

Angelo State University



Biological Safety Plan

December 2020

Approved via IBC Member email approval

Angelo State University
Biological Safety Plan

Table of Contents

1. Purpose	1
2. Scope and Key Terms.....	1
3. Contact Information	1
3.1. Emergencies (Remember to dial 9 for an outside line if using an internal ASU phone).....	1
3.2. Non-Emergencies	1
4. Culture of Safety	1
5. Bloodborne Pathogens.....	2
6. Responsibilities and Authority	2
6.1. Departments.....	2
6.2. Laboratory Supervisors	3
6.3. Laboratory Personnel (Including Students)	3
6.4. Principal Investigator (Research Settings).....	4
6.5. Environmental Safety, Health, and Risk Management (EHSRM).....	4
7. Principles of Biosafety	5
7.2. Primary and Secondary Containment	5
7.3. Elements of Containment	5
8. General Biosafety Guidelines for Infectious Agents	5
8.1. Warning Signs and Postings	5
8.11. Personal Hygiene Guidelines.....	8
8.12. Clothing Guidelines.....	8
8.13. Handling Procedures	9
8.14. Transportation and Shipment.....	9
8.15. Syringes and Sharps	9
8.16. Work Area	10
8.17. Universal Precautions	10
9. CDC and NIH Biosafety Levels	10
9.3. Biosafety Level 2.....	10
9.4. Biosafety Level 3.....	11
9.5. Biosafety Level 4.....	11
9.6. Biosafety Summary	11
9.7. Animal Biosafety.....	12
10. Recombinant DNA Research	12
11. Disinfection and Sterilization	12
11.2. General Guidelines for Biological Disinfection and Sterilization	12
11.3. Disinfection Method Table.....	13
11.4. Sterilization Methods.....	13
12. Biological Safety Cabinets and Clean Benches.....	15
12.2. Types of Biological Safety Cabinets	15
12.3. Using Biological Safety Cabinets.....	16
12.4. Experiment Completion.....	17
12.5. Clean Benches	17
13. Importing and Shipping Biological Materials	17
14. Biological Spill Response.....	17
15. Biological Waste Disposal	19
15.1. Biological Waste and Biohazardous Waste	19
15.2. Segregation of Biological Waste	20
15.3. Storage of Biological Waste	20
15.4. Treatment of Biohazardous Waste.....	21
15.5. Handling and Transport of Biological Waste	21
15.6. Labeling of Biohazardous Waste.....	21
15.7. Disposal Methods	21
15.8. Disposal Training and Hazard Communication.....	23

Angelo State University
Biological Safety Plan

15.9. Waste Treatment Procedures and Records	23
16. Shipment of Biological Agents.....	24
16.3. Category A Infectious Substances	24
16.4. Category B Infectious Substances	24
16.5. Exempt Human Specimen	25
16.6. Biological Product	25
17. Record Retention.....	25
18. Training	25
19. Reference Material	26
APPENDIX A: Definitions	27
1. Biosafety Plan Definitions.....	27
APPENDIX B: rDNA Research Policy.....	29
1. rDNA Research Policy	29
2. Institutional Biosafety Committee.....	30
3. Principal Investigator (PI)	30
4. Reporting of Laboratory Incidents or Noncompliance Involving Recombinant DNA.....	31

Angelo State University
Biological Safety Plan

1. Purpose

The Biological Safety Plan is intended to assist Departments in developing procedures to protect Angelo State University (ASU) faculty, students, visitors, and staff from biological health hazards associated with laboratory and research environments.

2. Scope and Key Terms

- 2.1. This procedure applies to all Angelo State University laboratories and academic activities containing biological hazards or biological experiments, to all employees and students of the University, and to external organizations who work in or use ASU laboratories containing biological hazards. **Remember, safety is everyone's responsibility.**
- 2.2. Laboratory Supervisor means the faculty member or graduate assistant in charge of the curriculum and laboratory preparation.
- 2.3. 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.
- 2.4. 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.
- 2.5. 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.

3. Contact Information

- 3.1. Emergencies (Remember to dial 9 for an outside line if using an internal ASU phone)
 - A. General emergency number: 9-911
 - B. ASU Police Department Emergency number: (325) 942-2071 (x2071)
 - C. City of San Angelo Fire Department: (325) 657-4283
 - D. City of San Angelo Police Department: (325) 657-4315
 - E. Poison Control number: 1-800-222-1222
 - F. ASU Environmental Health, Safety, & Risk Management (EHSRM) (325) 942-2180 (x2180)/(325) 486-6725/(325) 486-6275
- 3.2. Non-Emergencies

For small spills or with questions or concerns about laboratory safety contact EHSRM at (325) 942-2180 (x2180).

4. Culture of Safety

- 4.1. Safety and training programs have been implemented to promote the safe handling of biological agents from ordering to disposal, and to train Laboratory Personnel in safe practices. The welfare and safety of each individual depends on clearly defined attitudes of teamwork and personal responsibility. Learning to participate in this culture of habitual risk assessment, experiment planning, and consideration of worst-case possibilities - for oneself and one's fellow workers - is as much part of a scientific education as learning the theoretical background of experiments or the step-by-step protocols for doing them in a professional manner. A crucial component of biological education for all

Angelo State University
Biological Safety Plan

personnel is to nurture basic attitudes and habits of prudent behavior so that safety is a valued and inseparable part of all laboratory activities throughout our careers.

- 4.2. A sound safety organization that is respected by all requires the participation and support of laboratory administrators, workers, and students. A successful health and safety program requires a daily commitment from everyone in the organization. To be most effective, safety and health must be balanced with, and incorporated into, laboratory processes.
- 4.3. In order to perform work in a prudent manner, Laboratory Personnel must consider the health, physical, and environmental hazards of the biological agents and processes they plan to use in an experiment. However, the ability to accurately identify and assess laboratory hazards must be taught and encouraged through training and ongoing organizational support. This training must be at the core of every good health and safety program. For management to lead, personnel to assess worksite and laboratory hazards, and hazards to be eliminated or controlled, everyone involved must be trained.

5. **Bloodborne Pathogens**

- 5.1. ASU's Bloodborne Pathogen Exposure Control Plan is contained in OP [34.22](#) and is incorporated by reference as though fully stated here.
- 5.2. All Laboratory Supervisors and Laboratory Personnel shall review the Exposure Control Plan, receive Bloodborne Pathogen Awareness training through Blackboard, and be offered HBV vaccination before being permitted to participate in laboratories that may have an exposure to blood or other potentially infectious material, and should contact EHSRM if they have any questions related to the Plan or training.

6. **Responsibilities and Authority**

- 6.1. Departments
 - A. 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 this Plan and the Exposure Control Plan.
 - B. Review and approve the protocols provided by principal investigators, clinic directors, or Laboratory Supervisors relating to the use of biological agents.
 - C. Establish centralized processes for approval, procurement, receiving, transportation, storage, and disposal of biological agents that are consistent with this Plan.
 - D. Review activities involving biological agents and determine the appropriate biosafety containment level of laboratories, clinics, and practices.
 - E. Consistent with this 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.
 - F. Ensure the department chair and EHSRM provide written consent for all activities identified as Biosafety Level 2 or higher (described in Section 9).
 - G. Require consultation with EHSRM during the planning phase for all construction or modifications where Biosafety Level 2 or higher work is to be conducted.

Angelo State University
Biological Safety Plan

- H. Provide for specialty signage and access control when required due to the character of research being conducted.
- I. Require consultation with EHSRM before an area where biological hazards were previously used is modified for another use.
- J. Participate in the annual review and update to ASU's Biological Safety Plan and Bloodborne Pathogens Exposure Control Plan.

6.2. Laboratory Supervisors

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. Must ensure Laboratory Personnel know all biological and physical hazards associated with the work being conducted in laboratories under their supervision.
- F. Are responsible for ensuring all Laboratory Personnel have required training for the work being conducted in laboratories under their supervision. By not 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 18.2).
- 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.

6.3. Laboratory Personnel (Including Students)

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

Angelo State University
Biological Safety Plan

6.4. Principal Investigator (Research Settings)

While other persons may be officially designated as the Principal Investigator for sponsored activities, for purposes of this 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).

6.5. Environmental Safety, Health, and Risk Management (EHSRM)

- A. 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.
- B. 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.
- C. 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.
- D. 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.
- E. EHSRM will assist colleges and departments in development and delivery of training.

