## I. Introduction

Texas Christian University ("TCU") is committed to ensuring that research activities involving biological materials and organisms conducted under the auspices of TCU are conducted as safely as feasible and in accordance with Applicable Law, as defined below.

To assist with this commitment, and ensure compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines"), TCU has established an Institutional Biosafety Committee, which is responsible for overseeing the compliance of all research and teaching activities that are conducted by faculty, staff, students, and/or any other individuals at, or under the auspices of TCU, and that involve the use of recombinant or synthetically derived nucleic acid molecules or other biohazardous materials.

This policy outlines responsibilities of the Institutional Biosafety Committee and establishes the minimum requirements for the safe, secure, and compliant use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials.

## II. Definitions

The definitions used in this policy, but not otherwise defined, have the same meaning given to them in the NIH Guidelines.

Applicable Law. A collective reference to the applicable law, regulations and guidelines, including:

- CDC/NIH: *Biosafety in Microbiological and Biomedical Laboratories*, current edition.
- Department of Transportation (DOT): 49 CFR Parts 171-177, *Hazardous Materials Regulations.*
- NIH: *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*
- OSHA: 29 CFR 1910.1030, *Bloodborne Pathogens*.
- U.S. Public Health Service (USPHS): 42 CFR Part 72, *Interstate Transportation of Etiologic Agents.*
- U.S. Department of Agriculture (USDA): 7 CFR Part 331 and 9 CFR Part 121, *Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Select Agents and Toxins, Final Rule*. Department of Health and Human Services (DHHS): 42 CFR Parts 72 and 73, *Office of Inspector General* and 42 CFR Part 1003 *Possession, Use and Transfer of Select Agents and Toxins, Final Rule.*
- U.S. Patriot Act of 2001.

Biohazard. Infectious agents presenting a risk or potential risk to the well-being of humans or other animals directly through infection or indirectly through disruption of the environment. Examples include recombinant DNA; select agents; human pathogens; and cells, tissues.

Institutional Biosafety Committee ("IBC"). A committee that (1) meets the requirements for membership specified in the NIH Guidelines; and (2) reviews, approves, and oversees projects in accordance with the responsibilities defined in the NIH Guidelines.
Human Pathogen. A biological agent that can cause disease in human beings.

Recombinant DNA ("rDNA"). Referral to rDNA throughout this policy will apply to (i) molecules that a) are constructed by joining nucleic acid molecules, and b) can replicate in a living cell (i.e. recombinant nucleic acids); (ii) 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 (iii) molecules that result from the replication of those described in (i) or (ii) above.

Registration. The process of completing the appropriate institutional registration form and submitting it to the IBC chairperson for review and receiving IBC approval.

Select Agents. Microorganism (viruses, bacteria, fungi, prions) or toxins that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.

## III. Applicability

This policy applies to all research and teaching activities that are conducted at, or under the auspices of, TCU, and that involve the use of rDNA or other biohazardous materials (regulated human, animal and plant pathogens and biological toxins).

## IV. Policy Requirements

A. General. All research and teaching activities that are conducted at, or under the auspices of, TCU, and that involve the use of rDNA or other biohazardous materials, regardless of funding source, must be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules and must be registered with the TCU IBC. All current and new research or teaching activities must be approved by the TCU IBC. Only TCU faculty or staff may serve as the principal investigator, unless otherwise approved by the TCU IBC and the Associate Provost for Research.

B. IBC.

1. Responsibilities. The TCU IBC is charged with the following tasks:

   a. reviewing research subject to this policy pursuant to NIH Guidelines, the Biosafety in Microbiological and Biomedical Laboratories (currently in 5th edition, 2007); and the OSHA laboratory health standard Occupational Exposures to Hazardous Chemicals in Laboratories (29 CFR 1910.1450), as well as applicable TCU policies and procedures; registering and reviewing research utilizing Risk Group 2 or higher biological agents and to approve research that contains adequate safeguards to protect the health and safety of the laboratory personnel, students, staff, and visitors; to interpret Applicable Law and to provide technical assistance to the Office of Research, and Environmental Health Safety ("EHS") on these matters;

   b. Considering policies and procedures pertaining to the safe handling, transport, use, and disposal of materials under its

purview and to recommend the adoption of appropriate new or revised policies to the Office of Research through the Director of Research Compliance and Training;

c. In conjunction with the EHS, assisting with safe handling, transport, use, and disposal of rDNA, microorganisms, select agents, biological toxins, regulated and particularly hazardous chemicals; and

d. Rendering advice in consideration for space and facilities for research involving rDNA, microorganisms, select agents, biological toxins, regulated and particularly hazardous chemicals.

