BIOLOGICAL SAFETY PLAN

THE UNIVERSITY OF TEXAS AT SAN ANTONIO

OFFICE OF RESEARCH INTEGRITY

LABORATORY SAFETY DIVISION

REVIEW PAGE

This version of the manual has been reviewed for regulatory compliance and best management practices by the listed individuals and committees and is hereby adopted for use and compliance by all employees at The University of Texas at San Antonio owned or operated facilities.

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COMMITTEE REVIEW

COMMITTEE	REVIEW DATE	APPROVAL DATE
Institutional Biosafety Committee	10-03-2018	10-03-2018

Rewrite: September 12, 2018
Replaces: June 7, 2016
Review Frequency: Annual

This plan represents a significant rewrite. The September 12, 2018 version replaces the June 7, 2016 version.

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I. OVERVIEW AND PURPOSE

The Laboratory Safety Division and Office of Research Integrity prepared this plan after review of pertinent federal and state regulatory requirements from the following agencies and organizations:

- Occupational Health and Safety Administration (OSHA)
- Texas Department of State Health Services (TDSHS)
- Texas Commission on Environmental Quality (TCEQ)
- Centers for Disease Control and Prevention (CDC) https://www.cdc.gov/biosafety/publications/bmbl5/index.htm
- National Institutes of Health – *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* https://osp.od.nih.gov/biotechnology/nih-guidelines/.
- U.S. Department of Health and Human Services – Policy of Institutional Oversight of Life Sciences Dual Use Research of Concern http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

Research and education in science laboratories involves a variety of hazards. It is The University of Texas at San Antonio's (UTSA) policy to protect and promote the health and safety of students and employees as well as the environment. This plan outlines basic good laboratory safety practices, special procedures for this institution, federal and state guidelines and references to other information sources for work in laboratories that handle, use or store biological agents. This is not intended to be a fully comprehensive reference but rather a guidebook. There may be agents, procedures and other circumstances in each laboratory that present unique or unusual hazards not addressed in this manual. If necessary, such hazards are best addressed by the principal investigator or supervisor of the respective laboratory in consultation with the Laboratory Safety Division.

Faculty, staff, and students who may be exposed to biological hazards in the laboratory must be informed of the nature of these hazards and how to protect themselves and others who may also be exposed. Safety in the laboratory can be achieved only with the exercise of sound judgment and proper use of facilities by informed, responsible individuals.

II. SCOPE

This plan applies to all UTSA operated (leased or owned) facilities and equipment (including vehicles). It also applies to any UTSA employee, volunteer or student worker(s) who work directly with, or in close proximity to anyone conducting research that falls under federal and state regulations or guidelines for working with biological agents. The NIH guidelines are mandatory for all researchers at institutions receiving NIH funding. Even those researchers who are not receiving NIH funding must follow the NIH guidelines. All federal NIH funding can be removed from an institution for violations of the guidelines by any researcher. Thus, the guidelines apply to all UTSA research.

III. PERIODIC REVIEW

This plan will be reviewed as needed, and yearly by the Institutional Biosafety Committee. The online version of this plan will be reviewed periodically for updates on the VPREDKE website at: http://www.utsa.edu/safety/#/laboratory/manuals. Questions can be addressed to the Interim Laboratory Safety Manager who also serves as the Institutional Biosafety Officer through the Office of Research Integrity at 210-458-8515.

IV. ROLES & RESPONSIBILITIES

A. The Laboratory Safety Division

1. Establish the general policies and standards for the use of biological hazards at UTSA in conjunction with the Institutional Biosafety Committee (IBC), Laboratory Safety Advisory Committee, and as per directives in HOP 9.05 – Occupational Safety & Health and 9.22 – Acquired Immune Deficiency Syndrome, Human Immunodeficiency Virus and Hepatitis B Virus http://www.utsa.edu/hop/chapter9/index.html
2. Provide consulting services for work with biological agents.
3. Review applications and protocols for work with potentially infectious materials or hazardous biological agents and provide recommendations to the Principal Investigator (PI), Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or University Veterinarian.
4. Develop safety plans and training programs for work with all risk groups of biological agents, blood borne pathogens, and other potentially infectious materials in use at UTSA facilities.
5. Contract for the annual certification, maintenance, and repair of biological safety cabinets to ANSI/NSF-49.
6. Provide support to the biological waste disposal program operated by EHSRM as needed.
7. Supervise decontamination and clean-up activities following spills or exposures.
8. Ensure periodic review of the Biological Safety Plan and update as necessary.
9. Maintain qualified staff to act as the Responsible or Alternate Responsible Official for Select Agent Program work at UTSA and as the Institutional Biosafety Officer
10. Investigate and provide support following biological exposure incidents.
11. Evaluate laboratories periodically to ensure compliance with institutional, state, and federal guidelines/regulations as they pertain to biosafety.
12. Provide the final clearance for the safe demolition, renovation or reassignment of UTSA facilities and equipment that used or contained hazardous biological agents or potentially infectious materials.

B. Principal Investigators (PI) or Laboratory Supervisors will:

1. Submit protocols for all non-exempt biological work to the IBC (as defined in the IBC policy) and await approval prior to conducting work covered by the protocol.

2. Enforce all UTSA procedures and policies regarding all risk groups of biological agents.
3. Ensure laboratory personnel have been properly trained to work safely within their laboratory to include required safety training provided by UTSA.
4. Develop and train laboratory personnel on safety procedures and protocols that are specific for their lab(s).
5. Advise the Laboratory Safety Division of any significant protocol changes and prior to bringing new biologically hazardous agents onto campus.
6. Report any exposures, spills, thefts or other incidents involving biological safety to the Laboratory Safety Division immediately or as soon as possible.
7. Maintain a clean and sanitary workplace.
8. Report any plans to remodel or alter UTSA Facilities (HOP 8.3) to Facilities, the Laboratory Safety Division and EHSRM to get permission before proceeding.

C. Laboratory Staff or Worker will:

1. Observe the established guidelines, protocols, and policies for biological safety.
2. Attend all necessary or required training.
3. Report all spills or incidents to their supervisor and to the Laboratory Safety Division if necessary.
4. Report to the supervisor or the Laboratory Safety Division any unsafe practices or conditions in the laboratory.
5. Properly dispose of all laboratory wastes.

D. The Institutional Biosafety Committee (IBC) will:

1. Assist in approving general policies and procedures for the biohazards at UTSA.
2. Review and exercise approval authority of protocols provided by Principal Investigators relating to the use of biohazards and recombinant and synthetic nucleic acids.
3. Maintain the required records of the protocol review, approval, and monitoring of the use and disposal of biohazards, as required by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
4. Serve as an avenue of appeal in case of dispute between the Laboratory Safety Division and the PI.

E. The Laboratory Safety Advisory Committee (LSAC) will:

1. Assist in reviewing new safety issues involving laboratories.
2. Review facility safety issues involving laboratories.
3. Review continuing safety issues involving laboratories.
4. Provide guidance to the Laboratory Safety Division for the resolution of ongoing safety issues.
5. Develop and review policies to support the safety culture at UTSA as needed.

