



# TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

## Operating Policy and Procedure

### **HSCEP OP: 75.10, Biological and Chemical Hazards Policy for Research Facilities and Personnel**

**PURPOSE:** It is the policy of Texas Tech University Health Sciences Center El Paso (TTUHSCEP) to protect personnel working in biohazard and research laboratories at TTUHSC from possible harm resulting from exposure to biological or chemical materials and to comply with applicable federal, state and local rules, regulations, and policies governing hazardous biological and chemical materials.

**REVIEW:** This HSCEP OP will be reviewed on May 15 of each even-numbered year (ENY) by the Senior Director of Safety Services, the Managing Director of Facilities and Support Services, and the Vice President of Research, with recommendations for revisions submitted to the Chief Operating Officer by August 31.

### **POLICY/PROCEDURES:**

#### **1. Definitions:**

- a. Amendment: Document indicating any changes from submissions previously approved by the Institutional Biosafety Committee (IBC).
- b. Biohazard Registration: Approval of protocol(s) by the IBC of a laboratory as a location for work with hazardous biological or chemical materials and approval of laboratory workers authorized/credentialed to work with those materials.
- c. Credentialing: Credentialing of laboratory workers includes documentation of basic laboratory safety training and/or experience.
- d. Biohazard Laboratory: Any laboratory (excluding accredited space occupied by the LARC) in which hazardous biological or chemical materials are or will be stored or used. A biohazard laboratory requires IBC protocol approval.
- e. Research Laboratory: Any laboratory (excluding accredited space occupied by the LARC) in which biological or chemical materials not requiring registration with the IBC are or will be stored or used. All research laboratories are required to submit and maintain a chemical/biological inventory.
- f. Laboratory Worker: Any person, regardless of the person's employment status, working in a laboratory. This includes faculty, staff, students, volunteers and visiting associates. (See HSCEP OP 75.09, Section 1.g.)
- g. TTUHSCEP Biohazardous Material and Research Laboratory License: Document signifying approval by the IBC of a laboratory. This document shall indicate the location of the laboratory, the number of the approved protocol, if applicable, the date of expiration and the names of the principal investigator and credentialed laboratory workers. It also shall contain information on how to obtain information or have questions answered about the biological or chemical materials being used. The license shall be displayed prominently in the approved laboratory.

- h. Biological Safety Officer (BSO): A staff person employed in the Department of Safety Services who is trained and certified as a Biological Safety Officer (BSO) who will be responsible for conducting laboratory safety trainings, conducting inspections of laboratories, reviewing and records and act as an agent for the IBC. The BSO serves as a member of the IBC and reports to the Senior Director of Safety Services or designee with indirect reporting responsibility to the IBC.
- i. Hazardous Biological or Chemical Materials: [Referenced in the Laboratory Compliance Manual (July 2008)]. Includes, but is not limited to, human fluids and tissues identified in the OSHA Bloodborne Pathogens Standard 29CFR1910.1030, comparable non-human primate fluids and tissues and all human or non-human primate cell lines. Additionally, includes microorganisms classified at or above Biosafety Level (BSL) 2 by the U.S. Public Health Service in the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). Finally, certain chemicals as characterized below:
- (1) Chemicals or toxins with an animal: LD50 of  $\leq 50$  mg/kg.
  - (2) Select agents as defined or identified in 42 CFR, Sections 73.3 and 73.4; 7 CFR, Section 331.3; and 9 CFR, Sections 121.3 and 121.4.
  - (3) Proprietary compounds of unknown toxicity.
- Risk varies according to the specific material and the conditions under which it is used. The above identified materials require a higher level of training, protective measures, and surveillance. These materials require IBC protocol approval for use.
- j. Institutional Biosafety Committee (IBC): A Committee designated to oversee the use of biological or chemical materials for research and educational purposes within the institution with an emphasis on the above defined hazardous biological and chemical materials. Committee members are appointed and/or confirmed annually by the Assistant Vice President for Research. Appointments may also be made throughout the year. The IBC will identify hazardous biological or chemical materials, review proposed usage, perform a risk analysis of this usage, approve or disapprove protocols and/or workers, oversee training activities, credential users, review inspection reports and require revision or suspension of biohazard laboratory procedures in conjunction with safety procedures as necessary for protection of laboratory workers and the general public. IBC has final authority for protocol approval and decisions involving compliance. IBC records are maintained by the Research Integrity Office. Lists of approved laboratories and laboratory workers are forwarded to the Department of Safety Services. Safety Services will inform the IBC of completion of essential laboratory safety training by potential laboratory workers and safety considerations pertaining to facilities under consideration as biohazards laboratories.
- k. Placard: A sign posted at each public entrance of a laboratory. The placard shall display the types of hazards present, or likely to be present in the lab, and special entry and exit requirements, as well as contact information for the PI and an alternate, if possible, for both regular and after hours.
- l. Principal Investigator (PI): That person who has been designated as being responsible for the laboratory space, including supervision of research and staff. Such designation shall be made in writing by the Department Chair/Center of Excellence Director/Unit Supervisor. An alternate individual shall be designated as responsible when the principal investigator is unavailable or absent.
- m. Protocols: Descriptions of the procedures involving use of hazardous materials, the biohazards laboratory in which the procedures will be performed and the