2. Composition. The composition of the IBC meets the requirements as specified in the NIH Guidelines which includes two community members that are not affiliated with TCU. The members of the committee are appointed by the Chancellor. Members of the committee, other than those specified by virtue of their position, will be nominated by the Associate Provost for Research and the Provost. Each member will serve a term of three years except when lesser terms may be required to maintain balanced membership and continuity of committee operations. Reappointments are permissible. All officer appointments, including chairperson, are made by the Associate Provost for Research.

C. Review for Experiments that Require IBC Approval. The Principal Investigator must prepare and electronically submit the *appropriate forms* to the IBC chairperson. The IBC Chairperson will make preliminary determination as to whether the project is exempt from the review by the IBC under federal guidelines; however, the final determination rests with the IBC. The IBC will review the protocols and transmit its decision in writing to the principal investigator and the Office of Research Services. Experiments may be initiated immediately upon approval by the IBC.

D. Written Safety Plan. A pathogen safety plan is required for any research activities involving Biohazards. The program should provide the necessary information, training, work practices and procedures to ensure the health and safety of individuals exposed to biohazardous agents in the workplace. Work areas that use infectious agents or biological materials, such as specimens or cultures, in research or clinical labs, or engage in activities involving human or animal specimens are responsible for implementing and maintaining a lab specific Biological Safety Training Program. Failure to comply with instructions found in the manual may result in a violation of the General Duty Clause of the United States Occupational Safety and Health Act. This law states that employers must furnish employees a place of employment that is free from recognized hazards likely to cause death or serious physical harm. Paramount to a safe workplace is the establishment of a program that defines and details the necessary practices that guide the handling and use of biohazardous agents.

E. Principal Investigators Responsibilities. Laboratory supervisors and principal investigators are responsible for biological safety in their laboratories. Principal Investigators/supervisors must:

- possess a thorough knowledge of current biological safety requirements;
- determine required levels of personal protective equipment and ensure adequacy of facilities and equipment;
- ensure that workers know and follow proper biological safety procedures and complete appropriate training;
- ensure accidents or hazardous conditions are promptly reported;
- maintain accurate records of the safety program; training (including who was trained, content of the training, who provided the training, and date); and medical services (excluding actual medical records);
- perform regular biosafety inspections of their facilities and equipment; and
- Submit the appropriate forms for approval by the IBC.

F. Training. Any person participating in activities subject to this policy must have adequate training. Such training must include:

- location and availability of the written Biological Safety Manual and associated reference material;
- health hazards, signs and symptoms associated with exposures to the biohazardous agents used in the work area; and
- measures employees must take to protect themselves from these hazards (work practices, emergency procedures, and personal protective equipment).

G. Occupational Medical Services. Principal investigators must provide persons working in their labs with an opportunity to receive medical attention upon exposure to such agents, including any follow-up examinations which the examining physician deems necessary. In addition, Principal Investigators are required to offer CDC recommended vaccinations, when appropriate, to potentially exposed staff (e.g., vaccinia and hepatitis B vaccinations). Medical surveillance, vaccinations, and examinations must be performed by, or under the supervision of a licensed physician, and be provided without cost to the employee and without loss of pay.

## V. Enforcement

Failure to comply with this Policy could result in disciplinary action, including termination of employment.

## VI. Questions/Reports

If you have any questions about this Policy or would like to report a potential violation, please contact the Research Integrity Officer. Reports regarding violations of this Policy may be submitted anonymously by using the independent Ethics and Compliance Hotline at 1-877-888-0002.

## VII. Related Policies and Procedures

Research Integrity Policy and Procedures
Academic Conduct Policy
Code of Conduct
Chemical Spills Policy and Procedures
Managing Hazardous Materials and Waste Policy and Procedures
Bloodborne Pathogen Exposure Control Plan
Hazard Communication Plan
Institutional Animal Care and Use Committee Policies and Procedures
Institutional Review Board Policies and Procedures

## VIII. History

Effective Date:June 18, 2018
Last Revised Date: