TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

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

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

REVIEW: This HSC OP will be reviewed on June 1 each odd-numbered year (ONY) by the Director of Safety Services and the Assistant Vice President for Research Integrity, with recommendations for revisions forwarded to the Senior Vice President for Research (SVPR) by June 15.

POLICY/PROCEDURE:

1. **Compliance with federal, state, and local rules, regulations, and laws.**

TTUHSC adopts and continues its policy that all research involving hazardous chemicals and biological materials conducted or sponsored by TTUHSC 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 TTUHSC 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.

2. **Authority and Responsibility**

The Senior Vice President for Research (SVPR) has been given the authority and responsibility by the President of TTUHSC to establish, maintain, and oversee research involving hazardous chemical and biological materials and recombinant/synthetic nucleic acid molecules. In performing these duties, the SVPR has the responsibility to provide for necessary resources in order to carry out this policy. The SVPR has the authority to delegate activities as necessary to fulfill the duties. The Assistant Vice President for Research Integrity and the Director of Safety Services (or designees) will respond to initiatives from the SVPR concerning the goals of this operating procedure. The primary administrative responsibility for the day-to-day operation of the TTUHSC Institutional Biosafety Committee lies with the TTUHSC Research Integrity Office.

3. Establishment and Operation of the Institutional Biosafety Committee (IBC).

a. Establishment and Authority of IBC. In furtherance of this policy, TTUHSC directs that an Institutional Biosafety Committee (IBC) shall be maintained in accordance with this policy and federal and state regulations. The purpose of the IBC shall be to review and provide oversight of all research involving biologically hazardous and chemically hazardous materials, including recombinant and synthetic nucleic molecules, and any research deemed Dual Use Research of Concern (DURC) that takes place at TTUHSC campuses and facilities or is conducted by TTUHSC faculty and/or contractors in their role at TTUHSC. No such research may be initiated without prior approval by the IBC.

b. Membership: The IBC shall consist of a minimum of five TTUHSC faculty members with attempts to include representation from each TTUHSC school and campus whose faculty conduct basic laboratory research. In addition:

1) The Biological Safety Officer must serve as a voting member.

2) Representatives from the Office(s) of Safety Services from each TTUHSC campus where basic laboratory research is conducted will be appointed as voting members.
3) Two (2) voting members must not be two affiliated with TTUHSC (including family members). These members will represent the interests of the West Texas area with respect to health and protection of the environment.
4) At least one voting member must have expertise in animal containment principles;
5) At least one voting member must have expertise in genetics, micro-organisms, recombinant or synthetic nucleic acid molecule technology, biological safety and/or physical containment;
6) At least one voting member must represent the laboratory technical staff;

A single voting member may hold multiple roles on the IBC.

c. Authority 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.

d. Responsibilities of the IBC. The IBC shall be responsible for monitoring TTUHSC compliance with applicable federal, state, and local rules, regulations, and laws with regard to research involving biologically and chemically hazardous materials, Recombinant or Synthetic Nucleic Acid Molecules, and Dual Use Research of Concern (DURC). In conjunction with the Department of Safety Services, the committee shall monitor and review all TTUHSC research and research facilities utilizing biologically hazardous materials or toxins and recombinant or synthetic nucleic acid molecules in accordance with established policies and procedures. Please see HSC OP 75.10, Biological and Chemical Hazards Policy for Research Facilities and Personnel.

e. Confidential Medical Committee. The Institutional Biosafety Committee is considered a “Medical Committee” as defined under Texas Health & Safety Code chapter 161, and/or other applicable state and federal statutes. All documents generated by, submitted to, or created for purposes of fulfilling IBC duties are considered confidential and privileged as “medical committee documents.”