7. Principles of Biosafety

- 7.1. The primary principle of biological safety (i.e., biosafety) is containment. The term containment refers to a series of safe methods for managing infectious agents in the laboratory. The purpose of containment is to reduce or eliminate human and environmental exposure to potentially harmful agents.
- 7.2. Primary and Secondary Containment
- A. There are two levels of biological containment: primary and secondary.
 - B. **Primary containment** protects people and the immediate laboratory environment from exposure to infectious agents. Good microbial techniques and safety equipment provide sufficient primary containment. Examples of primary barriers include safety equipment such as biological safety cabinets, enclosed containers, and safety centrifuge cups. Occasionally, when it is impractical to work in biological safety cabinets, personal protective equipment, such as lab coats and gloves, may act as the primary barrier between personnel and infectious materials.
 - C. **Secondary containment** protects the environment external to the laboratory from exposure to infectious materials. Good facility design and operational practices provide secondary containment. Examples of secondary barriers include work areas that are separate from public areas, decontamination facilities, hand- washing facilities, special ventilation systems, and airlocks.
- 7.3. Elements of Containment
- The three key elements of biological containment are:
- A. Laboratory practices
 - B. Safety equipment
 - C. Facility design.
- 7.4. To minimize exposure to an acceptable level, Laboratory Supervisors and Laboratory Personnel must assess the hazards associated with their work and determine how to apply the biosafety principle appropriately.
- IMPORTANT: Everyone working with infectious agents or potentially infectious materials must be aware of the hazards associated with their work. Laboratory Personnel must be trained and proficient in biosafety procedures and techniques.

8. General Biosafety Guidelines for Infectious Agents

- 8.1. Warning Signs and Postings
- A. The universally accepted biological hazard warning symbol shall be used throughout the university to warn about the presence of infectious agents.
 - B. The biohazard symbol on postings shall be orange or red in color with a contrasting background.
 - C. Evaluate and select the location of warning posting locations to provide an opportunity to recognize the hazard before opening or entering a room, storage location, or containment device.
 - D. Specialty signage and access control shall be used when unauthorized entry could be hazardous to persons or could jeopardize research.
 - E. All individual containers of biological agents shall be labeled to identify the content and any special precautionary measures that should be taken.



Angelo State University
Biological Safety Plan

- F. Universal biohazard labels must be affixed to containers of regulated waste, and to refrigerators, freezers, and other containers used to store, transport, or ship blood or other potentially infectious materials.
- G. Acceptable color coded (red or orange) bags or containers may be used in place of universal biohazard labels.

8.2. Eating, Drinking, Smoking

- A. Smoking shall not occur in any ASU laboratory.
- B. Eating and drinking shall not be allowed in a laboratory that has chemical, biological, or radiological materials. This includes the chewing of gum, tobacco, vaping, and the use of snuff or medications of any kind.
- C. Do not place hands or fingers in or near the mouth.
- D. Do not place hands near the face. This includes the application of cosmetics.
- E. Wash hands immediately and thoroughly when leaving the laboratory even if gloves were worn.
- F. Food items shall not be allowed in a laboratory.
 - 1) Exceptions based on the researcher's need can be made. Contact EHSRM.
 - 2) If exceptions are made, food items intended for human consumption shall be stored in a refrigerator (labeled "FOOD ONLY") that contains no chemical, biological, or radiological materials.
 - 3) Refrigerators used to store/hold items for laboratory use shall not contain food items for human consumption and shall be labeled "RESEARCH ONLY" and "NO FOOD OR DRINK".

8.3. Equipment and Glassware

- A. Proper equipment selection and maintenance is essential to a safe laboratory.
- B. Inspect all glassware and equipment prior to each use.
 - 1) Follow manufacturer recommendations for inspections and maintenance.
 - 2) Documentation of all equipment inspections and maintenance are the responsibility of the Laboratory Supervisor and maintenance and inspection records must be stored in a binder specific for that piece of equipment. Laboratory Supervisors may contact EHSRM for assistance in scheduling maintenance or inspections and record keeping.
 - 3) Dispose of damaged or broken glassware in broken glass containers.
- C. Glassware must be properly handled and stored. Any glassware with cracks or chips must not be used and must be discarded immediately in an approved broken glass container.
- D. Vacuum-jacketed glassware must be handled with extreme care to prevent implosion.
 - 1) Do not handle broken glass with bare hands. Use tongs, tweezers, puncture-resistant gloves, or brush/broom and dustpan.
 - 2) Use extreme caution when using force to attach or remove hoses or other items to or from glass. Always wear appropriate PPE to ensure hands, body, and eyes are protected.

8.4. Exiting the Laboratory

Angelo State University
Biological Safety Plan

- A. Ensure work area is clean and uncluttered prior to exiting.
- B. Ensure all biological agents are properly labeled and stored before exiting.
- C. Remove lab apparel prior to exiting the laboratory.
- D. When leaving a laboratory, always wash your hands as soon as feasible.

8.5. Horseplay

Horseplay shall not be allowed in ASU laboratories.

- 1) Horseplay includes “rough fun,” doing foolish, useless things, or using little or no judgment or common sense.
- 2) Horseplay may distract, startle, or confuse other workers/students and may create hazardous situations.

8.6. Mouth Pipetting

- A. The use of mouth suction (pipetting, siphoning) is not permitted.
- B. Always use mechanical means to create suction.

8.7. Personal Apparel

- A. Long hair and loose clothing shall be confined at all times in a laboratory, including facial hair.
- B. Close-toed shoes shall be worn at all times in a laboratory. Sandals & perforated shoes are not permitted. In addition, sneakers are not recommended for students. Staff and Laboratory Personnel shall wear proper shoes for the chemical and quantity being used as directed by the Safety Data Sheets (SDS).
- C. Minimize skin exposure as appropriate by wearing long pants and long sleeves or cover exposed skin with a lab coat or appropriate PPE. Follow guidance of SDS or contact EHSRM.

8.8. Personal Protection Equipment

- A. Personal Protective Equipment (PPE) includes all clothing and work accessories designed to protect employees from workplace hazards. Protective equipment should not replace engineering, administrative, or procedural controls for safety; it should be used in conjunction with these controls. Laboratory Personnel must wear protective equipment as required and when instructed by a supervisor.
- B. Always wear the appropriate hand and arm protection.
- C. Select and wear appropriate body protection.
- D. Select and wear appropriate hearing protection.
- E. Use safety glasses, safety goggles, or face shields, as appropriate.
- F. Do not wear contact lenses in laboratories without full eye protection.
- G. Use proper head and foot protection as needed.
- H. Respirators must be used when dealing with inhalation hazards above regulated or recommended atmospheres.

8.9. Housekeeping

Angelo State University
Biological Safety Plan

- A. Work areas shall remain clean and uncluttered.
- B. Safety equipment and the pathway leading to the equipment must remain clear of obstructions at all times, if applicable.
 - 1) Fire extinguishers
 - 2) Safety showers
 - 3) Eyewash stations
 - 4) First Aid Kits
 - 5) Automated External Defibrillators (AEDs)
- C. Breaker panels require a clearance of 3 feet.

8.10. Planning

- A. Proper planning is essential in creating a safe work environment when handling biological agents.
- B. Know the locations of exits and all emergency exit routes prior to conducting any experiment.
- C. Know emergency phone numbers prior to conducting any experiment. (Internal phones – dial 9)
 - 1) General emergency number : 9-911
 - 2) ASU Police Department Emergency: (325) 942-2071 (x2071)
 - 3) City of San Angelo Fire Department: (325) 657-4283
 - 4) City of San Angelo Police Department: (325) 657-4315
 - 5) Poison Control number: 1-800-222-1222
 - 6) EHSRM (325) 942-2180 (x2180)/(325) 486-6725/(325) 486-6275
- D. Know all physical biological hazards associated with agents being used.
 - 1) Select procedures based on physical and biological hazards.
 - 2) Select equipment based on physical and biological hazards.
- E. Know the location and proper operation of all safety equipment.
- F. Understand proper disposal of hazardous materials (see Section 15).

8.11. Personal Hygiene Guidelines

- A. Wash your hands thoroughly:
 - 1) After working with any biohazard.
 - 2) After removing gloves, laboratory coat, and other contaminated protective clothing.
 - 3) Before eating, drinking, smoking, or applying cosmetics.
 - 4) Before leaving the laboratory area.
- B. Do not touch your face when handling biological material. Never eat, drink, smoke, or apply cosmetics in the work area.

8.12. Clothing Guidelines

- A. Always wear a wrap-around gown or scrub suit, gloves, and a surgical mask when working with infectious agents or infected animals.
- B. Wear gloves over gown cuffs.

Angelo State University
Biological Safety Plan

- C. Never wear contact lenses around infectious agents.
- D. Do not wear potentially contaminated clothing outside the laboratory area.
- E. To remove contaminated clothing:
 - 1) Remove booties from the back.
 - 2) Remove head covering from the peak.
 - 3) Untie gown while wearing gloves.
 - 4) Remove gloves by peeling them from the inside out.
- F. Remove the gown by slipping your finger under the sleeve cuff of the gown.



