

Approved: November 23, 2015

Next Scheduled Review: November 23, 2020

RULE STATEMENT

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 AgriLife Research (AgriLife Research) will comply with all applicable laws and regulations relating to activities involving biohazardous materials and recombinant DNA, and will ensure the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations, and guidelines. Additionally, AgriLife Research is committed to the shared responsibility of upholding the integrity of science, and to reducing the risk of its misuse.

REASON FOR RULE

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 or/recombinant DNA, and research which may constitute Dual Use Research of Concern (DURC).

PROCEDURES AND RESPONSIBILITIES

1.0 GENERAL

- 1.1 In accordance with A&M System Regulation 15.99.06, AgriLife Research 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, 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
- 1.3 Texas A&M AgriLife (AgriLife) Risk and Compliance is the responsible office for compliance associated with AgriLife Research 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 AgriLife Research has an intrasystem agreement in place with TAMU to utilize their IBC and IRE as necessary. AgriLife Research will comply with all the rights, duties, and responsibilities as outlined in this agreement as it pertains to such research.

2.0 INSTITUTIONAL OFFICIAL

- 2.1 The Director or designee is the Institutional Official (IO) for AgriLife Research. 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, University policies, procedures, and guidelines

3.0 PROCEDURES FOR REVIEW AND APPROVAL

- 3.1 All research conducted under AgriLife Research—including cooperative research in which biohazardous materials or recombinant DNA are used—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](#).
- 3.2 SRS is responsible for sponsored research administration for AgriLife Research, and will notify AgriLife Risk and Compliance of all compliance issues for AgriLife Research involving the use of biohazardous materials, biological toxins, or recombinant DNA in research.
- 3.3 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 unit/department head in coordination with SRS and AgriLife Risk and Compliance.
- 3.4 Policies and procedures for criteria, review, and approval by the TAMU IBC for research involving biohazardous materials, biological toxins, and recombinant DNA 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*.
- 3.5 The TAMU Vice President of Research staff will meet with the AgriLife Research IO no less than annually to provide a report on the services covered under the intrasystem agreement.

4.0 REGULATED TRANSGENIC FIELD TRIALS

- 4.1 Any AgriLife Research PI who is to conduct a field trial with a regulated transgenic organism which requires a USDA Permit or Notification is required to complete form [AG-719, Transgenic Field Trial Certification](#).
 - 4.1.1 AG-719 shall be completed and submitted to AgriLife Risk and Compliance via Laserfiche (Work In Progress Compliance / AG-719 folder) for any new field trial with a regulated transgenic organism that is to occur on TAMU or AgriLife property.
 - 3.1.2 A copy of all supplemental USDA permits or notifications associated with conducting a regulated transgenic field trial shall also be submitted to AgriLife Risk and Compliance with the AG-719.

5.0 NON-COMPLIANCE

Reports and allegations of noncompliance with applicable laws, policies, regulations, rules, and procedures may be submitted to the Assistant Director for Risk and Compliance in AgriLife Administrative Services or the TAMU Office of Research Compliance and Biosafety.

6.0 EXPORT CONTROLS

Procedures and responsibilities related to export controls compliance can be found in the AgriLife [Export Controls Compliance Manual](#).

7.0 RECORDKEEPING

Records will be kept in accordance with AgriLife Research procedure 61.99.01.A0.01, *Retention of State Records*.

RELATED STATUTES, POLICIES, OR REQUIREMENTS

Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121)
<http://www.selectagents.gov/Regulations.html>

NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines)
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

Biosafety in Microbiological and Biomedical Laboratories (BMBL)
<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

[A&M System Regulation 15.99.06](#), *Use of Biohazards in Research, Teaching and Testing*

[A&M System 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*

[AgriLife Research Procedure 61.99.01.A0.01](#), *Retention of State Records*

CONTACT OFFICE

For additional questions, contact AgriLife Risk and Compliance at 979-845-7879.