techniques/procedures used to contain hazardous material and protect personnel. Protocols will be submitted on forms provided by the IBC and submitted to the IBC for review, action and approval prior to the commencement of any activity. IBC will develop specific Standard Procedures, which may be referred to in the protocols with any modifications or exceptions specified in detail.

- n. Restricted Access: Limitation of access for unauthorized personnel to an area because of the nature or type of use of hazardous materials used or stored in the area.
- o. Standard Procedures: A set of descriptions of commonly used procedures and safety measures which are universally accepted.
- p. Training: Information and instruction about the biohazard and research laboratories at TTUHSC El Paso, the potential risks of biological or chemical materials, regulations pertaining to their use, proper safety procedures to be used to minimize risks and provisions for asking questions and expressing concerns about the use of biological or chemical materials. Training is provided through formal presentations and on-the-job instruction designed to be appropriate for the hazard level. Site-specific or on-the-job instruction will be provided by the laboratory supervisor/supervisor/principal investigator.

## 2. **Guidelines.**

This policy establishes guidelines for identifying and managing biological and chemical hazards. The following guidelines shall be observed:

- a. Identify laboratories where biological or chemical material is used and the personnel involved in usage;
- b. Reduce institutional risk through implementation of a chemical/biological inventory and accountability program, including procurement review;
- c. Review protocols for Institutional Biosafety Committee (IBC) approval to use hazardous biological or chemical material;
- d. Perform a risk analysis for potentially hazardous biological or chemical materials under the conditions that they will be used;
- e. Establish appropriate safety measures to be used in each laboratory;
- f. Verify that laboratory personnel are appropriately trained and have access to appropriate personal protective equipment (PPE) to work with biological or chemical materials and are properly trained and/or credentialed;
- g. Provide a mechanism for inspection of laboratories; and,
- h. Provide mechanisms for central control and record keeping consistent with federal, state, and local rules, regulations, policies, and accepted standards of practice.

## 3. **Program.**

- a. Requirements:
  - (1) Acquisition, use, place of use, conditions of use, training and credentialing of personnel for use and disposition of hazardous biological or chemical materials are under control of the IBC. All approvals and credentialing are made by the

IBC. The BSO, acting as the representative of the IBC, will conduct activities as designated by the IBC.