8.13. Handling Procedures

- A. Use mechanical pipetting devices.
- B. Minimize aerosol production.
- C. Add disinfectant to water baths for infectious substances.
- D. Use trunnion cups with screw caps for centrifuging procedures. Inspect the tubes before use.
- E. Use secondary leak-proof containers when transporting samples, cultures, inoculated petri dishes, and other containers of biohazardous materials.

8.14. Transportation and Shipment

- A. Use sturdy secondary containment to prevent spilling or leakage. If the material to be transported could puncture the primary containment, a secondary puncture-resistant container should be used.
- B. Disinfect the exterior of the secondary containment.
- C. Any equipment suspected of being contaminated must be contained or decontaminated prior to movement or service work.
- D. When transported, infectious substances and diagnostic/clinical specimens are classified as dangerous goods and must be shipped in accordance with federal and state regulations. See Section 16 for shipping requirements for Category A, Category B, exempt human specimen genetically modified organisms, and biological products.

8.15. Syringes and Sharps

Avoid using syringes and needles whenever possible. If a syringe is necessary, minimize your chances of exposure by following these guidelines:

- A. Use a needle-locking or disposable needle unit.
- B. Be especially cautious with a used needle.
- C. Place used syringes that need decontamination into a pan of disinfectant without removing the needles.
- D. Do not place used syringes in pan containing pipets or other glassware that requires sorting.
- E. Do not recap used needles.

Angelo State University
Biological Safety Plan

- F. Dispose of needles in an approved sharp container.
 - 1) Sharps containers should be replaced when they are $\frac{3}{4}$ full.
- G. Contact [EHSRM](#) for removal and replacement of sharps containers. ASU EHSRM (325) 942-2180 (x2180)/(325) 486-6725/(325) 486-6275

8.16. Work Area

- A. Keep laboratory doors shut when experiments are in progress.
- B. Limit access to laboratory areas when experiments involve biohazardous agents.
- C. Ensure that warning signs are posted on laboratory doors. These signs should include the universal biohazard symbol and the approved biosafety level for the laboratory.
- D. Ensure that vacuum lines have a suitable filter trap.
- E. Decontaminate work surfaces daily and after each spill.
- F. Decontaminate all potentially contaminated equipment.
- G. Transport contaminated materials in leak-proof containers.
- H. Keep miscellaneous material (i.e., books, journals, etc.) away from contaminated areas.
- I. Completely decontaminate equipment before having maintenance or repair work done.

8.17. Universal Precautions

Clinical and diagnostic laboratories often handle specimens without full knowledge of the material's diagnosis; these specimens may contain infectious agents. To minimize exposure, observe universal precautions when handling any biological specimen. Consider all specimens to be infectious and treat these materials as potentially hazardous.

9. CDC and NIH Biosafety Levels

- 9.1. The Centers for Disease Control (CDC) and the National Institute of Health (NIH) have established four biosafety levels (risk groups) consisting of recommended laboratory practices, safety equipment, and facilities for various types of infectious agents. Each biosafety level accounts for the following:

- A. Operations to be performed
- B. Known and suspected routes of transmission
- C. Laboratory function

9.2. Biosafety Level 1

Biosafety Level 1 precautions are appropriate for facilities that work with defined and characterized strains of viable organisms that do not cause disease in healthy adult humans (e.g., *Bacillus subtilis* and *Naegleria gruberi*). Level 1 precaution relies on standard microbial practices without special primary or secondary barriers. Biosafety Level 1 criteria are suitable for undergraduate and secondary education laboratories.

9.3. Biosafety Level 2

- A. Biosafety Level 2 precautions are appropriate for facilities that work with a broad range of indigenous moderate-risk agents known to cause human disease (e.g., hepatitis B virus, *salmonellae*, and *Toxoplasma spp.*). Level 2 precautions are necessary when working with human blood, body

Angelo State University
Biological Safety Plan

fluids, or tissues where the presence of an infectious agent is unknown. The primary hazards associated with Level 2 agents are injection and ingestion.

9.4. Biosafety Level 3

- A. Biosafety Level 3 precautions apply to facilities that work with indigenous or exotic agents with the potential for aerosol transmission and lethal infection (e.g., *Mycobacterium tuberculosis*). The primary hazards associated with Level 3 agents are autoinoculation, ingestion, and inhalation. Level 3 precautions emphasize primary and secondary barriers. For primary protection, all laboratory manipulations should be performed in a biological safety cabinet or other enclosed equipment. Secondary protection should include controlled access to the laboratory and a specialized ventilation system.
- B. There are no Biosafety Level 3 facilities at ASU.

9.5. Biosafety Level 4

- A. Biosafety Level 4 precautions are essential for facilities that work with dangerous and exotic agents with a high risk of causing life-threatening disease, the possibility of aerosol transmission, and no known vaccine or therapy (e.g., Marburg or Congo-Crimean viruses). Level 4 agents require complete isolation. Class III biological safety cabinets or full-body, air-supplied, positive-pressure safety suits are necessary when working with Level 4 agents. In addition, isolated facilities, specialized ventilation, and waste management systems are required.
- B. There are no Biosafety Level 4 facilities at ASU.

9.6. Biosafety Summary

Safety Level	Agent Characteristics	Safety Practices	Primary Barriers	Secondary Barriers
BSL 1	Not known to cause disease in healthy adults.	Standard Microbial Practices	None	Open bench top sink required.
BSL 2	Associated with human disease.	Level 1 precautions plus: <ul style="list-style-type: none"> Limited access Biohazard warning signs Biosafety manual defining needed waste decontamination or medical surveillance policies 	<ul style="list-style-type: none"> Class I or II Biological safety cabinet or other physical containment devices: Laboratory coat Gloves Face protection as needed 	Level 1 precautions plus: <ul style="list-style-type: none"> Autoclave available
BSL 3	Indigenous or exotic agent with the potential for aerosol transmission. Known to cause disease with serious or lethal consequences.	Level 2 precautions plus: <ul style="list-style-type: none"> Controlled access Decontamination of all waste Decontamination of laboratory clothing before laundering Baseline serum collected and stored 	<ul style="list-style-type: none"> Class I or II Biological safety cabinet or other physical containment Protective clothing Gloves Respiratory protection as needed 	Level 2 precautions plus: <ul style="list-style-type: none"> Physical separation from access corridors Self-closing, double door access Exhausted air not recirculated Negative airflow into laboratory

Angelo State University
Biological Safety Plan

Safety Level	Agent Characteristics	Safety Practices	Primary Barriers	Secondary Barriers
BSL 4	Dangerous/exotic agents which pose high risk of life-threatening disease and aerosol transmitted infection. Related agents with unknown risk of transmission.	Level 3 precautions plus: <ul style="list-style-type: none"> • Clothing change before entering • Shower upon exit • All material decontaminated upon exit from facility 	All procedures conducted in Class III biological safety cabinets or in Class I or II safety cabinets with full-body, air supplied, positive pressure personnel suits.	Level 3 precautions plus: <ul style="list-style-type: none"> • Separate building or isolated zone • Dedicated supply/exhaust, vacuum, and decontamination system • Other requirements, as necessary

9.7. Animal Biosafety

A copy of the CDC/MIH criteria for laboratory and animal biosafety levels is available [here](#).

10. Recombinant DNA Research

- 10.1. ASU is obligated to ensure that all recombinant DNA (rDNA) work conducted by its faculty and staff conforms to federal rDNA guidelines. This task falls jointly to the department chair and the Institutional Biosafety Committee (IBC). The IBC reviews all protocols involving rDNA, decides the appropriateness of proposed containment procedures, and sets suitable Biosafety Levels. If a Biosafety Officer (BSO) has been appointed, the BSO inspects individual laboratories and verifies that practices and facilities meet the requisite biosafety level assigned by the IBC.
- 10.2. The federal rDNA guidelines define rDNA as "...molecules which are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell." The federal definition also includes the replicated progeny of these molecules as well as cells, plants, and animals that harbor such molecules. Transgenic plants and animals also come under the guidelines, even if the transgenic DNA was not cloned prior to introduction. Investigators, researchers, or faculty who possess rDNA in any form must notify their department chair and EHSRM.
- 10.3. See Appendix B for general requirements for use of rDNA. See the IBC documents and webpage for specific information.

11. Disinfection and Sterilization

- 11.1. Biological safety depends on proper cleanup and removal of potentially harmful agents. Disinfection and sterilization are two ways to help ensure biological safety in the laboratory. These methods, along with several others, are regulated by the Texas Department of State Health Services in [25 TAC § 1.131 - 1.137](#).
 - A. Disinfection: Reduction of the number of pathogenic organisms by the direct application of physical or chemical agents.
 - B. Sterilization: Total destruction of all living organisms.
- 11.2. General Guidelines for Biological Disinfection and Sterilization
 - A. Choosing the best method for disinfection and sterilization is very important. The proper method depends on the following:
 - 1) Target organisms to be removed.
 - 2) Characteristics of the area to be cleaned.