V. BIOLOGICAL LABORATORY SAFETY

A. Biosafety

Safety is vital in biological laboratories due to the nature of many of the organisms studied, the high concentrations involved, and the infectivity of many organisms. History has shown laboratory workers can become infected with the biological agents they routinely work with and such incidents continue to occur globally. These infections are referred to as Laboratory Acquired Infections (LAI). Due to the variety of ways agents are manipulated in laboratories, LAI's may be acquired by routes not typically seen in nature.

Biosafety is the combination of laboratory practice and procedure, laboratory facilities, and safety equipment when working with potentially infectious microorganisms. Following biosafety practices provide protection for laboratory workers (yourself), the products you are working with, co-workers within the laboratory, people outside the laboratory (including families), and the environment. Because chemicals are also used in biological laboratories, chemical safety must also be observed (refer to the UTSA Chemical Safety Plan).

B. Basic Safety Guidelines

1. No mouth pipetting: Use only pipetting devices.
2. No food or drink stored or consumed in the laboratory.
3. No cell phones or mobile devices should be used while conducting experiments.
4. Wash hands frequently: After working with contaminants, following the removal of gloves, before leaving the work area or touching common use items such as computer keyboards, telephones, or door handles.
5. Always wear appropriate Personal Protective Equipment (PPE) and remove PPE before exiting the laboratory and entering common areas.
6. Remove gloves before touching common use items and before exiting the laboratory.
7. **Syringes, Needles, and Sharps**

    - Plastic-ware should be substituted for glassware whenever possible.
    - Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce the risk of sharps injuries.
    - Examples of engineering controls include: Self-sheathing needles, needleless systems, and blunt tipped equipment such as scalpels and scissors.
    - Examples of work practice controls include: Not recapping needles and pointing sharps away from the user, especially when carrying out an injection.
    - Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination (i.e. autoclaving).
    - Syringes must be handled with great care and only after adequate training.

- After filling, excess fluid and bubbles should be expelled from syringes vertically into a plastic test tube containing a sterile cotton pledget to minimize aerosolization or this procedure can be performed in a class II biosafety cabinet.
- Contaminated needles and syringes must be discarded into a sharps container.
    - Do not fill sharps containers greater than ¾ full to avoid possible sharps injuries during disposal.
    - Do not recap sharps.
    - Once discarded, items must not be removed from the sharps container.
- Prior to disposal, never bend, shear, break, remove disposable syringes or otherwise manipulate needles by hand.
- Needles used for blood drawing (phlebotomy) should also be placed in an appropriate sharps disposal container. DO NOT RECAP NEEDLES.
- Any sharps injury must be reported to EHSRM via the First Report of Injury Form available at the department's website: http://www.utsa.edu/Safety/?section=workplace&page=wci. See Appendix IV for bloodborne pathogen exposure emergency procedures. The Biosafety Officer must also be notified of any sharps injuries.

8. Broken Glass: Clean up broken glass as soon as possible to prevent injuries. If broken glass is contaminated with a potentially biohazardous substance, disinfect with appropriate biocide treatment and contact time prior to cleaning to avoid possible aerosol and cross contamination. Collect broken glass using a broom and dustpan where possible. Inside a BSC or other piece of equipment, tongs or forceps can be used to collect the broken glass. NEVER use your hands to pick up broken glass even if gloves are worn. Place any broken glass in a puncture-resistant container. When this container is approximately three quarters full, seal the container, and dispose of it or make arrangements with Housekeeping to dispose of it.
9. Bio-aerosol formation should be avoided or minimized. Bio-aerosols are formed when the liquid-air interface is disturbed. Inhalation of bio-aerosols can lead to infections even by organisms not generally known to be transmitted by the aerosol route. To prevent bio-aerosols hazards:
    - Use absorbent paper on workbench.
    - Perform all bio-aerosol forming procedures inside a BSC or substitute with other procedures.
    - Evaluate potential aerosol generating devices such as flow cytometers and cell sorters for efficacy of containment and establish standard operating procedures to control potential exposure to bio-aerosols in surrounding areas.

    Examples of some bio-aerosol forming laboratory activities:

    - Opening centrifuge tubes
    - Flaming loops
    - Blowing the last drop out of pipets

- Splashes
- Vortexing and homogenization
- Operating a flow cytometer or cell sorter
- Working with a cryostat

Additional sources of bio-aerosols can include residue from biological cultures and culturing equipment, lab surface contamination and dust from animal caging.

VI. PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) is a device or clothing worn to help protect you from direct exposure to hazardous materials. Examples include safety glasses or goggles, laboratory coats or aprons, gloves, face shields, and respirators. Remember, PPE only protects you if you use it properly.

A. Eye and Face Protection

Eye protection must meet standards for impact resistance and should also, provide splash protection and should provide UV protection. Safety glasses with side shields usually provide adequate impact resistance with limited splash protection. Chemical splash goggles (with no perforations around the goggles) provide adequate impact resistance, and splash protection, and limited vapor protection, and therefore provide the best all-around eye protection. Vapor-resistant goggles are available if needed. In addition to protective eyewear, face shields or freestanding shields should be used in situations where implosion or explosion may occur. Follow these guidelines for effective eye and face protection:

1. Wear protective eyewear at all times in the laboratory when conducting experiments.
2. Wear chemical splash goggles for maximum protection, especially if you wear corrective lenses (eyeglasses or contacts lenses).

B. Hand Protection

Gloves protect your skin from the biological agents you work with. Disposable nitrile gloves protect against water, dirt and microorganisms with minimal chemical resistance. Due to latex allergies or the possibility of developing such allergies, gloves made from other materials should be available in the laboratory. Appropriate gloves should be selected that have resistance to any chemicals being used in the laboratory. Information is available online, from the manufacturer or from the Laboratory Safety Division on the different types of gloves available. Follow these guidelines for effective hand protection.

1. Wear gloves that provide the greatest protection from the biological agents and chemicals with which you are working.
2. Wash your hands promptly after removing protective gloves to avoid exposure due to microscopic holes, tears, or accidental contact with the outside of the gloves when removing them.
3. Remove gloves when handling common laboratory items (telephones, doorknobs, etc.) to prevent their contamination.

C. Body Protection

The most common form of body protection in the laboratory is the laboratory coat. Laboratory coats protect your skin and clothes in the event of a spill or a splash. Follow these guidelines for effective body protection.

1. Protective clothing should be easily removable and free from rips or tears.
2. Wear your laboratory coat or apron only in the lab to prevent the potential spread of contamination.
3. Laboratory clothes should not be taken home for laundering.
4. The following are not to be worn in laboratories: high-heeled or open-toed shoes, sandals or woven shoes, shorts/capris or miniskirts, excessive or dangling jewelry.

D. Respiratory Protection

Respiratory protection in the laboratory is normally provided by engineering controls such as the ventilation system and the biological safety cabinet(s). When a higher level of respiratory protection is required, an N-95 or PAPR (Powered Air Purifying Respirator) can be used. Contact EHSRM for assistance in selecting the correct respirator. Medical assessment, fit testing and training on proper use and storage are necessary prior to using a respirator. Follow these guidelines for effective respiratory protection:

1. Do not use a respirator unless you have been trained to do so and have undergone a medical evaluation.
2. If you are wearing a respirator, be sure appropriate fit-testing has been performed.
3. Properly store a respirator to prevent continued contamination.

VII. LABORATORY EQUIPMENT

A general understanding of laboratory equipment and how it works is essential to work safely in the laboratory.

A. Biological Safety Cabinets

Biological Safety Cabinets (BSCs) are among the most effective and most commonly used primary containment devices in laboratories working with infectious agents. The BSCs are designed to capture, contain infectious particulates or aerosols generated within the BSCs, and exhaust them through a HEPA filter. Since HEPA filters are ineffective against volatile chemicals, these chemicals should never be used in the BSCs.

Most BSCs recirculate 30 or 70% of their air within the cabinet. During this recirculation, the air passes over motors and wiring which are incompatible with a flammable atmosphere. For this reason flammables are not recommended for use in BSCs. Open flames can be problematic as well. The accidental release of flammable gas into the ventilation system of a BSC can result in a fire. Heat buildup from the use of a flame in a BSC can damage the HEPA filter, releasing infectious agents into the laboratory or the environment. The use of open flames in BSC's can disrupt the laminar flow of the air and cause contamination problems within the cabinet or in the laboratory.

For information on alternatives to flames in BSC's contact the Institutional Biosafety Officer. NEVER have a BSC connected to natural gas lines without first gaining permission from the Biosafety Officer.

BSCs must be installed and annually certified by a certified professional. Laboratory Safety Division arranges the annual certification. BSCs that have been moved must be recertified before use. Contact the Laboratory Safety Division to arrange recertification.

B. Classes of Biosafety Cabinet

1. **Class I BSCs** -These offer HEPA-filtered exhaust air. However, the supply air is not HEPA-filtered ("dirty room air" is drawn inside). This offers minimal protection to the user's hands, arms, and vulnerable research materials inside the BSC. The Class I BSC is designed for general microbiological research with low- and moderate-risk agents (Biosafety Level 1 and 2 agents). In addition, the class I BSC is useful for the containment of mixers, blenders and other equipment. Class I BSC's are not routinely made.

2. **Class II BSCs** - There are different types of Class II BSCs, but they all offer HEPA-filtered supply and exhaust air. This BSC protects the user, environment and research materials and is suitable for work with moderate- to high-risk agents (Biosafety Level 2 and 3 agents). Class II BSCs are the most commonly used.

    a. **Class II Type A1 BSC:** Type A1 cabinets were previously called Type A. This type of BSC recirculates 70% of the air and exhausts 30%. It has a positive pressure plenum.

    b. **Class II Type A2 BSC:** Type A2 cabinets resemble the Type A1, but the positive pressure plenum is surrounded by negative pressure plenum. This cabinet was previously known as the Type B3. It can be connected to building exhaust with a thimble unit. Due to 2014 NSF/ANSI standards all A2 cabinets need to have an exhaust flow alarm.

    c. **Class II Type B1 BSC:** Type B1 cabinets are hard-ducted to an external exhaust system. The Type B1 recirculates 30% of the air and exhausts 70%. The cabinet has a positive pressure plenum with all contaminated air contained within a negative pressure plenum. The supply blower is interlocked to prevent it from operating when the exhaust is insufficient. Emergency power can be connected to the exhaust blower to prevent the blower from shutting down.

    d. **Class II Type B2 BSC:** Type B2 cabinets are total exhaust cabinets. Its blower is interlocked. Contaminated air is contained in positive pressure plenums enclosed in a negative pressure plenum. This is the only BSC in which small amounts of toxic chemicals, volatiles, and radionuclides (may need charcoal filters) may be used.

3. **Class III BSCs** - Often referred to as "glove boxes," these gas-tight BSCs are under negative pressure. All work in the cabinet is done through rubber gloves attached to entry portals. The exhaust is double HEPA filtered and/or incinerated. Materials must enter through a sealed airlock and exit through an autoclave or dunk tank. Class III BSCs offer the highest level of protection and are suitable for work with extremely high-risk agents (Biosafety Level 4).

4. Laminar flow clean air stations, laminar flow benches, aseptic workstations, or horizontal/vertical flow benches function differently from BSC's. They deliver HEPA filtered air across a bench top, providing product protection. They can be used with sterile equipment and for the assembly of equipment and preparation of sterile media. The air blows towards the worker. This can cause exposure to workers if improperly used with infectious materials. Reverse-flow cabinets of this type pull air from the front of cabinet through a pre-filter and HEPA filter at the rear. It can be used for cage changes, but PPE must be worn. These cabinets are not for work with biohazards since there is no containment.

C. Correct Techniques for Working in a Biosafety Cabinet

- Ensure the BSC sash is at the correct height.
- Always enter straight into the cabinet with no sweeping motions.
- Place materials well within the cabinet.
- Place the discard pan within cabinet.
- Watch for disruptions of the laminar flow.
- Decontaminate items and gloved hands before removal from the cabinet.
- Protect vacuum lines with HEPA filters or traps.

D. Compressed Gas Cylinders

Compressed gas cylinders can present a dual hazard in the laboratory because the contents are under pressure and may contain hazardous materials, such as flammables, corrosives or toxics.

Follow these guidelines for proper use of compressed gas cylinders:

1. Empty or full compressed gas cylinders must be chained in place or otherwise secured at all times.
2. Cylinder caps must be in place except when the cylinder is in use.
3. Do not transport gas cylinders without the cylinder cap in place and on an appropriate dolly with a securing strap.
4. Cylinder and delivery valves must be closed when not in use (especially true for toxic, flammable or corrosive gases).
5. Highly toxic, corrosive, and reactive gases present greater degrees of hazard. Work with these gases might require special containment, PPE, ventilation, piping or alarm systems. Prior to ordering or working with these types of gases, contact Laboratory Safety and EHSRM for a risk assessment and determination of requirements.
6. Liquid nitrogen or any other liquefied gas can present additional hazards for handling and storage. Details on proper handling and storage can be found in the Chemical Safety Plan.

E. Centrifuges

Improper centrifuge use can result in the generation and release of hazardous aerosols. Centrifuges present a contamination problem when tubes break and the contents are released.

Follow these guidelines for proper centrifuge use:

1. Make sure the lid is on and secured before operating the centrifuge. The lid must remain secured until the centrifuge has come to a complete stop.
2. Always balance the load in the centrifuge. If you are not filling the entire centrifuge rack, position the tubes opposite one another. If you have an odd number of samples, use an empty tube with enough water to be of equivalent weight.

3. If vibration occurs, stop the centrifuge and check the load balances. Never operate an unbalanced centrifuge. This could result in breaking the centrifuge tube(s) and generating hazardous aerosols. Also, unbalanced rotors have the potential to become projectiles.
4. Keep the rotors and buckets clean, and promptly clean up breakages or spills.
5. Ensure that the proper rotor is used for the centrifuge and the conditions of centrifugation.

F. Refrigerators

Follow these guidelines for proper laboratory refrigerator use:

1. Never place food or beverages in a refrigerator where biohazardous materials are stored.
2. Refrigerators containing biohazardous materials must be labeled "Biohazard" with the appropriate biohazard symbol in black on an orange-red background.
3. Never store Dry Ice in a refrigerator.

VIII. BIOLOGICAL AGENTS AND BIOHAZARDOUS MATERIAL

A. Biological Agent Classification

Biological agent classification is determined through risk assessment. This risk assessment considers features of the microorganisms as well as host and environmental factors that influence the potential for individuals to have a biohazard exposure.

B. Risk Groups

The National Institutes of Health (NIH) has classified four Risk Categories (summarized below). In cases where the hazard is unknown, a higher risk level will be applied.

Risk Group	Agent
Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans.
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available (high individual risk, but low community risk).
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available (high individual risk and high community risk).

C. Biosafety Levels

The 5th edition of the BMBL (Biosafety in Microbiological and Biomedical Laboratories) defines the 4 Biosafety Levels (BSL) through a combination of laboratory practices and techniques, safety equipment, laboratory facilities and engineering controls. Each combination is specifically appropriate for the risk group classification, laboratory operations, documented or suspected routes of transmission of the infectious agents, and for the function or activity. The recommended BSL for an organism represents the conditions under which the agent can be ordinarily handled safely. When specific information is available to suggest that virulence, pathogenicity,

antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered; more or less stringent practices may be specified by the BSO or IBC. Below is a summary of the recommended biosafety levels for infectious agents.

It is important to note that the Risk Group and the Biosafety Level are not automatically the same (for example something may be categorized as a Risk Group 3 but a Biosafety Level 2).

Biosafety Level (BSL)	Requirements/Special Practices	Facility Requirements
Biosafety Level 1 (BSL-1): Involves agents not known to cause disease in healthy adults. This is the level of operation for most UTSA teaching laboratories. Few special precautions are necessary when working at this level.	• Standard Microbiological Practices. • Limited or restricted access to the laboratory when work is in progress. • Biohazard warning signs must be in place. ▪ No eating, drinking or smoking in laboratory. • No mouth pipetting. • Hands must be washed after handling viable materials and when leaving the laboratory. • Efforts to minimize splashes and aerosols must be made. • Work surfaces must be decontaminated daily and immediately after spills. • Wastes must be decontaminated. • An insect and rodent control program must be maintained. • Personal protective equipment will be required at the discretion of the laboratory supervisor. • No Special Practices Required	• Doors for the laboratory, hand washing sink available, work surfaces made from easily cleanable material, bench tops made from material impervious to water, sturdy furniture, and any windows are fitted with fly screens. • No special Facilities are required
Biosafety Level 2 (BSL-2): Involves agents that are known to cause disease in humans. The diseases are not known to result in major illnesses in healthy adults. Some precautions are necessary when working at this level. Gloves must be worn and laboratory coats are strongly suggested. Any work that can result in the creation of bio-aerosols should be carried out in the appropriate Biological Safety Cabinet (BSC), and goggles should be worn as a protective barrier for the eyes.	All BSL-1 Practices Plus: • Use of Class II Biosafety Cabinets (BSC) for work with infectious agents involving aerosols and splashes, large volumes or high concentrations. • ***Special Practices:*** • Policies and procedures must be in place for workers to gain entry. • Laboratory specific biosafety manual must be written by the PI or laboratory supervisor. • Training, including annual updates, must be provided for laboratory specific issues and SOP's. • Leak-proof transport containers are necessary. • Immunizations against agents being worked with must be available to laboratory staff. • Baseline serum samples should be banked. • Work surfaces must be decontaminated. • Spills and accidents must be reported. • No animals or plants allowed unless they are part of the research. • Sharps precautions must be followed to include disposal of sharps in a sharps container, no recapping, bending, breaking	• Adequate illumination. • Eyewash inside the laboratory. • Laboratory pressure negative to the hallway. • Air from the laboratory cannot be re-circulated within the building. • The door must be lockable to limit access when work is in progress. • Autoclave must be available, and the lab must be separated from public areas of the building.

Biosafety Level (BSL)	Requirements/Special Practices	Facility Requirements
	or reusing needles or syringes and never use your hands to pick up broken glass.	
Biosafety Level 3 (BSL-3): Involves agents that are known to cause disease through aerosol infection. These diseases are usually not communicable, but can result in serious illness. They have a high morbidity rate, but the mortality rate is not high. There may be treatment available for some BSL-3 agent infections.	All BSL-1 and/or BSL-2 Practices Plus: • All manipulations of infectious agents must be carried out inside a class II or III BSC. • Personal Protective Equipment for BSL-1 and BSL-2 and respiratory protective equipment as indicated by agent(s) in question. ***Special Practices*** BSL-2 Practices Plus: • When carrying out bio-aerosol forming procedures, bio-aerosol containing equipment must be used. • All spills must be promptly decontaminated.	All requirements for BSL-1 and BSL-2 Plus: • The laboratory should be in a separate building or in an isolated zone. Double door entry into the laboratory. • Single pass air with 10-12 air changes per hour. Room penetrations must be sealed. Walls, floors and ceilings must be water resistant. • Vacuum lines must be protected by traps or HEPA filters.
Biosafety Level 4 (BSL-4): Involves agents that cause serious diseases which have high mortality rates and for which there is no known cure. There are very few laboratories in the U.S. that operate at this level. UTSA does not have a laboratory of this type.	All BSL-1, 2 and 3 Plus: • A Class A positive pressure suit must be worn for entry into the laboratory. ***Special Practices:*** BSL-3 Plus: • All liquid effluent and solid waste must be decontaminated prior to disposal. • Personnel must enter through a changing room and must change into laboratory clothes to wear underneath the positive pressure suit. • Supplies must enter the laboratory through double door autoclaves or fumigation chambers.	All requirements for BSL-1, 2 and 3 Plus: • A dedicated supply, exhaust, vacuum and decontamination system. • Double door autoclaves. • The walls, ceilings and floors must be sealed. • The doors must be interlocked. • Communication system between the laboratory and the outside is needed. • There must be emergency breathing air available at all times. • An emergency generator and an emergency exit.

D. Vertebrate (Animal) Biosafety Level

The 5th edition of the BMBL provides a complete description of the four animal biosafety levels (ABSLs). The levels are combinations of practices, safety equipment and facilities for experiments on animals infected with agents that produce or may produce human infection. Below is a summary of the recommended animal biosafety levels for infectious agents.

Animal Biosafety Level (ABSL)	Requirements/Special Practices	Facility Requirements
Animal Biosafety Level 1 (ABSL-1): Suitable for work involving well-characterized agents that are not known to cause disease in healthy adult humans, and that are of minimal potential hazard to laboratory personnel and the environment.	Mimics BSL-1 except for facility requirements.	• Must have self-closing and lockable doors. • The interior surfaces must be water resistant. • Windows are not recommended. • The floor drain traps must be filled with water and disinfectant. • The air cannot be re-circulated. • The laboratory air pressure must be negative to the hallway.
Animal Biosafety Level 2 (ABSL-2):	Mimics BSL-2 except for facility requirement additions.	ABSL-1 Plus: • Must have a mechanical cage washer capable of operating at 180°F.

Animal Biosafety Level (ABSL)	Requirements/Special Practices	Facility Requirements
Involves practices for work with those agents associated with human disease. It addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1.		• Autoclave must be available within the facility. • Hand washing sink must be in the room.
Animal Biosafety Level 3 (ABSL-3): Involves practices suitable for work with animals infected with indigenous or exotic agents that present the potential of aerosol transmission and of causing serious or potentially lethal disease. ABSL-3 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-2.	Mimics BSL-3 except for facility requirement additions.	ABSL-2 Plus: • Laboratories must be physically separated from access corridors, with self-closing double-door access, preferably interlocked or alarmed, and windows and penetrations must be sealed.
Animal Biosafety Level 4 (ABSL-4): Involves practices suitable for addressing dangerous or exotic agents that pose high risk of life threatening disease, aerosol transmission or related agents with unknown risk of transmission. ABSL-4 builds upon the standard practices, procedures, containment equipment and facility requirements of ABSL-3. Procedures must be developed locally to address specific operations of the Class III cabinet line or the suit laboratory.	Mimics BSL-4 except for facility requirement additions.	ABSL-3 Plus: • Should have two workers in the laboratory when working with infected animals, and the cages must be autoclaved or decontaminated before being cleaned.

E. Plant Biosafety Levels

Biosafety levels for plants are defined in Appendix P of the NIH Guidelines. The requirements for practices and facilities are divided into Greenhouse Access levels (BL1-4-P) and standard laboratory plant biosafety levels (BL1-4-P).

Greenhouse Access Levels (GAL)	Plant Biosafety Levels (BL-P)
Greenhouse Access Level 1 (BL1-P) is a standard greenhouse with open windows and gravel walks permitted.	**Standard Laboratory Plant Biosafety Level 1 (BL1-P):** • Has limited access. • An entry log is maintained. • A standard procedures manual must be used. • Experimental organisms must be inactivated. • Pest, rodent and weed control program must be in place.

Greenhouse Access Level 2 (BL2-P) is GAL-1 (BL1-P) plus screens over the openings and an autoclave available.	**Standard Laboratory Plant Biosafety Level 2 (BL2-P) is BL1-P plus biohazard signs in place where applicable:** • Cages for small animals. • Procedures to minimize the escape of motile organisms.
Greenhouse Access Level 3 (BL3-P) is: • GAL-2 (BL2-P) plus an anteroom or head house • Impervious bench tops and work surfaces. An autoclave inside the facility • An independent air supply with negative pressure • The exhaust must have a HEPA filter. • A security fence or an equivalent form of security is present.	**Standard Laboratory Plant Biosafety Level 3 (BL3-P) is:** • BL2-P plus access restricted to trained workers • Equipment and supplies must be decontaminated, • Biohazards signs in place, • Efforts to minimize the formation of aerosols must be made, • The surfaces of secondary containers used to take live organisms out of the laboratory must be decontaminated. • A written record of accidents must maintained. • Special clothing must be worn in the laboratory and the clothing must be decontaminated prior to laundering.
Greenhouse Access Level 4 (BL4-P) is: • GAL-3 (BL3-P) plus the area is accessed through an airlock. • There is a shower facility at all entrances. • A dunk tank or fumigation chamber.	**Standard Laboratory Plant Biosafety Level 4 (BL4-P) is:** • BL3-P plus an entry/exit log. • Must be strictly maintained. • Personnel must shower and change into special clothing upon entry and exit. • All experimental materials and clothing must be decontaminated prior to removal. • All accidents must be reported immediately.

F. Large Scale Work and Biosafety Levels

Large scale work with infectious agents is defined as any work involving ten liters, or more, in a single container. Prior to conducting large scale work at UTSA the BSO must be consulted and approval received from the IBC. Large scale work will potentially alter the Biosafety Level at which work can be conducted.

G. Human blood, blood products, body fluids and tissues

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UNIVERSAL PRECAUTIONS

Universal Precautions is the concept of treating all human / primate blood and body fluids, tissues and cells (including cell lines) as if they are known to be infected with bloodborne pathogens

Work with materials known or suspected to contain Bloodborne Pathogens (BBP's) is regulated by both the federal and state governments. OSHA regulates work with BBP's through 29 CFR 1910.1030, the Bloodborne Pathogens Rule which became final in December 1991. In the state of Texas, the Texas Department of State Health Services regulates work through 25 TAC Part 1 Chapter 96, Bloodborne Pathogen Control, which became final September 1, 2000. The regulation mandates a combination of engineering and work practice controls, annual training and Hepatitis B vaccination.

Disposal of waste which contains or could contain BBP's is regulated by the Texas Commission on Environmental Quality through 30 TAC Chapter 330, 1201-1221, the Regulated Medical Waste Rule.

Both the federal and state regulations require annual training on BBP's and a BBP Exposure Control Plan. UTSA's Bloodborne Pathogens Exposure Control Plan can be found at the EHSRM website http://utsa.edu/safety/#/safetymanuals.

H. Signage

Laboratories working with biohazardous materials must have door signage indicating these materials are used in the room. Laboratories working with BSL-2 and BSL-3 agents must have a sign indicating the specific agents used and any special precautions for entering as well as the biohazard symbol. Freezers, refrigerators and any equipment where agents are used/stored must be labeled with the biohazard symbol. The Biosafety Officer Laboratory Safety Division Personnel will provide and post the signs and labels for the lab.

IX. RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS

The use of recombinant DNA (rDNA) and synthetic nucleic acids (sNA) are regulated by the National Institutes of Health (NIH); the guidelines can be found in the publication *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) (OBA – NIH Guidelines) (http://osp.od.nih.gov/office-biotechnologyactivities/biosafety/nih-guidelines). These guidelines are the official guide to all rDNA and sNA work done at UTSA. It is important to realize that following these guidelines is the responsibility of all investigators at UTSA and not solely that of investigators that are funded by NIH.

Before experiments involving recombinant or synthetic nucleic acids can begin, the P.I. must submit an IBC Application http://research.utsa.edu/research-funding/institutional-biosafety-committee-ibcnew/ .

All recombinant and synthetic nucleic acid protocols require the P.I. to make an initial determination of the required level of physical and biological containment and the applicable area of the guidelines (the Biosafety Officer can assist with this if needed).

NIH specifies six categories of experiments addressing recombinant nucleic acid research that are summarized below:

NIH Section	Description
III-A	Includes experiments involving human gene transfer. These experiments cannot be initiated without submission of relevant information to the Office of Science Policy at the NIH. In addition, the proposal has to be published in the Federal Register for 15 days, be reviewed by the Recombinant DNA Advisory Committee (RAC) and specific approval obtained from NIH. The containment conditions will be specified by the NIH based on the RAC recommendations. IBC approval must be obtained before initiation.
III-B	The research cannot be initiated without submission of relevant information on the proposed experiment to NIH/OSP (For exceptions see the NIH guidelines). Experiments covered in III-B include the cloning of toxic molecules. The containment conditions for such experiments will be determined by NIH/OSP in consultation with *ad hoc* experts. Such experiments require IBC approval before initiation. Please refer to the guidelines for more specifics.
III-C	Covers experiments with human subjects. These experiments require IBC and IRB (Institutional Review Board) approval and NIH/OSP registration before initiation.

III-D	Covers whole animal or plant experiments as well as projects involving DNA from Risk Group 2, 3 or 4 agents. Prior to the initiation of an experiment that falls into Section III-D, the P.I. must submit an IBC Biosafety Application to the Institutional Biosafety Committee. The IBC reviews and approves all experiments in this category prior to their initiation.
III-E	Experiments require that the filing of an IBC Biosafety Application with the IBC at the time the experiment is initiated. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiment is not required.
III-F	Experiments that are exempt from the NIH Guidelines but a UTSA IBC protocol is required.

A. Viral Vectors and Transgenes

All vectors are not the same. More importantly, the class of gene insert can change the biosafety level of the construct. It is also important to realize that obtaining a cloning/expression vector from a commercial source does not mean it is automatically exempt or a BSL-1. Some inserts such as oncogenes or toxins will raise the biosafety containment level of the viral vector as may certain envelopes. Summarized below are many of the more common viral vectors in combination with associated BSL levels.

Gene Transfer Vector	Host Range	Biosafety Level (Dependent on insert)
MMLV based – *gag, pol,* and *env* deleted	Ecotropic Amotropic, VSV-G pseudotyped	BSL-1, BSL-2, BSL-2+, BSL-3
Herpesvirus based - nonlytic	Broad host range	BSL-2, BSL-2+, BSL-3
Lentivirus based- HIV, SIV, EIAV, FIV etc - *gag, pol, env, nef* and *vpr* deleted	Ecotropic, amphotropic, VSV-G pseudotyped	BSL-2, BSL-2+, BSL-3
Adenovirus based – serotypes 2, 5 and 7; E1 and E3 or E4 deleted	Broad host range, infective for many cell types	BSL-2, BSL-2+, BSL-3
Alphavirus based – SFV, SIN	Broad host range	BSL-2, BSL-2+, BSL-3
Baculovirus based	Broad mammalian host cell range	BSL-1, BSL-2, BSL-2+ / BSL-3
AAV based – *rep, cap* defective	Broad host range, infective for many cell types including neurons	BSL-1, BSL-2, BSL-2+ / BSL-3
Poxvirus based – canarypox, *Vaccinia*	Broad host range	BSL-2, BSL-2+, BSL-3

For further guidance on recombinant AAV vectors please refer to IBC AAV policy http://research.utsa.edu/wp-content/uploads/2014/10/IBC_Policy_AAV-rAAV.pdf

B. Reporting Requirements for Incidents Involving Recombinant or Synthetic Nucleic Acids, Violations of the NIH Guidelines, or other Significant Research Related Accidents.

The NIH Guidelines state that any significant problems, violations of the NIH Guidelines, or any significant research related accidents, exposures and/or illnesses must be reported to the NIH Office of Biotechnology Activities (OBA). Spills or accidents in BSL-2 or BSL-3 laboratories that result in an overt exposure must be

reported to the Biosafety Officer (x8515) immediately. The Biosafety Officer will then contact NIH OBA immediately.

C. Reportable incidents

Any spill or accident involving recombinant or synthetic nucleic acid molecules that occurs in BSL-2 laboratories or higher, leads to a personal injury or illness or results in a breach of containment, must be reported to NIH OBA. Examples of such incidents are:

1. Skin punctures with needles containing recombinant or synthetic nucleic acid molecules
2. The escape or improper disposition of a transgenic animal
3. Spills of high risk recombinant or synthetic nucleic acids outside of a biosafety cabinet
4. Failure to adhere to containment requirements and appropriate biosafety practices as outlined in the NIH Guidelines must be reported to NIH OBA.

If there is any doubt about whether an incident should be reported please contact the Biosafety Officer at 210-458-8515.

D. Reporting Procedure at The University of Texas at San Antonio

1. Incidents that occur at UTSA that involve recombinant or synthetic nucleic acid molecules, incidents that result in an overt exposure to materials containing recombinant or synthetic nucleic acids or any risk group 2 agent in a BSL-2/ABSL-2 laboratory or higher must be reported to the Biosafety Officer.
2. The Biosafety Officer, in consultation with the IBC Chair, will work with the Principal Investigator to gather the details of the incident to determine if the incident needs to be reported to NIH OBA, and if deemed necessary, consult with NIH OBA to determine if the incident warrants a report.
3. If a report is deemed necessary, the Biosafety Officer will work with the Principal Investigator to complete the report. The report should contain sufficient information to explain the nature and consequences of the incident as well as the cause. The report should also include the measures that were taken to mitigate the problem and to prevent a similar incident from happening again. An incident reporting template and additional information is available from NIH OBA to facilitate the reporting process.
4. The Biosafety Officer shall inform the IBC and Institutional Official of the incident and provide a copy of the report for review.
5. NIH OBA may require other information be provided such as
    a. A copy of the IBC meeting minutes documenting approval of the relevant protocol for the research laboratory in which the incident occurred.
    b. A copy of the IBC minutes documenting that the incident was reviewed.
    c. Policies that were in place at the time the incident occurred.
    d. Revised policies or procedures that were prepared in response to the incident.
    e. Training records for the personnel who were involved in the incident.

6. The Biosafety Officer shall submit the written report to NIH OBA.

X. INSTITUTIONAL BIOSAFETY COMMITTEE

The UTSA Institutional Biosafety Committee is a registered committee with the National Institutes of Health. This Committee approves research protocols that involve infectious agents, recombinant DNA, and the use of tissue isolated from vertebrates. The IBC is composed of UTSA research faculty, representatives from the UTSA Office of Environmental Health, Safety and Risk Management, and community members outside the University. The committee meets the first Wednesday of each month. Research applications for IBC approval must be submitted by the 15th of the month prior to the monthly IBC meeting.

1. Committee Charge

The charge of the Committee is to formulate and implement procedures to assure the University's compliance with all federal regulations. The federal regulations are implemented for the construction, handling and disposal of recombinant molecules, organisms, viruses containing recombinant DNA molecules, other biologically hazardous organisms, and toxins at UTSA. The Committee reviews and exercises approval authority of all proposals for grants, contracts that involve recombinant DNA molecules, other biologically hazardous organisms, and toxins. They also monitor the use and maintain the required records of the review, approval, and disposal of all projects that involve recombinant DNA molecules, other biologically hazardous organisms, and toxins.

2. Application to IBC for Approval

The application for submitting research to the IBC for approval can be found online at the IBC website http://research.utsa.edu/research-funding/institutional-biosafety-committee-ibcnew/. Fill out only the portion of the application pertaining to your research. The application should be submitted by the 15th of the month for review at the next month's IBC meeting. For more information contact the IBC chair or the Institutional Biosafety Officer.

XI. SELECT AGENTS

A. General Information

The Federal Select Agent Program (FSAP) under the CDC and USDA Animal and Plant Health Inspection Services (APHIS) oversees the possession, use and transfer of specific pathogens and biological toxins viewed as posing a severe threat to public health and safety. The FSAP ensures worker safety and requires biosecurity measures to ensure that these "select agents and toxins" are not acquired by unauthorized personnel may misuse them.

The select agent and toxin regulations require that any entity, facility and personnel involved in possession, use or transfer of select agents and toxins be registered with the FSAP. This process includes, among other measures, Security Risk Assessments for all personnel; development and review of biosafety, biosecurity and incident response plans; and regular inspections by the CDC. Criminal penalties for non-compliance with the FSAP include up to 10 years in prison and/or $250,000 fine per individual per violation.

