



Angelo State University
Operating Policy and Procedure

OP 34.29: Biosafety Plan and Institutional Biosafety Committee

DATE: July 10, 2019

PURPOSE: The purpose of this Operating Policy/Procedure (OP) is to implement the Angelo State University (ASU) biosafety plan and institutional biosafety committee as directive guidance for all ASU laboratories.

REVIEW: This OP will be reviewed in November every three years, or as needed, by the director of risk and emergency management with recommended revisions forwarded through the vice president for finance and administration and provost and vice president for academic affairs to the president by December 15 of the same year.

POLICY/PROCEDURE

1. Scope

- a. The provisions of the [Biosafety Plan](#) shall apply to all ASU laboratories with potential biological exposure.
- b. The institutional biosafety committee (IBC) approves and monitors all research falling within the National Institutes of Health [NIH Guidelines](#). All research projects involving recombinant DNA (including research falling into [NIH Guidelines](#) exceptions) or biohazardous material must be registered with the IBC. See the [IBC Policy and Procedures](#) for additional definition.

2. Intent

The intent of this OP is to:

- a. Comply with the provisions of the Occupational Safety and Health Administration's standard for occupational exposure in laboratories;
- b. Comply with the provisions of the [NIH Guidelines](#);
- b. Establish other laboratory safety guidelines regarded as essential to a minimum safe program by nationally recognized organizations; and
- c. Provide the safest laboratory workplace that can reasonably be achieved.

3. Key Terms

- a. EHSRM means ASU's Office of Environmental Health, Safety, and Risk Management.
- b. Laboratory Supervisor means the faculty member or graduate assistant in charge of the curriculum and laboratory preparation.
- c. Laboratory Personnel means all persons present or participating in a teaching or research laboratory, including employees, students, and volunteers, and may include or exclude the Laboratory Supervisor depending upon context.
- d. Principal Investigator (PI) means the one individual researcher who is designated by the institution to direct a project or program and who is responsible to the institution for the scientific and technical direction of that project or program.
- e. Laboratory means the teaching and research space being used and not a specific room. A course may use multiple rooms and a room may be used by multiple classes and Laboratory Supervisors.

4. Responsibilities and Authority

- a. Departments
 - (1) Implement policies and procedures to ensure the health of all individuals, and compliance with all applicable federal, state, and local statutes, regulations, procedures and principles relating to the purchase, storage, use, and disposal of biological agents used in research, clinical, and educational programs, including the [Biosafety Plan](#) and the [Bloodborne Pathogens Protection Program](#).
 - (2) Review and approve the protocols provided by principal investigators, clinic directors, or Laboratory Supervisors relating to the use of biological agents.
 - (3) Establish centralized processes for approval, procurement, receiving, transportation, storage, and disposal of biological agents that are consistent with the Biosafety Plan.
 - (4) Review activities involving biological agents and determine the appropriate biosafety containment level of laboratories, clinics, and practices.
 - (5) Consistent with the Biosafety Plan, determine the need for general and specific training programs for research, clinical, and teaching activities dealing with biological agents and review the appropriateness and effectiveness of training programs.
 - (6) Ensure the department chair and EHSRM provide written consent for all activities identified as Biosafety Level 2 or higher (as defined in [Biosafety Plan](#) and the [IBC Policy and Procedures](#)).
 - (7) Require consultation with EHSRM during the planning phase for all construction or modifications where Biosafety Level 2 or higher work is to be conducted.

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- (8) Provide for specialty signage and access control when required due to the character of research being conducted.
- (9) Require consultation with EHSRM before an area where biological hazards were previously used is modified for another use.
- (10) Participate in the annual review and update to ASU's [Biological Safety Plan](#) and [Bloodborne Pathogens Protection Program](#).

b. Laboratory Supervisors

- (1) Laboratory Supervisors are faculty, staff, or graduate assistants of ASU who are assigned as the individual responsible for controlling or administering the work being conducted in a laboratory. Laboratory Supervisors:
 - (a) Are responsible for all experiments that occur in laboratories under their supervision.
 - (b) Identify Laboratory Personnel handling biological agents.
 - (c) Must establish safe procedures based on biological and physical hazards.
 - (d) Are responsible for implementation of all ASU safety procedures and must ensure that safety procedures are followed by all occupants of supervised laboratories.
 - (e) Are responsible for ensuring all Laboratory Personnel have required training for the work being conducted in laboratories under their supervision. By no later than the second laboratory session, all Laboratory Personnel shall receive orientation and complete an exercise that documents their training on additional hazards and procedures for laboratories under their supervision (see section 4.a below).
 - (f) Must ensure Laboratory Personnel know all biological and physical hazards associated with the work being conducted in laboratories under their supervision.
 - (g) Provide regular, formal biological and housekeeping inspections, including routine inspections of emergency equipment.
 - (h) Monitor the facilities, special ventilation, and containment systems to ensure they are maintained and function properly. Report problems with the facilities or systems.
 - (i) Must report any evidence of exposure to Laboratory Personnel to EHSRM immediately. The Laboratory Supervisor shall follow up with a Bloodborne Pathogens Exposure Incident Report, Employee Accident/Incident Report or Student Accident/Incident Report, as appropriate.