Angelo State University
Biological Safety Plan

- B. Once you have chosen the proper method for disinfection or sterilization, follow these guidelines to ensure laboratory safety:
- 1) Frequently disinfect all floors, cabinet tops, and equipment where biohazardous materials are used.
 - 2) Use autoclavable or disposable materials whenever possible. Keep reusable and disposable items separate.
 - 3) Minimize the amount of materials and equipment present when working with infectious agents.
 - 4) Sterilize or properly store all biohazardous materials at the end of each day.
 - 5) Remember that some materials may interfere with chemical disinfectants. Use higher concentrations or longer contact time.
 - 6) Use indicators with autoclave loads to ensure sterilization.
 - 7) Clearly mark all containers for biological materials (e.g., *BIOHAZARDOUS - TO BE AUTOCLAVED*).

11.3. Disinfection Method Table

Use the following table to aid in the selection of disinfectants:

Disinfectant	Uses
Alcohols	Ethyl or isopropyl alcohol at 70-80% concentration is a good general purpose disinfectant; not effective against bacterial spores.
Phenols	Effective against vegetative bacteria, fungi, and viruses containing lipids, unpleasant odor.
Formaldehyde	Concentration of 5-8% formalin is a good disinfectant against vegetative bacteria, spores, and viruses; known carcinogen; irritating odor.
Quaternary Ammonium Compounds	Cationic detergents are strongly surface-active; extremely effective against lipoviruses; ineffective against bacterial spores; may be neutralized by anionic detergents (i.e., soaps).
Chlorine	Low concentrations (50-500 ppm) are active against vegetative bacteria and most viruses; higher concentrations (2,500 ppm) are required for bacterial spores; corrosive to metal surfaces; must be prepared fresh; laundry bleach (5.25% chlorine) may be diluted and used as a disinfectant.
Iodine	Recommended for general use; effective against vegetative bacteria and viruses; less effective against bacterial spores; Wescodyne diluted 1 to 10 is a popular disinfectant for washing hands.

11.4. Sterilization Methods

There are three common methods for sterilizing laboratory materials: wet heat, dry heat, and ethylene oxide gas.

A. Wet Heat

- 1) When used properly, the damp steam heat from an autoclave effectively sterilizes biohazardous waste. Sterilization occurs when contaminated materials reach 15-psi pressure at 250 degrees F or 121 degrees C for at least 30 minutes.
- 2) For the autoclave process to be effective, sufficient temperature, time, and direct steam contact are essential.

Angelo State University
Biological Safety Plan

- 3) Every ASU department that autoclaves biohazardous waste should have written documentation to ensure the waste is sterile.
- 4) Parameters for sterilization and standard operation procedures should include requirements for verifying sterilization.
- 5) Potential problems with wet heat sterilization and autoclaves include the following:
 - a) Heavy or dense loads require higher temperature for sterilization.
 - b) Poor heat conductors (e.g., plastic) take longer to sterilize.
 - c) Containers may prevent steam from reaching the materials to be sterilized.
 - d) Incomplete air removal from the chamber can prevent contact between the steam and the load.
 - e) Deep trays can interfere with air removal.
 - f) Tightly stacked loads can impede steam circulation and air removal.
 - g) Double bagging will impede steam penetration.
 - h) Carcasses do not allow steam penetration.
 - i) Some bags and containers rated as autoclavable have thermal stability but they do not allow steam penetration.
- 6) To ensure that all materials are sterile, always test autoclave loads. Remember, however, that some sterilization indicators are incomplete. Autoclave tape, for example, verifies sufficient external temperature exposure, but it does not indicate internal equipment temperature, exposure time, or steam penetration. Thermocouples or other instrumentation can also indicate temperature, but they do not verify sterility. A biological indicator is the most effective monitor to ensure sterility. Commercially available strips or vials of *Bacillus* species endospores, for example, are suitable biological indicators.

B. Dry Heat

Dry heat is less effective than wet heat for sterilizing biohazardous materials. Dry heat requires more time (two to four hours) and a higher temperature (320-338 degrees F or 160-170 degrees C) to achieve sterilization. A *Bacillus* species biological indicator can verify dry heat sterilization.

C. Ethylene Oxide Gas

- 1) Ethylene oxide gas is lethal to all microorganisms. Because it is also a known carcinogen and potentially explosive (Freon and carbon dioxide mixtures are stable), minimize your exposure and use extreme care when working with this gas. Ethylene oxide sterilizers and aerators must be properly vented. Ethylene oxide gas is most effective with heat-resistant organisms and heat sensitive equipment.
- 2) The effectiveness of ethylene oxide gas may be affected by the following:
 - a) Temperature: The antimicrobial activity of ethylene oxide increases with increased temperature. Normal sterilization temperature is 120-140 degrees F or 49-60 degrees C
 - b) Ethylene Oxide Concentration: Sterilization time decreases with increased gas concentration. Normal concentration is 500-1000 mg/L.
 - c) Humidity: Relative humidity of 30-60% is necessary.

d) Exposure Time: Follow the manufacturer's recommendations.

12. Biological Safety Cabinets and Clean Benches

- 12.1. A biological safety cabinet is a primary barrier against biohazardous or infectious agents.
- A. Although biological safety cabinets surround the immediate workspace involving an agent, they do not provide complete containment (i.e., aerosols can escape). Therefore, careful work practices are essential when working with agents that require a biological safety cabinet.
 - B. A biological safety cabinet is often referred to by other names such as biohood, tissue culture hood, or biological fume hood.
 - C. All biological safety cabinets contain at least one High Efficiency Particulate Air (HEPA) filter. These cabinets operate with a laminar airflow (i.e., the air flows with uniform velocity, in one direction, along parallel flow lines).
 - D. Biological safety cabinets must be inspected and certified:
 - 1) When newly installed
 - 2) After filter or motor replacement
 - 3) After being moved
 - 4) Annually
 - E. Cabinets that are not certified shall have a notice affixed clearly indicating "Cabinet not certified. Do not use for pathogens."
 - F. Contact EHSRM for more information about inspection.

12.2. Types of Biological Safety Cabinets

The following table outlines various types of biological safety cabinets:

Type of Cabinet	Operation and Use
Class I	Only exhaust air is filtered. The user and environment are protected but the experiment is not. Operator's hands and arms may be exposed to hazardous materials inside the cabinet. This cabinet may be used with low- to moderate-risk biological agents.
Class II	Vertical laminar air flow with filtered supply and exhaust air. The user, product, and environment are protected.
Class II Type A1	Recirculates 70% of the air inside the cabinet. Do not use with flammable, radioactive, carcinogenic, or high-risk biological agents. MIR Center, Lab 101, Fisher Hamilton, model #54L936, serial #10273, tested on 6/12/2018 Center for Human Performance, 141 Research Lab, Labconco, model #3440009, serial #120762064C, tested on 6/12/2018
Class II Type A2	Same as Class II Type A1, but vented to the outside of the building. Cavness Building, Lab 005, Labconco, model #3460981, serial #100627018C, tested on 6/12/2018, NSF

Angelo State University
Biological Safety Plan

Type of Cabinet	Operation and Use
Class II Type B1	Recirculates 30% of the air inside the cabinet and exhausts the rest to the outside. May be used with low- to moderate-risk agents and small amounts of chemical carcinogens or volatiles.
Class II Type B2	Offers total exhaust with no recirculation.
Class III or Glove Box	Gas-tight and maintained under negative air pressure. Used to work with highly infectious, carcinogenic, or hazardous materials. All operations are conducted through rubber gloves attached to entry portals.

12.3. Using Biological Safety Cabinets

A. Preparation

- 1) Leave safety cabinets on at all times. Otherwise, turn the blower on and purge the air for at least five minutes before beginning work.
- 2) Never turn off the blower of a biological safety cabinet that is vented to the outside.
- 3) Turn off the UV light if it is on. Never work in a unit with the UV light illuminated as UV light will damage your eyes.
- 4) Do not depend on the UV germicidal lamp to provide a sterile work surface; wipe down the surface with a disinfectant (70% alcohol is usually suitable).
- 5) Place everything needed for your procedure inside the cabinet prior to beginning work. Arrange the equipment in logical order.
- 6) Provide a container for wastes inside the cabinet. (Remember, nothing should pass through the air barrier until the entire procedure is complete.)
- 7) Never place any items on the air-intake grilles.
- 8) Place a disinfectant-soaked towel on the work surface to contain any splatters or spills that occur.
- 9) Keep the laboratory door shut and post signs stating "CABINET IN USE" on all the doors. Restrict activities that will disturb the cabinet's airflow, such as entry, egress, and walking traffic.

B. Cabinet Use

- 1) Conduct work at least four inches from the glass view panel. The middle third area is ideal.
- 2) Limit arm movement and avoid motions that could disturb airflow.
- 3) If a burner is necessary, use the Touch-O-Matic type with a pilot light. Since flames cause air turbulence, place burners to the rear of the workspace.
- 4) Never use flammable solvents in a biological safety cabinet unless it is a total-exhaust cabinet (e.g., Class II B2).
- 5) Do not use as a storage cabinet.

12.4. Experiment Completion

- A. Enclose or decontaminate all equipment that has been in direct contact with the infectious agent.
- B. Cover all waste containers.
- C. To purge airborne contaminants from the work area, allow the cabinet to operate for five minutes with no activity inside the cabinet.
- D. Remove all equipment from the cabinet.
- E. Decontaminate interior work surfaces.
- F. *IMPORTANT:* Biological safety cabinets are not a substitute for good laboratory practices. Because aerosols can escape, take precautions to minimize aerosol production and protect yourself from contamination.

12.5. Clean Benches

A clean bench has horizontal laminar air flow. The HEPA-filtered air flows across the work surface towards the operator, providing protection for the product but no protection for the user. Because clean benches offer no protection, use a clean bench only to prepare sterile media. Do not use clean benches when working with pathogenic organisms, biological materials, chemicals, or radioactive materials.

13. Importing and Shipping Biological Materials

The Public Health Service provides Foreign Quarantine regulations for importing etiologic agents and human disease vectors. Other regulations for packaging, labeling, and shipping are administered jointly by the Public Health Service and the Department of Transportation. The U.S. Department of Agriculture regulates the importation and shipment of animal pathogens. It prohibits the importation, possession, and use of certain animal disease agents that pose a serious threat to domestic livestock and poultry.

14. Biological Spill Response

- 14.1. The exact procedure for responding to a biological spill depends on the material, amount, and location of the spill. In general, follow these steps immediately after a biological spill occurs:
 - A. Warn others.
 - B. Leave the room; close the door.
 - C. Remove contaminated garments.
 - D. Wash your hands.
 - E. Notify your department chair/supervisor and EHSRM.
- 14.2. The following steps are general guidance for cleanup of a biological spill inside a safety cabinet:
 - A. Wear laboratory coat, eye protection, and gloves during clean-up.
 - B. Allow cabinet to continue to run during clean-up.
 - C. Apply an approved disinfectant and allow a minimum of 15 minutes contact time.
 - D. Wipe up spillage with disposable disinfectant-soaked cloth or tissue.
 - E. Wipe the walls, work surface and any equipment in the cabinet with a disinfectant-soaked cloth.

Angelo State University
Biological Safety Plan

- F. Discard contaminated disposable materials in appropriate hazardous biological waste container(s) and autoclave before discarding as waste.
 - G. Place contaminated reusable items in biohazard bags or in autoclavable pans with lids before autoclaving and cleanup.
 - H. Expose non-autoclavable materials to disinfectant and allow 15 minutes contact time before removing from the biological safety cabinet.
 - I. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving if necessary.
 - J. Run cabinet at least 15 minutes after cleanup before resuming work or turning cabinet off.
- 14.3. The following steps are general guidance for cleanup of a biological spill in a laboratory, outside a safety cabinet:
- A. Clear area of all personnel. Wait approximately 30 minutes for the aerosols to settle before entering spill area.
 - B. Remove any contaminated clothing and place in biohazard bag to be autoclaved.
 - C. Wear a disposable gown, shoe covers, eye protection and gloves. In a Biosafety Level 3 (BSL-3) facility, respiratory protection is usually required.
 - D. Initiate cleanup with disinfectant as follows:
 - 1) Soak paper towels in disinfectant and place over spill.
 - 2) Encircle the spill with additional disinfectant being careful to minimize aerosolization during pouring while assuring adequate contact. Start from the periphery and work toward the center.
 - 3) Decontaminate all items within the spill the area.
 - 4) Allow 15 minutes contact time to ensure germicidal action of disinfectant before passing items to clean area.
 - 5) Place disposable contaminated spill materials in appropriate biological hazardous waste container(s) for treatment.
 - 6) Place contaminated reusable items in autoclavable containers
- 14.4. The following steps are general guidance for cleanup of a biological spill inside a centrifuge:
- A. Clear the immediate area of all personnel. Wait 30 minutes for aerosol to settle before attempting to clean up spill. Keep centrifuge closed.
 - B. Wear a laboratory coat, eye protection, and gloves during cleanup.
 - C. Remove rotors and buckets to nearest biological safety cabinet for clean-up.
 - D. Thoroughly disinfect inside of centrifuge.
 - E. After thorough disinfection of rotor or rotor cups, remove contaminated debris and place in appropriate hazardous biological waste container(s) and autoclave before disposing.
- 14.5. The following steps are general guidance for cleanup of a biological spill outside the laboratory during transport:

Angelo State University
Biological Safety Plan

- A. Transport hazardous biological materials in an unbreakable sealed primary container, placed inside a second unbreakable lidded container. Label the outer container with the biohazard symbol if material is Risk Group 2 or higher.
- B. Should a spill occur in a public area, do not attempt to clean it up without appropriate PPE. Contact EHSRM for assistance.
- C. As an interim measure, wear gloves and place paper towels, preferably soaked in disinfectant, directly on spilled materials to prevent spread of contamination. To assure adequate contact, surround the spill with disinfectant, if available, taking care to minimize aerosols.

15. Biological Waste Disposal

15.1. Biological Waste and Biohazardous Waste

In Texas, disposal of biohazardous waste is regulated by the Texas Commission on Environmental Quality (TCEQ). Depository landfill regulations also apply.

- A. "BIOLOGICAL WASTE" means discarded biological material from teaching and research laboratories and operations. This does not include household or office trash, waste from Food Services, Physical Plant, bedding and manure from normal agricultural operations or bedding and litter from noninfectious animals.
- B. "BIOHAZARDOUS WASTE" means any solid or liquid biological waste that is hazardous because of its physical and/or biological nature and is differentiated from that which contains hazardous chemicals or radioactive materials. All waste that contains infectious material or which, because of its biological nature, may be harmful to humans, animals, plants or the environment is biohazardous waste. This includes:
 - 1) Waste from infectious animals, bulk human blood, or blood products.
 - 2) Infectious microbiological waste, including contaminated disposable culture dishes and disposable devices used to transfer, inoculate, and mix cultures.
 - 3) Pathological waste.
 - 4) Sharps.
 - 5) Hazardous products of recombinant DNA biotechnology and genetic manipulation.
- C. Definitions of other terms used in this document can be found in APPENDIX A.
- D. Biohazardous waste generated at ASU is deposited at the Student Health Center and collected monthly by a contracted biowaste transportation company or is treated by thermal or chemical disinfection or by encapsulation (solidification) and then discarded with routine municipal solid waste. Biohazardous waste may also be called "medical waste," "special waste," "red bag waste," "infectious waste," or "pathological waste." For simplicity, this Plan refers to all such material as "BIOHAZARDOUS WASTE." Definitions in this document are derived from Title 25, Texas Administrative Code Chapter 1.
- E. Sharps must be segregated from other waste and placed in puncture resistant containers. Sharps which have been treated by an approved method which incorporates grinding and/or shredding may be disposed as routine municipal solid waste if the sharps have been made unrecognizable and significantly reduced in ability to cause puncture wounds.

Angelo State University
Biological Safety Plan

- F. Unused hypodermic needles, syringes with attached needles, and scalpel blades shall be disposed of as sharps. Liquid waste should be disinfected and discharged into the sewer system. Treatment of all laboratory biological waste prior to disposal is good laboratory practice, and is highly recommended. Biohazardous waste must be treated and properly labeled and records must be maintained. Personnel with potential for contact with biohazardous material must be appropriately trained in the safe handling of the material.
- G. Never attempt to retrieve items from a sharps container.
- H. Biohazardous waste which is mixed with hazardous chemical waste, radioactive waste, or both must be treated to eliminate the biohazard prior to disposal. After treatment, the waste must be managed as hazardous chemical waste through [EHSRM](#).

15.2. Segregation of Biological Waste

- A. Any waste that could produce laceration or puncture injuries must be disposed of as "SHARPS." Sharps must be segregated from other waste. Metal sharps and broken glass may be commingled with each other but not with non-sharp waste.
- B. Waste that is to be incinerated should not be commingled with glass or plastics.
- C. Biological waste must not be commingled with chemical waste or other laboratory trash.
- D. Hazardous biological waste should be segregated from other biological waste.
- E. Containers

Containers must be appropriate for the contents, not leak, be properly labeled, and maintain their integrity if chemical or thermal treatment is used. Containers of biohazardous material should be kept closed. The proper containers and labeling methods for biological waste are given below.

