TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.05, **Research Involving Hazardous Materials, and Recombinant or Synthetic Nucleic Acid Molecules**

PURPOSE: The purpose of this Texas Tech Health Sciences Center El Paso (TTUHSCEP) Operating Policy and Procedure (HSCEP OP) is to provide a framework for compliance with federal, state, and local rules, regulations, and laws regarding hazardous materials and recombinant or synthetic nucleic acid molecules.

REVIEW: This HSCEP OP will be reviewed by June 1 each odd-numbered year (ONY) by the Director of Safety Services or designee, and by the Managing Director of Office of Research Resources (ORR), with recommendations for revisions submitted to the Vice President for Research (VPR) by June 15.

POLICY/PROCEDURE:

I. Compliance with federal, state, and local rules, regulations, and laws.

TTUHSCEP adopts and continues its policy that all research involving hazardous materials conducted at or sponsored by TTUHSCEP shall be conducted in accordance with federal, state, and local rules, regulations, and laws. In addition, all research involving recombinant or synthetic nucleic acid molecules conducted at TTUHSCEP shall also adhere to federal, state, and local rules, regulations, and laws, including the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* published in 2013, and all subsequent revisions.

II. Compliance policy.

In furtherance of the above-mentioned policy, TTUHSC El Paso enacts the following directives:

A. *Establishment of IBC.* TTUHSCEP shall establish an Institutional Biosafety Committee (IBC) whose members shall be appointed by the VPR. The IBC may create standing or *ad hoc* subcommittees to meet its purpose as long as conducted in accordance with the NIH guidelines.

The membership of the IBC shall be in accordance with the requirements of the NIH Guidelines. The current (2013) guidelines require the following:

- At least 5 individuals,
- A collective experience in recombinant and synthetic nucleic acid technology safety and risk to the public and environment,
- At least two members not affiliated with the institution who represent the interest of the surrounding community,
- A biosafety officer (if recombinant/synthetic nucleic acid research is conducted in large scale or at A/BSL3 or A/BSL4),
- At least one member with expertise in plant, plant pest, and plant pathogen containment (as appropriate),
- At least one scientist with expertise in animal research containment (as appropriate),
- Expertise and training in human gene therapy (as appropriate).

The purpose of the IBC is to fulfill the requirements of the NIH Guidelines, provide local oversight of all A/BSL3 research activities, provide oversight of all research involving biologically hazardous and acutely hazardous chemical materials (excluding radioactive materials or radiation producing devices) as used by TTUHSCEP faculty at TTUHSCEP facilities.

B. *Appointment of BSO.* The Director of Safety Services or designee shall appoint a Biological Safety Officer (BSO)

C. *Responsibilities of the IBC.* The IBC shall be responsible for monitoring compliance at TTUHSCEP with applicable federal, state, and local rules, regulations, and laws with regard to research involving biologically and chemically hazardous materials, and Recombinant or Synthetic Nucleic Acid Molecules. In conjunction with the Department of Safety Services, the committee shall monitor and review all TTUHSCEP research utilizing hazardous materials and recombinant or synthetic nucleic acid molecules in accordance with the NIH Guidelines and established policies and procedures.

D. *Authorities of the IBC.* The IBC is authorized to inspect research facilities, obtain information relating to laboratory practices and procedures, and take such actions as are in their judgment necessary to insure compliance with the NIH Guidelines, applicable federal, state, and local rules, regulations, and laws, and established policies and procedures, including the suspension of research in the event of a violation of policy or procedure which may create a safety hazard.

E. *Responsibilities of the* VPR. The VPR shall be responsible for the implementation of this policy through the provision of necessary resources, and the establishment of appropriate policies and procedures. The Managing Director of the ORR or designee will respond to initiatives from the VPR concerning the goals of this operating procedure.