c. Laboratory Personnel (Including Students)

- (1) Read, understand, and follow all safety rules and regulations that apply to the work area.
- (2) Plan and conduct each operation in accordance with the institutional biological safety procedures.
- (3) Promote good housekeeping practices in the laboratory or work area.
- (4) Notify the supervisor of any hazardous conditions or unsafe work practices in the work area.
- (5) Use Personal Protective Equipment (PPE) as appropriate for each procedure that involves biological hazard.

d. Principal Investigator (Research Settings)

- (1) While other persons may be officially designated as the Principal Investigator for sponsored activities, for purposes of the [Biosafety Plan](#) the Principal Investigator is the person supervising or directing research activities or laboratory settings. The same person may serve as both the Laboratory Supervisor and Principal Investigator. The Principal Investigator shall be an employee or graduate student and shall:
 - (a) Be trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents and are responsible for the conduct of work with any infectious agents or materials.
 - (b) Carry out their research in compliance with all federal, state, and University requirements with approval from the Institutional Biosafety Committee (IBC).
 - (c) Limit exposure to biological hazards to the lowest practicable extent.
 - (d) Select and apply the recommended Biosafety Level for the work to be conducted.
 - (e) Be familiar with the required medical surveillance for each type of infectious agent and formally request these services for all exposed Laboratory Personnel.
 - (f) Develop laboratory safety procedures or protocols specific to that laboratory, placing a priority on engineering controls, then administrative controls, then work practice controls (such as biosafety cabinets and containment levels), and finally personal protective equipment to eliminate or minimize exposure.
 - (g) Personally train or arrange for training of all Laboratory Personnel prior to working with or exposure to biological agents. Each person's proficiency must be demonstrated to the Principal Investigator prior to working with any infectious agent, and continuing through its use.

- (h) Be responsible for lab manuals, Standard Operating Procedures (SOPs), IBC compliance, licenses, material transfer agreements, and permits for transport and use of biological agents and recombinant DNA (rDNA).
- e. Environmental Safety, Health, and Risk Management (EHSRM)
 - (1) EHSRM plans, organizes, and directs Risk Management, Environmental Health and Safety, Emergency Management, and related programs and activities in accordance with Federal, State, and University laws, regulations, rules, and procedures.
 - (2) EHSRM may adopt and direct policies, practices, or procedures necessary to ensure a safe and healthful workplace and may stop any work or activity determined to be an immediate hazard to life or property.
 - (3) Colleges and departments are responsible for maintaining a safe and healthful learning environment and workplace free from recognized hazards, ensuring work environments and practices are consistent with TTUS and EHSRM policies and practices, and requiring employees and students to comply with regulations, rules, and procedures.
 - (4) EHSRM serves as a technical resource to assist colleges and departments, faculty, staff, and students, as ASU fosters a safe and healthful learning and workplace free from recognized hazards.
 - (5) EHSRM will assist colleges and departments in development and delivery of training.

5. Training

- a. For teaching laboratories and research that are not subject to IBC registration or approval:
 - (1) All Laboratory Personnel must review the general Biological Safety Training and successfully pass the accompanying exam, and shall review the [Biological Safety Plan](#) before participating in a laboratory setting with biological hazards.
 - (a) Instructors may, in their sole discretion, assign laboratory credit for review and successfully passing the test or may treat it as pass/fail.
 - (b) Students do not need to retake the program and test unless it is significantly revised or it is specifically required by their instructor or laboratory supervisor.
 - (2) Instructors and laboratory supervisors are responsible for additional training required due to specific activities or environment. Training shall be documented in BlackBoard.
 - (3) It is best practice to include a hazard assessment and safety briefing based upon planned activities in every lab. A “safety minute” can be used if no hazard assessment is necessary for the day.