- 1) Metal sharps: Place in a rigid, puncture resistant container (heavy walled plastic is recommended). The container should be used for encapsulation and disposal. Label the container "ENCAPSULATED SHARPS." Container and encapsulated contents must withstand an applied pressure of 40 psi without rupture.
- 2) Broken Glassware: Place in a rigid, puncture resistant container (plastic, heavy cardboard, or metal). Seal securely and clearly label "BROKEN GLASS."
- 3) Solid Biohazardous Waste: Use heavy-duty plastic "BIOHAZARD BAGS" (autoclave bags) or containers for solid biohazardous waste (including contaminated disposable plastic labware, paper, bedding, etc., but not SHARPS).
- 4) Nonhazardous Biological Waste: Heavy duty plastic bags or other appropriate containers without a biohazard label are preferred. Red or orange biohazard bags or containers should not be used for nonhazardous material.
- 5) Liquids: Liquids should be placed in leak-proof containers able to withstand thermal or chemical treatment. Do not use plastic bags to contain liquids.
- 6) *Note:* If the waste contains free liquids in containers, the plastic bag and/or the rigid container shall contain absorbent material sufficient to absorb 15% of the volume of free liquids in the container.

15.3. Storage of Biological Waste

Angelo State University
Biological Safety Plan

Biohazardous waste should be treated and disposed of promptly and not allowed to accumulate. Containers holding biohazardous material must be clearly labeled, including the Biohazard Symbol. Biological waste may be held temporarily under refrigeration, prior to disposal, in a safe manner that does not create aesthetic (visual or odor) problems. Storage enclosures must be clean and orderly with no access to unauthorized persons and warning signs must be posted.

15.4. Treatment of Biohazardous Waste

Biohazardous waste must be rendered harmless by appropriate treatment prior to disposal. Waste should be treated as near the point of origination as possible. Treatment methods include incineration, chemical disinfection, thermal disinfection, and encapsulation.

15.5. Handling and Transport of Biological Waste

- A. Properly trained laboratory personnel (not custodial staff) shall be responsible for transporting treated biological waste from the generation site to the dumpster or outside trash barrel. Untreated biohazardous waste shall only be handled by properly trained technical personnel.
- B. Treated waste must be properly contained and labeled before transport to the ASU dumpster or trash barrel for disposal.
- C. Transport of untreated biohazardous materials or foul or visually offensive material through nonlab or populated areas should be avoided.
- D. Trash/laundry chutes, compactors, and grinders shall not be used to transfer or process untreated biohazardous waste.

15.6. Labeling of Biohazardous Waste

- A. Each container of untreated biohazardous waste must be clearly identified as such and must be labeled with the Biohazard Symbol.
- B. Each container of treated biohazardous waste intended for disposal must be labeled to indicate the method of treatment and to cover biohazard markings.
- C. Label autoclave bags with commercially available autoclave indicator tape that changes color upon adequate thermal treatment. Apply this tape across the Biohazard Symbol on the bag before autoclaving.
- D. All containers of encapsulated sharps must be labeled as "ENCAPSULATED SHARPS."
- E. Containers of nonhazardous biological waste should be labeled as "NONHAZARDOUS BIOLOGICAL WASTE."

15.7. Disposal Methods

- A. Material that remains hazardous because it contains hazardous chemicals must be disposed of through [EHSRM](#). Do not dispose of hazardous chemicals in municipal waste or discharge into the sewer system.
- B. Animal carcasses and body parts are not defined as medical waste unless the animals were intentionally infected with a human pathogen. Landfill disposition of uninfected animal parts is acceptable.
- C. Avoid conditions that may create visual or odor problems.

Angelo State University
Biological Safety Plan

- D. Metal sharps (contaminated or not) that may cause puncture or cuts, must be placed in the appropriate container and disposed of in a manner that prevents injury to laboratory, custodial, and landfill workers. Needles, blades, etc., are considered biohazardous even if they are sterile, capped, and in the original container. Encapsulation provides the highest degree of safety possible at a reasonable cost and also eliminates the possibility of the use of needles/syringes for illegal purposes. The disposal methods for sharps include:
- 1) Encapsulation (solidification) in a properly labeled, puncture resistant container; place in an ASU dumpster or trash barrel. (See "Encapsulation" APPENDIX A.)
 - 2) Needles, such as those used for gas chromatography, should be thoroughly rinsed to remove hazardous chemicals and then disposed with non-contaminated broken glassware.
- E. *NOTE:* Never place sharps that are not encapsulated in a trash container or plastic bag that might be handled by custodial staff or attempt to recap, bend, break, or cut discarded needles.
- F. Pasteur Pipets and Glassware:
- 1) Contaminated With Biohazardous Material
 - a) Disinfect by thermal or chemical treatment; place in a properly labeled, leak proof and puncture resistant container; place in an ASU dumpster or trash barrel.
 - b) Encapsulate in a properly labeled, rigid, puncture resistant container, and place in an ASU dumpster or trash barrel.
 - c) Encapsulation is required if glass is commingled with metal sharps.
 - 2) Not Contaminated: Place in a puncture resistant container, then place in an ASU dumpster or trash barrel. The container must be clearly labeled to indicate that it contains broken glass.
- G. Plastic Waste:
- 1) Contaminated With Biohazardous Material: Place in a properly labeled, leak proof container, disinfect by thermal or chemical treatment, and place in an ASU dumpster or trash barrel.
 - 2) Not Contaminated: Place in an ASU dumpster or trash barrel.
- H. Microbiological Waste:
- 1) Solid waste must be placed in a properly labeled, leak-proof container, disinfected by thermal or chemical treatment, and placed in an ASU dumpster or trash barrel.
 - 2) Liquid waste should be disinfected by thermal or chemical treatment then discharged into the sewer system.
 - a) Excess proteinaceous material can clump and cause drain clogging. Grinding of treated waste may be necessary. Do not grind untreated biohazardous material.
- I. Human Pathological Waste:
- 1) Human cadavers and recognizable body parts must be cremated or buried in accordance with [25 TAC 1.136\(a\)\(4\)](#).
 - 2) Other pathological waste from human and higher primates must be incinerated.
- J. Genetic Material: Disposal of materials containing recombinant DNA or genetically altered organisms must be consistent with applicable [NIH Guidelines](#), in addition to complying with the requirements contained in this document.

Angelo State University
Biological Safety Plan

K. Nonhazardous Biological Waste

- 1) Biological waste that is not infectious or otherwise hazardous to humans, animals, plants, or the environment may be discarded as regular municipal waste (solid) or sewage (liquid).
- 2) There are no record keeping or labeling requirements for nonhazardous biological waste.
- 3) It is good laboratory practice to autoclave or disinfect all microbial products. Culture materials and biological specimens, including bacterial or "normal" cell cultures and primary tissues should be autoclaved or treated with a 10% sodium hypochlorite (or equivalent) solution. Liquid waste should be discharged into the sewer system. Avoid conditions that may create visual or odor problems.
- 4) Nonhazardous waste should not be identified as hazardous. Containers should be labeled "NONHAZARDOUS LABORATORY WASTE." Do not use biohazard bags or "red bags" for nonhazardous waste.

L. Nonhazardous bedding (laboratory animal) and agricultural waste such as bedding, manure, etc. should be used as compost or fertilizer whenever practicable.

M. Chemical Waste: Biohazardous waste which also contains hazardous chemicals must be treated to eliminate the biohazard and then managed as hazardous chemical waste through [EHSRM](#). Hazardous chemicals must not be disposed of in dumpsters or discharged into the sewer system.

15.8. Disposal Training and Hazard Communication

The Laboratory Supervisor or Principal Investigator must assure that all personnel who dispose of potentially biohazardous material are informed of the hazards and are trained in the proper procedures and equipment needed to avoid exposure, proper disposal of biohazardous wastes, and recognition of symptoms of infection or exposure.

15.9. Waste Treatment Procedures and Records

A. All departments that treat waste are required to keep records that include the following:

- 1) Date of treatment
- 2) Treatment method or condition
- 3) Quantity of waste treated (pounds)
- 4) Printed name of person treating the waste
- 5) Verification of operating procedures or biological monitoring

B. This information can be recorded on autoclave use and efficacy forms. Autoclave use log books shall be located in each room where an autoclave is used for onsite treatment of infectious waste.

