



TEXAS TECH UNIVERSITY™

## Operating Policy and Procedure

### **OP 74.05: Institutional Biosafety Committee**

**DATE:** September 20, 2019

**PURPOSE:** The purpose of this Operating Policy/Procedure (OP) is to establish procedures for the review and conduct of research by Texas Tech University (TTU) faculty, staff, and students involving recombinant DNA molecules in a manner consistent with the guidelines issued by the National Institutes of Health, published as a notice in the *Federal Register* 59 (127): 34495–34547 (July 5, 1994), or any subsequent federal guidelines relating to the subject matter of research involving recombinant DNA molecules. In conjunction with these federal guidelines, TTU has established the Institutional Biosafety Committee (IBC) to act on its behalf in ensuring that recombinant DNA activities comply with the federal guidelines.

The TTU IBC is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals (<http://www.cdc.gov/od/sap>), and biological toxins. The IBC is additionally charged to review and approve life science research that is Dual Use Research of Concern (DURC).

**REVIEW:** This OP will be reviewed in September of odd-numbered years by the Assistant Vice President for Research (Environmental Health and Safety) and the Institutional Official for animal care with substantive revisions forwarded through the Associate Vice President for Research (Responsible Research) to the Vice President for Research (VPR).

### **POLICY/PROCEDURE**

Safety in activities involving recombinant DNA depends on the individual conducting them. The federal guidelines and this OP cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment.

The federal guidelines and this OP are intended to help TTU, the IBC, the biological safety officer (BSO), and the principal investigator determine the safeguards that should be implemented. The federal guidelines will never be complete or final, since all conceivable experiments involving the materials of concern cannot be foreseen. Therefore, it is the responsibility of TTU and those associated with it to adhere to the intent of the federal guidelines and this OP, as well as to their specifics.

It is the policy of TTU to implement a review process for all research that will involve recombinant DNA molecules. The following is a summary statement of procedures that the IBC follows in this review process.

## 1. **Committee Make-up and Appointment**

Membership of Texas Tech University's IBC will include:

- a. A member of the Institutional Animal Care and Use Committee;
- b. At least two citizens of the Lubbock community;
- c. At least three faculty members from TTU with expertise in biohazards;
- d. One member from the laboratory technical staff;
- e. The Assistant Vice President for Research (Environmental Health and Safety) and/or a designated representative; and
- f. The University Biological Safety Officer.

Members of the IBC, other than those specified by virtue of position, will be appointed by the VPR. Each will serve a term of three years, except when lesser terms may be required to maintain balanced membership and continuity of IBC operations. The chairperson of the IBC will be appointed by the VPR.

## 2. **Definitions**

- a. *Biohazard* – A contraction of the words "biological hazard." 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.
- b. *Biohazard Symbol* – Used internationally to indicate the actual or potential presence of a biohazard and to identify equipment, rooms, containers, materials, experimental animals, or combinations thereof that contain or that are contaminated with viable hazardous agents.
- c. *Biotechnology* – The use of advanced genetic techniques to construct novel microbial and plant strains and obtain site-directed mutants to improve the quantity or quality of products.
- d. *Institution* – Any public or private entity (including federal, state, and local government agencies).
- e. *Institutional Biosafety Committee (IBC)* – A committee that (1) meets the requirements for membership specified in the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, Institutional Biosafety Committee (IBC), and (2) reviews, approves, and oversees projects in accordance with the responsibilities defined in the *NIH Guidelines*.
- f. *Institutional Official for Animal Care* – Institutional Official (IO) means the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of 9 CFR parts 1, 2, and 3 will be met (from the Animal Welfare Act). The IO is designated by the president to oversee the animal care and use program.

- g. *Office of Biotechnology Activities (OBA)* – The office within the NIH that is responsible for (1) reviewing and coordinating all activities relating to the *NIH Guidelines*, and (2) performing other duties as defined in the *NIH Guidelines*.
- h. *Recombinant DNA Advisory Committee (RAC)* – The public advisory committee that advises the Department of Health and Human Services (DHHS) secretary, the DHHS assistant secretary for health, and the NIH director concerning recombinant DNA research. The RAC shall be constituted as specified in the *NIH Guidelines*.
- i. *Recombinant DNA Technology* – A laboratory technique used to join deoxyribonucleic acid (DNA) from different sources to produce an individual with novel gene combination (also known as gene splicing).

### 3. **Committee Charge**

The IBC is charged:

- a. To consider 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 university administration through TTU EH&S;
- b. To review for compliance with the relevant federal guidelines and university OPs and to approve research that is in conformity with these standards; to register and review 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 guidelines and/or regulations of the U.S. Public Health Service, the Occupational Safety and Health Administration, and others and to provide technical assistance to TTU EH&S on these matters;
- c. To review proposed or enacted legislation impacting the TTU community and to inform departments, schools, and colleges of this legislation and its potential implications;
- d. In conjunction with TTU EH&S, to assist colleges, schools, and departments with safety committees or programs related to the safe handling, transport, use, and disposal of recombinant DNA, microorganisms, select agents, biological toxins, Dual Use Research of Concern; and
- e. To render advice in consideration for space and facilities for research involving recombinant DNA, microorganisms, select agents, biological toxins, regulated and particularly hazardous chemicals.

### 4. **Criteria for Categorization of Research**

Experiments involving recombinant DNA and hazardous materials have been divided into five classes/categories:

- a. Those requiring RAC/NIH and IBC approval before initiation;
- b. Those requiring NIH/OBA and IBC approval before initiation;
- c. Those requiring IBC approval before initiation;

- d. Those requiring IBC notification simultaneous with initiation; and
- e. Those exempt from the *NIH Guidelines*.

Note: If an experiment falls under Section 4.a or 4.b and one of the other categories, the rules pertaining to Section 4.a or 4.b shall be followed. If an experiment falls under Section 4.e and under either of the categories in Section 4.c or 4.d, the experiment is considered exempt from the *NIH Guidelines*.

See *Federal Register* 51, Number 88, pages 16959-16961 (51FR 16959-16961) for a more comprehensive list of experiments that fall into each of these classes/categories.

#### 5. **Review Procedures for Experiments that Require IBC Approval under Federal Guidelines**

The investigator(s) will prepare and electronically submit the *Biohazard Application Form* (<http://www.dept.ehs.ttu.edu/ehs/ehshome/committee/ibcommittee>) to the Assistant Vice President for Research (Environmental Health and Safety) or the University Biological Safety Officer. The Assistant Vice President for Research (Environmental Health and Safety) or the University Biological Safety Officer 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 at the request of the IBC.

The IBC will 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.