compliance issues for TVMDL involving the use of biohazardous material.

4.3 Responsibility for ensuring that all activities involving biohazardous materials is submitted to the Texas A&M IBC for review and approval lies with both the PI and unit/department head in coordination with SRS and AgriLife Ethics and Compliance.

4.4 Policies and procedures for criteria, review, and approval by the Texas A&M IBC for activities involving biohazardous material will be conducted in accordance with Texas A&M Rule 15.99.06.M1, *Use of Biohazards, Biological Toxins and Recombinant DNA, and Dual Use Research of Concern*.

4.5 Staff from the Office of the Texas A&M Vice President of Research will meet with the TVMDL IO no less than annually to provide a report on the services covered under the intrasystem agreement.

5.0 NONCOMPLIANCE

Reports and allegations of noncompliance with applicable laws, policies, regulations, rules, and procedures may be submitted to the Director for Ethics and Compliance in AgriLife Administrative Services or the Texas A&M Office of Research Compliance and Biosafety.

2.0 EXPORT CONTROLS

Procedures and responsibilities related to export controls compliance can be found in the AgriLife *Export Controls Compliance Manual*.

6.0 RECORDKEEPING

Records will be kept in accordance with TVMDL procedure 61.99.01.V0.01, *Retention of State Records*.

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 DNA Molecules (NIH Guidelines)

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

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

Texas Health & Safety Code §§ 81.301-81.306

Texas Administrative Code §§ 96.101-301

A&M System Regulation 15.99.06, *Use of Biohazardous Materials in Research, Teaching and Testing*

A&M System Regulation 61.99.01, *Retention of State Records*

Texas A&M Rule 15.99.06.M1, *Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern*

AgriLife Research Procedure 61.99.01.A0.01, *Retention of State Records*

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) and 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 of Biotechnology*;

(c) Human and non-human primate blood, tissue, cells, and cell lines;

(d) Toxins of biological origin as defined in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) document and;

(e) Recombinant and Synthetic Nucleic Acid Molecules, as defined in the *NIH Guidelines*:

  (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

  (3) Molecules that result from the replication of those described in (1) or (2) above.

CONTACT OFFICE

Questions concerning this procedure should be referred to AgriLife Ethics and Compliance at 979-845-7879.

REVISION HISTORY

Approved: January 4, 2016
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