C. If an entity generates more than fifty (50) pounds of biohazardous waste per calendar month, the records must also include:

- 1) A written procedure for the operation and testing of any equipment used and a written procedure for the preparation of any chemicals used in treatment.
- 2) Processes for which the manufacturer documents compliance with specified performance standards (e.g., temperature, pressure, pH), and for processes which produce a continuous readout (e.g. strip chart or chart paper), routine parameter monitoring may be used to verify

Angelo State University
Biological Safety Plan

efficacy. Otherwise, biological monitoring is required to document a 99.99% reduction using an appropriate biological indicator (Bacillus species) at the following intervals:

- a) 50-100 pounds per calendar month requires testing once per month.
 - b) 101-200 pounds per calendar month requires testing biweekly.
 - c) More than 200 pounds per calendar month requires testing weekly.
- D. Records must be maintained for at least three (3) years for EACH CONTAINER of biohazardous waste treated (including sharps that are encapsulated).
- E. Departments not having proper equipment to effectively treat infectious or biological waste may request offsite treatment by a licensed vendor. [EHSRM](#) will coordinate all vendor disposal services and maintain required documentation.

16. Shipment of Biological Agents

- 16.1. Laboratory personnel must be properly trained on transportation and shipment regulations before shipping an infectious substance.
- 16.2. Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.
- 16.3. Category A Infectious Substances
- A. Are capable of causing permanent disability, life threatening or fatal disease in humans or animals when exposure occurs.
 - B. Are shipped as infectious substances, affecting humans (UN2814), or infectious substances affecting animals (UN2900). Examples of Category A infectious substances can be found listed in [US DOT Transportation Regulations](#) and the [IATA Dangerous Goods Regulations](#).
 - C. Shipping Requirements
 - 1) Triple layer packaging
 - 2) Materials used for transport must be tested to ensure the sample will not leak
 - 3) Absorbent material
 - 4) Itemized contents list
 - 5) Outer package must bear Class 6.2 Infectious Substance label
 - 6) Additional labeling and marking requirements
 - 7) Shipper's Declaration required
- 16.4. Category B Infectious Substances
- A. Are materials that are infectious, but do not meet the standard for inclusion in Category A (i.e. unscreened human blood or human tissue).
 - B. Are shipped with the proper shipping name "biological substance, category B" and are assigned to UN3373.

Angelo State University
Biological Safety Plan

C. Shipping Requirements

- 1) Triple layer packaging
- 2) Materials used for transport must be tested to ensure sample will not leak
- 3) Outer package and air waybill must bear "UN3373" and "Biological substance, category B"
- 4) No Shipper's Declaration required

16.5. Exempt Human Specimen

- A. Has minimal likelihood of containing pathogens and is exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and must be based on the patient's medical history, symptoms, local conditions, and individual circumstances.
- B. If there is more than minimal likelihood that a patient specimen contains pathogens, it must be shipped as an infectious substance (either Category A under UN2814 or UN2900, or Category B under UN3373).
- C. Infectious substance or patient specimen shipments with dry ice
 - 1) Never place dry ice in a sealed air tight container!
 - 2) Outer package must be approved to hold dry ice, otherwise use an overpack.
 - 3) UN 1845 Dry Ice label, including estimated weight of dry ice.
 - 4) Affix a Class 9 Dangerous Goods label.

16.6. Biological Product

- A. Are products derived from living organisms that are known not to produce viruses, toxins, etc. and are manufactured and distributed in accordance with requirements of national government authorities. These include, but are not limited to, finished or unfinished products such as vaccines.
- B. Biological products are not currently regulated for the purposes of shipping.

17. Record Retention

- 17.1. No official state records may be destroyed without permission from the Texas State Library as outlined in [Texas Government Code, Section 441.187](#) and [Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7](#). The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.
- 17.2. ASU's Records Retention Schedule is certified by the Texas State Library and Archives Commission. Departments and EHSRM shall follow ASU's Records Retention Schedule as stated in the Operating Procedure [OP 02.07 Records Retention](#). All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

18. Training

- 18.1. All laboratory personnel and students must review the general Biosafety Training in Blackboard and successfully pass the accompanying exam before participating in a laboratory setting with biological hazards. Training shall be documented in Blackboard.
 - A. Instructors may, in their sole discretion, assign laboratory credit for review and successfully passing the test or may treat it as pass/fail.

Angelo State University
Biological Safety Plan

- B. Laboratory personnel and 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.
- 18.2. Instructors and laboratory supervisors are responsible for additional training required due to specific activities or environment (i.e., Lab Safety and Chemical Hygiene, Hazardous Communications, or Bloodborne Pathogen). Training shall be documented in Blackboard or Citi, as appropriate.
- 18.3. 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.

19. Reference Material

The following references were used in drafting this Plan or provide additional information:

- A. Centers for Disease Control/National Institutes of Health, [Biosafety in Microbiological and Biomedical Laboratories, 5th Edition](#), 2009.
- B. Safety Data Sheets (SDS) for Infectious Agents
- C. [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#) (2016)
- D. CDC Importation Permit Program [Website](#) (for Etiologic Agents)
- E. CDC [Interstate Shipment of Etiologic Agents/Packaging and Shipping of Biomedical Material](#) (2009)
- F. US DOT Shipping Regulations [49 CFR 173.134](#)
- G. USDA Animal and Plant Health Inspection Service (APHIS) [Guidance Documents](#)
- H. American Biological Safety Association [Biosafety Links](#) Page
- I. Title [25 Texas Administrative Code, Chapter 1, 1.131-1.137](#). December 21, 1994. (Definition, Treatment and Disposition of Special Waste from Health Care Related Facilities).
- J. Title [30 Texas Administrative Code, Chapter 326](#). May 26, 2016 (Medical Waste Management, Disposal, Transportation, Collection, & Storage), formerly [Chapter 330](#).
- K. ASU [Institutional Biosafety Committee Policies and Procedures](#)
- L. ASU Bloodborne Pathogen Exposure Control Plan

APPENDIX A: Definitions

1. Biosafety Plan Definitions

- 1.1. **Animal Waste:** Includes carcasses; body parts; whole blood and blood products, serum, plasma and other blood components; and bedding of animals.
- 1.2. **Biohazardous Waste:** Includes any waste that is infectious or, because of its physical and/or biological nature, may be harmful to humans, animals, plants, or the environment. Biohazardous waste includes:
 - A. Animal waste known or suspected of being contaminated with a pathogen
 - B. Bulk human blood or blood products
 - C. Microbiological waste
 - D. Pathological waste
 - E. Infectious waste
 - F. Waste products of recombinant DNA biotechnology and genetic manipulation
 - G. Sharps
- 1.3. **Biological Indicator:** Commercially available microorganism (e.g. spore strips or vials of *Bacillus* species) that can be used to verify the performance of waste treatment equipment and/or processes.
- 1.4. **Bulk Blood and Blood Products:** Discarded bulk (>100 ml.) blood and blood products (higher primate or human) in a free draining, liquid state; body fluids contaminated with visible blood; and materials saturated or dripping with blood.
- 1.5. **Chemical Disinfection:** The use of a chemical agent such as 10% hypochlorite or EPA-approved chemical disinfectant/sterilant (used according to manufacturer's direction) to significantly reduce biological activity of biohazardous material.
- 1.6. **Deposition in a Transfer Station/Landfill:** Means in accordance with Title 30, Chapter 330 of the Texas Administrative Code.
- 1.7. **Discharge into the Sewer Station:** Means the discharge or flushing of treated biological waste into the local sewer system followed by copious quantities of water.
- 1.8. **Encapsulation:** The treatment of waste, especially sharps, using a material such as Plaster of Paris (or a commercial product such as Isolyser) which when fully reacted, will encase the waste in a solid protective matrix. The encapsulating agent must completely fill the container. The container and solidified contents must withstand an applied pressure of 40 psi without disintegration.
- 1.9. **Incineration:** Burning biological waste in an incinerator permitted by the Office of Air Quality, Texas Commission on Environmental Quality.
- 1.10. **Infectious Waste:** Waste containing pathogens or biologically active material, which because of its type, concentration, and quantity is capable of transmitting disease.
- 1.11. **Microbiological Waste:**
 - A. Discarded cultures and stocks of infectious agents and associated biological material.
 - B. Discarded cultures of specimens from medical, pathological, pharmaceutical, research, and clinical laboratories.
 - C. Discarded live and attenuated vaccines.
 - D. Discarded disposable culture dishes intentionally exposed to pathogens.