Entities registered with the FSAP must designate a Responsible Official (RO) who acts on behalf of the entity, ensures compliance with the FSAP requirements and serves as the main point of contact for all select agent

registration, reporting and compliance issues. One or more Alternate Responsible Officials (ARO) may also be designated to act in the RO's absence.

If you plan to work with select agents or toxins at UTSA, please contact the Biosafety Officer (210-458-8515) for further information.

B. Select Agent Toxins

1. **Permissible Amounts**

If the cumulative amount of a select toxin under the control of a P.I. and staff does not exceed a very small permissible amount set by the FSAP, the lab, personnel and facility are not required to register with the FSAP. Even in permissible amounts, select toxin use can pose biosafety and biosecurity concerns within a laboratory. The UTSA IBC requires a protocol for select toxins of any amount to ensure the proper biosafety and biosecurity measures are in place.

Permissible Toxin Amounts

Toxin	Amount
Abrin	1000mg
Botulinum neurotoxins	1mg
Short, paralytic alpha conotoxins	100mg
Diacetoxyscirpenol (DAS)	10,000mg
Ricin	1000mg
Saxitoxin	500mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D and E)	100mg
T-2 toxin	10,000mg
Tetrodotoxin	500mg

2. **Requirements for the Use and Storage of Select Agent Toxins under Permissible Amounts**

The safety standards relevant to use of biological toxins are described in the BMBL Appendix I. The IBC typically expects the following measures to be met:

a. BSL-2 Containment

b. Security measures ensuring restricted access to the toxins

c. Cumulative, up-to-date inventory

d. Toxin-specific SOPs

e. Toxin-specific training

3. **Inactivation of Select Agent Toxins**

Inactivation of select agent toxins must be performed and documented by authorized personnel before disposal or before the closure of a laboratory. Please contact the Biosafety Office for assistance. Approved methods for inactivation include:

Toxin	Disinfectant	Timing

Abrin	Autoclave	1hr, 121°C, liquid exhaust
Botulinum neurotoxins	>0.1% NaOCl	>30min
Short, paralytic alpha conotoxins	Glutaraldehyde	Contact Lab Safety
Diacetoxyscirpenol (DAS)	>1% NaOCl	>30min
Ricin	>1% NaOCl	>30min
Saxitoxin	>0.1% NaOCl	>30min
Staphylococcal Enterotoxins (Subtypes A, B, C, D and E)	>0.5% NaOCl	>30min
T-2 toxin	>2.5% NaOCl	>30min
Tetrodotoxin	>0.5% NaOCl	>30min

XII. DUAL USE RESEARCH OF CONCERN

Dual Use Research of Concern (DURC) refers to life sciences research involving 15 designated agents and toxins and 7 categories of experiments. These agents and experiments are viewed as reasonably likely to provide knowledge, information, products or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, plants, animals, the environment, military materials and equipment or national security.

Federal policies require institutions that receive U.S. Governmental funds to establish an Institutional Review Entity (IRE) to identify DURC and implement risk mitigation measures where applicable. At UTSA the IBC also acts as the IRE, in a separate convened meeting, to asses Dual Use Research. Further information on UTSA DURC policy is located at http://research.utsa.edu/research-funding/institutional-biosafety-committee-ibcnew/ .

A. Agents and Toxins Requiring DURC Review

1. Avian Influenza (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. *Variola major virus*
14. *Variola minor virus*
15. *Yersinia pestis*

B. 7 Categories of Experimental Effects of Concern

1. Enhance the harmful consequences of the agent or toxin

2. Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
3. Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that toxin or facilitate their ability to evade detection methodologies
4. Increase the stability, transmissibility or the ability to disseminate the agent or toxin
5. Alter the host range or tropism of the agent or toxin
6. Enhance the susceptibility of a host population to the agent or toxin
7. Generate or reconstitute an eradicated or extinct agent or toxin listed above

Requirements for working with these agents and can be found in the UTSA DURC policy.

XIII. DECONTAMINATION

Definitions:

1. **Sterilization:** A method that destroys all microbial life, including bacterial spores. Autoclaving (dry or steam) is one method of sterilization.

2. **Disinfection:** A method that reduces all forms of disease causing organisms on inanimate surfaces.

3. **Decontamination:** A method that reduces the numbers of organisms to acceptable levels.

4. **Antisepsis:** A method that reduces the number of organisms on living tissues.

Use of heat, radiation and chemicals are three decontamination methods that can be used for cleaning up biological spills, work areas, equipment or glassware. Heating involves dry or steam autoclaving which results in sterilization. Autoclaving may not be possible for all items. Autoclaves operate at high temperature and pressure these can present a physical hazard if not operated properly.

Follow these guidelines for proper autoclave use:

1. Users must be trained prior to operating any autoclave.

2. Ensure cycles are set correctly and completed for sterilization to be achieved.

3. Functionality tests must be performed periodically and recorded to confirm the autoclave is functioning properly.

4. Logs must be kept for each use of the autoclave.

Radiation in the form of ultraviolet light (UV) has limited effectiveness and should not be used as the only decontamination method.

Chemicals have varying degrees of effectiveness according to the biological agent involved. Phenolics are tuberculocidal, but present a physical and health hazard. Aldehydes are sterilants, but present a health hazard and have limitations on surfaces. Halogens such as chlorine and iodine are tuberculocidal, but present health hazards and are unstable. For example, bleach solutions must be made fresh daily. Alcohols have a low level of effectiveness on surfaces but, are tuberculocidal as a soak. Quaternary Ammonium Compounds have a low level of effectiveness. Peroxygen Compounds are high to intermediate level in effectiveness (sporocidal), but can be costly to use.

XIV. TRANSPORTATION AND SHIPPING

Biological agents fall into two categories for shipping:

- Category A – Infectious Substances (UN 2814 or UN 2900)
- Category B – Biological Substances (UN 3373)

There are various agencies and regulations to comply with when shipping. Entities involved in shipping include the USDA Animal and Plant Health and Inspection Service (APHIS), the Department of Transportation (DOT), the United States Postal Service (USPS), the Federal Aviation Administration (FAA), the International Air Transport Association (IATA), and the International Civil Aviation Organization (ICAO). Import/export permits are sometimes required, even within the US for specific agents. Specific shipping training with periodic re-training is required every 2 years for IATA member regulated air shipments and 3 years for DOT regulated ground shipments. Shipping without training can result in high fines and additional sanctions against the University.

1. Packaging and shipping biological agents requires a primary container with a positive seal surrounded by enough absorbent material to completely contain a spill. Secondary packaging which is watertight and leak proof holds the primary container. An outer container completes the packaging which must pass specific performance tests. Between the secondary and outer packaging, there must be a list of package contents with the shipper's label (including name, address and phone). The shipper's label must also be on the outer container.

XV. WASTE MANAGEMENT

For information on biological waste disposal, refer to the UTSA Biological Waste Management Plan found at: http://www.utsa.edu/safety/#/safetymanuals. All biological waste at UTSA is handled by EHSRM.