- b. For research that is subject to IBC registration or approval:
 - (1) IBC Committee, Biosafety Officer (BSO), and Principal Investigators
 - (a) All IBC members shall review and successfully complete the examinations for IBC member training identified in the [IBC Policy and Procedures](#) within 90 days of appointment. If a Biosafety Officer has not been appointed, at least two IBC members shall also complete the Biosafety Officer training.
 - (b) All appointed Biosafety Officers shall review and successfully complete the examinations for BSO training identified in the [IBC Policy and Procedures](#) within 90 days of appointment.
 - (c) All Principal Investigators shall review and successfully complete the examinations for Principal Investigator training identified in the [IBC Policy and Procedures](#) before final approval by the IBC.
 - (2) Training for Laboratory Research Personnel
 - (a) All laboratory research personnel shall have reviewed and successfully completed the examinations for the following courses before working in the laboratory:
 - 1) ASU's Biological Safety Program in BlackBoard, and
 - 2) Training identified in the [IBC Policy and Procedures](#).
 - (b) The PI shall identify and deliver additional training requirements based upon reviews required in in the [IBC Policy and Procedures](#). The training shall be documented.

6. Biosafety Plan

- a. The [Biosafety Plan](#) and related resources are available on the EHSRM [website](#).
- b. EHSRM shall maintain and update the [Biosafety Plan](#) as appropriate in consultation with the IBC and affected departments.
- c. The [Biosafety Plan](#) includes the following information, policies, and procedures:
 - (1) Purpose
 - (2) Scope and Key Terms
 - (3) Contact Information
 - (4) Culture of Safety
 - (5) Bloodborne Pathogens
 - (6) Responsibilities and Authority

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- (7) Principles of Biosafety
- (8) General Biosafety Guidelines for Infectious Agents
- (9) CDC and NIH Biosafety Levels
- (10) Recombinant DNA Research
- (11) Disinfection and Sterilization
- (12) Biological Safety Cabinets and Clean Benches
- (13) Importing and Shipping Biological Materials
- (14) Biological Spill Response
- (15) Biological Waste Disposal
- (16) Shipment of Biological Agents
- (17) Record Retention
- (18) Training
- (19) Reference Material

d. The [Biosafety Plan](#) appendices include the following:

- (1) Appendix A: Definitions
- (2) Appendix B: rDNA Research Policy

7. Institutional Biosafety Committee Policies and Procedures

- a. The [Institutional Biosafety Committee \(IBC\) Policy and Procedures](#) and related resources are available on the EHSRM [website](#).
- b. EHSRM and the IBC shall maintain and update the [IBC Policy and Procedures](#) as appropriate in consultation affected departments in an open process, always consistent with *NIH Guidelines*.
- c. The [IBC Policy and Procedures](#) includes the following information, policies, and procedures:
 - (1) General Requirements and Procedures for Recombinant DNA Research, Biohazardous Research, Synthetic Nucleic Acids (as defined by NIH) and Activities, Use, and Handling of Extremely Toxic/Hazardous Substances
 - (2) Registration, Review and Approval of Recombinant DNA Research, Biohazardous Research, Synthetic Nucleic Acids

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- (3) Responsibilities of Principal Investigators
 - (4) The Institutional Biosafety Committee
 - (5) The Biological Safety Officer (BSO)
 - (6) Record Retention
 - (7) Training
 - (8) Reference Material
- d. The [IBC Policy and Procedures](#) appendices include the following forms and information:
- (1) Appendix A: Institutional Biosafety Officer, Committee Chair, and Committee Members
 - (2) Appendix B: Biohazardous Use Protocol (BUP) for IBC Permit
 - (3) Appendix C: Self-Assessment Tool

7. Designation of IBC Members, Chair(s), and Biological Safety Officer(s)

- a. The Provost and Vice President for Academic Affairs nominates and the President approves the faculty, staff and outside IBC members. The Dean of the College of Graduate Studies and Research appoints the academic Chair. Members serve three year terms and there are no limitations on the number of terms a person may serve. Terms of service end on August 31st. The Director of Risk and Emergency Management shall be a continuous member and may serve as co-Chair at the request of the Dean of the College of Graduate Studies and Research.
- b. The [IBC Policy and Procedures](#) shall list IBC members in Appendix A.
- c. Appointment of a Biosafety Officer (BSO) is required if research is conducted at Biosafety Level 3 or above or for Large Scale Research.
 - (1) The BSO shall be designated by the Provost and Vice President for Academic Affairs to provide services and assistance as required by federal guidelines and regulations and Institutional requirements as described in the [IBC Policy and Procedures](#).
 - (2) If a BSO is not required or appointed due to the level and type of research, the Academic (co-)Chair shall ensure that the specific duties and responsibilities described in the [IBC Policy and Procedures](#) are accomplished.