- E. Discarded disposable devices used to transfer, inoculate, and mix cultures intentionally exposed to pathogens.
- 1.12. **Pathogens:** Any diseases transmissible to humans.
- 1.13. **Pathological Waste:** Materials from human and higher primates that includes, but is not limited to,
- A. Human materials removed during surgery, labor, delivery, spontaneous abortion, autopsy or biopsy, including body parts, tissues and fetuses, organs, bulk blood, and body fluids.
 - B. Laboratory specimens of blood, tissue, or body fluids after completion of laboratory examination.
 - C. Anatomical remains.
- 1.14. **Sharps Waste:** Any device having acute rigid corners or edges or projections capable of cutting or piercing, including:
- A. Hypodermic needles, syringes, and blades.
 - B. Glass pipets, microscope slides, and broken glass items.
- 1.15. **Thermal Treatment:**
- A. Autoclaving at a temperature of not less than 121 degrees C, and a minimum pressure of 15 psi for at least 30 minutes (longer times may be required depending on the amount of waste, water content, and type of container used).
 - B. Subjecting biological material to dry heat of not less than 160 degrees C under atmospheric pressure for at least two hours. (Exposure begins after the material reaches the specific temperature and does not include lag time.)
 - C. Treatment - chemical, thermal, or mechanical processes that significantly reduce or eliminate the hazardous characteristics or that reduce the amount of a waste.

APPENDIX B: rDNA Research Policy

1. rDNA Research Policy

- 1.1. It is the policy of ASU that research and teaching programs utilizing recombinant DNA technology will be conducted in full compliance with federal and state laws and regulations, irrespective of the source of funding for the research. Primary consideration will be given to:
 - A. Protection of the health of employees, students, and the public;
 - B. Protection of domestic and feral animal populations; and
 - C. Protection of all aspects of the environment.
- 1.2. Pursuant to the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#) ASU must:
 - A. Establish and implement policies that provide for the safe conduct of recombinant DNA research where it poses health and environmental risk concerns.
 - B. Establish an Institutional Biosafety Committee (IBC) as specified in the [NIH Guidelines](#).
 - C. Appoint a Biosafety Officer if the institution is engaged in recombinant DNA research at the Biosafety Level 3 or 4 containment level.
 - D. Require that investigators responsible for research covered by the [NIH Guidelines](#) comply with the appropriate sections of the [NIH Guidelines](#) and assist investigators to do so.
 - E. Ensure appropriate training for the IBC Chairperson and members; the Biosafety Officer, if appointed; and laboratory staff regarding the [NIH Guidelines](#), their implementation, and laboratory safety. Responsibility for training laboratory staff may be carried out through the PI. ASU is responsible for ensuring that the PI is adequately trained and may delegate that responsibility to the IBC.
 - F. Determine the required Biosafety Level for the project and the need for any health surveillance for research personnel.
- 1.3. Significant safety problems with recombinant DNA projects will be reported immediately to the chairperson of the IBC. That official will then be responsible for investigating the incidents and reporting appropriate details to the NIH Office of Biotechnology Activities.
- 1.4. The IBC will function as defined by the [NIH Guidelines](#). The committee will represent the University in ensuring compliance with relevant regulations and this policy. The IBC will:
 - A. Adopt and maintain policies and procedures consistent with the [NIH Guidelines](#) and establish training requirements for IBC members, Biosafety Officers, Principal Investigators, and laboratory research personnel.
 - B. Review non-exempt recombinant DNA research for compliance with NIH Guidelines as specified and approve projects found to be in conformity. The Committee will independently assess containment levels required by these Guidelines and will assess facilities, procedures, practices, personnel training, and personnel expertise, as appropriate.
 - C. Set containment levels for specified experiments including those involving whole animals or plants.
 - D. Review, periodically, recombinant DNA research being conducted to ensure fulfillment of the requirements of the [NIH Guidelines](#).

- E. Adopt emergency plans covering accidental spills and personnel contamination. Maintain copies of these plans for ready access in the event of an accident.
- F. Report significant problems to the appropriate institutional official immediately.
- G. Investigate all incidents, and jointly with the PI, report appropriate information to the NIH Office of Science Policy (NIH OSP) within 30 days.

1.5. Refer to the [Institutional Biosafety Committee Policy and Procedures](#) and webpage for specific information.

2. Institutional Biosafety Committee

- 2.1. The IBC may not authorize initiation of experiments not explicitly covered by the [NIH Guidelines](#) until authorized to do so by the NIH.
- 2.2. The Director of Risk and Emergency Management and the Biosafety Officer (if appointed) shall be members of the IBC.
- 2.3. Appointment of a Biosafety Officer is required if research is conducted at Biosafety Level 3 or above or for Large Scale Research. If a Biological Safety Officer 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 below are accomplished. The Biosafety Officer's duties include:
 - A. Conducting periodic inspections (at least annually for Biosafety Level 2 and monthly for Biosafety Level 3 & 4) to ensure that laboratory standards are rigorously followed.
 - B. Reporting significant problems, violations of the [NIH Guidelines](#), significant research related accidents and illnesses to the (co-)Chair of the IBC. The IBC (co-)Chair will investigate all incidents and violations with results reported to the Executive Vice President Academic Affairs. If appropriate, the details will be reported to the NIH OSP.
 - C. Developing emergency plans for dealing with accidental spills, personnel contamination and investigating laboratory accidents with assistance and consultation with EHSRM and the IBC.
 - D. Providing advice on laboratory security and research safety.

3. Principal Investigator (PI)

- 3.1. On behalf of the institution, the PI is responsible for complying fully with the [NIH Guidelines](#) in conducting recombinant DNA research. The PI will be fully informed of his/her responsibilities under the [NIH Guidelines](#) and will be knowledgeable regarding containment and safety requirements of ASU's laboratory safety, biological safety, and institutional biosafety Plans.
 - A. The Principal Investigator will:
 - 1) Not initiate or modify recombinant DNA research requiring IBC approval, until the research or proposed modification has been approved by the IBC.
 - 2) Make the initial determination of the required levels of containment in accordance with the [NIH Guidelines](#) and the select microbiological practices and laboratory techniques to be used. Request consultation from the IBC, if needed, to assist with planning of project safety and occupational health.
 - 3) Submit the initial research proposal (and subsequent changes) to the IBC for review and approval/disapproval if the protocol is covered under sections III-A through III-D of the [NIH Guidelines](#).

- 4) Remain in communication with the IBC throughout the conduct of the project.
- 5) Prior to initiation of the investigation, provide the laboratory staff copies of the safety protocols that describe potential hazards and precautions to be taken routinely and in the event of an accident. Ensure that a copy of the safety protocol is maintained in the laboratory.
- 6) Instruct and train the staff in practices and techniques required to ensure safety and procedures for dealing with accidents. Document the training by maintaining a record of date, time, attendees, and discussion content.
- 7) Inform the staff of reasons and provisions for precautionary medical practices (e.g. vaccinations, serum collection) advised or requested.
- 8) Report significant problems and violations of the [NIH Guidelines](#) to the IBC immediately. The IBC will investigate the problem, and with the PI, will report appropriate details to the NIH OSP within 30 days.
- 9) Report new information bearing on the [NIH Guidelines](#) to the IBC.
- 10) Become adequately trained in proper microbiological techniques, if inexperienced in safe methods of conducting recombinant DNA research.
- 11) Comply with shipping requirements for infectious vectors used in recombinant DNA research.
- 12) Adhere to IBC approved emergency plans in the event of accidental spills and/or personal contamination.
- 13) Submit information to NIH if required by the [NIH Guidelines](#). Obtain IBC concurrence if direct communication to NIH is required.

4. Reporting of Laboratory Incidents or Noncompliance Involving Recombinant DNA

- 4.1. Lab incidents involving recombinant DNA or Noncompliance with [NIH Guidelines](#)
 - A. Any significant problems, significant research-related accidents or illnesses involving rDNA, or noncompliance with the [NIH Guidelines](#) may be brought forward by any person, and should be promptly reported to EHSRM for investigation and reporting of the incident to the NIH OSP and the IBC if required. See OSP's [FAQ](#) for additional guidance.
 - B. ASU must report any significant problems or violations of the [NIH Guidelines](#) and any significant research-related accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days. Examples include needlesticks containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet.
 - C. Spills and accidents which result in overt exposures to Risk Group 2 (RG2) organisms or overt or potential exposures to Risk Group 3 (RG3) organisms containing recombinant DNA molecules must be immediately reported to EHSRM for investigation and reporting of the incident to the NIH OSP and the IBC if required. Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained.
- 4.2. Adverse Events Involving Recombinant DNA Human Gene Transfer
 - A. Human gene transfer experiments involve the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants. Researchers shall receive

IBC approval prior to beginning human gene transfer experiments and should consult Appendix M of the [NIH Guidelines](#) for pertinent requirements to conduct this research.

- B. For projects involving human gene therapy, a “serious adverse event” is any event occurring at any dose that results in any on the following outcomes: death, a life-threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization also may be considered a serious adverse event when, upon the basis of appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition
 - C. An adverse event is “associated with the use of a gene transfer product” when there is a reasonable possibility that the event may have been caused by the use of that product.
 - D. An “unexpected serious adverse event” is any serious adverse event for which the specificity or severity is not consistent with the risk information available in the current investigator’s brochure.
- 4.3. Contact EHSRM immediately if any of the above occur for investigation and reporting.