- (2) It is the responsibility of the principal investigator to consult with the IBC or the Biological Safety Officer (BSO) about whether a material they plan to use constitutes a potential hazard.
- (3) Any principal investigators intending to use biological or chemical material must have received approval (license and certification of training from the IBC) prior to beginning work.
- (4) All principal investigators shall provide a chemical/biological inventory to Safety Services upon initial assignment to a laboratory space, and shall provide an inventory update as appropriate.

b. Procedures:

- (1) IBC Protocol: Registration of principal investigators working with hazardous biological or chemical material through the Research Integrity Office is required annually.
- (2) Submission of Protocols: Principal Investigators anticipating use of hazardous biological or chemical materials, including tissues or fluids which are potentially infectious, must submit an application (protocol) to the IBC through the Research Integrity Office. This must include a description of the material and its potential hazards, the planned use of this material, the areas in which it will be used or stored, the safety procedures to be used, the personnel to be involved, their history of training and the methods for disposal of the material. Forms for the application will be developed, revised as appropriate and approved by the IBC and will be available through the Research Integrity Office.
- (3) Actions on the protocols by the IBC: The IBC will review the protocol according to currently accepted standards. The review will also include review of the training status of the laboratory workers. If the protocol is approved, the inspection passed and the laboratory workers credentialed, the IBC will issue a Biohazardous Material and Research Laboratory license to the principal investigator. The license shall be posted in the biohazard laboratory. A copy of the approved protocol should be kept in the principal investigator's Laboratory Compliance Manual.
- (4) Inspections: The IBC or its representative (BSO) will conduct periodic inspections of laboratories to identify hazards and review records. Reports of these inspections shall be maintained by Safety Services and reviewed by the IBC, as applicable. Any questions of compliance will be resolved with the Principal Investigator, as required by the IBC, with input, as necessary, through the Department of Safety Services and the Office of Research.
- (5) Amendments and Renewals: Any changes from submissions originally approved by the IBC will require additional approval by the IBC following review of an amendment submitted through the Research Integrity Office. Registrations will be renewed on an annual basis prior to the anniversary date by submission of an Annual Status Report. Protocols shall be renewed every third year by re-submission of the protocol application and addendums.
- (6) Training: Principal Investigators shall submit to the IBC, as part of a protocol or amendment, evidence of training in the use of biohazardous materials for

laboratory workers. Laboratory safety essentials training prior to the onset of work will be available online through the institutional training system and will be assigned as needed. Confirmation of that training will be the responsibility of the BSO reporting to the IBC. It will be the responsibility of the principal investigator to provide additional site-specific training for the laboratory workers which is specifically related to the procedures employed in that laboratory.

- (7) Records: Maintenance of records, including minutes of IBC meetings, current status of protocols, and up-to-date submissions from investigators will be the primary responsibility of the Research Committees Office as the administrative support entity for the IBC. Training records,, and inspection reports will be the primary responsibility of Safety Services. Copies of these records shall be exchanged between Safety Services and the Research Integrity Office as necessary.
- (8) Alternate Responsibility: The Principal Investigator shall provide on the lab placard the name and contact number of an approved alternate who is to be designated as the person responsible in the absence of the Principal Investigator.
- (9) Laboratory Requirements: Any approved laboratory shall be identified at each public entrance with a current lab placard. In addition, a copy of the current license shall be posted in a conspicuous location in the laboratory.
- (10) Concern about usage of hazardous biological or chemical material: A statement on the Biohazardous Material and Research Laboratory license will indicate that any laboratory worker with questions or concerns about biohazardous material shall first direct these to the principal investigator. If the response is insufficient or there exists a possible conflict of interest, further inquiries shall be addressed first to the Departmental Chair, COZE Director or Unit Supervisor, then to the BSO, the Director of Safety Services or designee and the IBC, if necessary.
- (11) Violations of Policy: Violations of this policy will be reviewed by the IBC. The Committee is empowered to take action deemed necessary, including suspension of activity within any laboratory upon verbal and written notice to the Principal Investigator (or designated representative), the Departmental Chair, COE Director or Unit Supervisor, and the Assistant Vice President for Research.
- (12) Implementation: This policy applies to the TTUHSCEP facilities and campus. Implementation will involve submission by the chief administrative officer of an addendum defining responsibilities under the direction of the IBC, BSO and Department of Safety Services.