XVI. TRAINING

Training requirements may vary depending on the hazards in the workplace and individual research projects. Please contact the Laboratory Safety Division to establish which courses will be required for your facility. UTSA offers the following standard safety training for laboratory personnel.

Course Number	Title	Description
SA483	Researcher Biological Safety and Bloodborne Pathogens	This course is based on basic biological safety and bloodborne pathogens and is designed for persons working in biological research laboratories at UTSA. This course includes information about the regulations and what UTSA is doing to comply; principles/concepts of biosafety, agent classes including bloodborne pathogens, recombinant DNA and safety levels, procedures and equipment that prevent exposure including engineering controls and personal

		protective equipment; sharps precautions, and clean-up procedures. New Employees (including transfers) are required to attend this training prior to initial assignment to duties that place them at risk of exposure to infectious agents. Current employees working with rDNA or biological agents must attend.
SA483	Annual Refresher Researcher Biological Safety and Bloodborne Pathogens	This course is designed to meet mandated requirements for an annual training refresher.
SA443.01	Hazard Communication and Laboratory Safety	Hazard Communication training is mandated by both the federal and state governments. If you will be exposed to hazardous chemicals within your work area, you must attend Hazard Communication and Laboratory Safety training. Hazardous chemicals are defined as chemicals which have a physical or health effect.
SA401	Hazardous Waste Generator	Hazardous Waste Generator training covers chemical and biological waste disposal procedures in accordance with federal, state and local regulations. Generators must understand the requirements for proper bulking, packaging, labeling and disposal of hazardous waste.
SA465	Laser Safety Training	This course is required by the State of Texas for all persons at UTSA planning to work with high powered lasers (class 3b and above) prior to beginning work. The course is also recommended for laser users working with lower powered lasers (such as class 2 and 3a). This course covers general laser safety such as appropriate PPE, beam and non-beam hazards, accident avoidance and laser generated air contaminant hazards. This course also covers the basic required documentation and regulations for laser users.
SA433	Radiation Safety Training	This course is required by the State of Texas for all persons at UTSA planning to work with radioactive materials prior to beginning work. Contents include: radiation nature and hazards, safety techniques, monitoring, dosimetry, documentation, ordering, usage and disposal requirements, as well as employee rights and emergency procedures.

XVII. EMERGENCY PROCEDURES

Due to the multiple hazards associated with laboratories, incidents are inevitable. Preparedness for emergencies is essential. A timely and efficient response can help minimize or avoid injury and damage to property. For a comprehensive discussion of UTSA emergency procedures, including internal (fire, bomb threat) and external (tornado, flooding) emergencies, see UTSA's Emergency Response Guide. UTSA has implemented a new safety app, called LiveSafe, which has safety links, procedures, and resources during an emergency. You can learn more and how to download LiveSafe at this link.

A. Biological spills

Response to biological spills (i.e. blood, tissue and recombinant nucleic acids) must be thorough and prompt to prevent further injury or contamination.

Each laboratory should design its own response plan based on its unique hazards and the location of the laboratory, in conjunction with the following general guidelines:

1. Notify the people in the immediate area and, if necessary, evacuate the laboratory. The decision to evacuate is a judgment call based on the properties and hazards of the spilled biological agent. If biological aerosols result from the spill, evacuation should follow. Contact the Laboratory Safety Division immediately (if unavailable contact Campus Police at 210-458-4911 or non-emergency 210-458-4242); tell them to shut off air handlers to prevent the spread of hazardous aerosols if they have escaped from the laboratory's containment.

2. Always attend to injured people before attending to the spill. Skin areas splashed by biologicals should be rinsed with water for at least 15 minutes in a sink, emergency shower or eyewash as appropriate. After thorough rinsing, seek medical help. Be sure to have the identity of the biological agent and other information available for medical help.

3. Try to contain the spill to keep it from spreading. Contact the Laboratory Safety Division to advise or assist in the containment, disinfection, and cleanup of the spilled biological agent. Do not attempt to clean the spill without proper spill-control supplies or equipment.

4. If the spill or release is likely to affect other facilities within the building or campus, contact the UTSA Police Department. UTSAPD can be reached in an emergency at X911 on a campus phone and 458-4911 on an outside phone, such as a cell phone.

B. Emergency Equipment

Laboratory emergency equipment includes emergency showers, eyewashes, and fire extinguishers. Staff in laboratories that do not have their own emergency shower and eyewash station should know where the closest one is located.

1. Showers

    a. An emergency shower is used to decontaminate someone who has been exposed to biological agents or chemicals.

    b. Remove clothing, jewelry, and shoes while standing under the shower. These items trap agents against the skin and will prevent proper cleaning if not removed.

    c. Remain under the shower for at least 15 minutes to ensure adequate flushing of exposed areas.

    d. Seek medical attention.

    e. If the shower does not have a drain, promptly clean up the water to prevent slip hazards adding the appropriate decontamination agent.

    f. Always keep the area under an emergency shower unobstructed.

2. Eyewashes

a. If biological agents are splashed into your eyes, locate the nearest eyewash station. Hold your top and bottom eyelids open, flush with water continuously for at least 15 minutes. Move the eye up, down and sideways to wash thoroughly between the eyeball and eyelids where agents could be trapped.

b. Seek medical attention.

c. Always flush your eyes immediately if biological agents are splashed into them. Immediate action may prevent an infection.

d. Continuous-flow eyewashes are preferred over the portable, squeeze-bottle type, whose disadvantages include an insufficient supply of water (not 15 minutes' worth), and easy contamination with microorganisms. Squeeze-bottle and non-plumbed eyewashes are not allowed at UTSA.

e. To ensure a clean supply of water in the eyewash, operate it weekly to flush out any impurities.

XVIII. LABORATORY DEACTIVATION AND EQUIPMENT DISPOSAL

A. Equipment Disposal Procedure: See Appendix II for details.

Equipment to be disposed of should be wiped down with an appropriate disinfectant solution such as a 10% bleach or a 70% ethanol solution.

Once the equipment has been cleaned, Laboratory Safety should be contacted to check the equipment. Laboratory Safety will place proper signage on it stating that it has been reviewed and is ready to be removed.

Laboratory personnel should then contact the Inventory and Surplus Department to have the equipment removed from the laboratory.

B. Laboratory Deactivation Procedure: See Appendix II for details.

The Laboratory Safety Division should be contacted before a laboratory deactivation begins. Pertinent personnel from Laboratory Safety will come to the laboratory to review what items need to be dealt with. For instance, laboratory safety personnel will review what areas and equipment need to cleaned due to possible biological or chemical contamination.

Radiation & Laser Safety Coordinator or other Laboratory Safety Division personnel will review for possible radiological contamination and determine what measures must be taken to deal with it. Chemical and biological wastes will also be reviewed by the appropriate personnel. Once areas and equipment have been properly cleaned using a disinfectant or appropriate solvent, Laboratory Safety personnel will need to review to determine if all cleaning has been done properly. Any equipment will be labeled as ready to move, repair, or for disposal. The area or laboratory itself will be labeled as appropriately decontaminated and ready for Housekeeping staff to do routine cleaning to prepare for its future occupants.

APPENDIX I – LIST OF SELECT AGENTS AND TOXINS

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 (1/12/2017)

HHS SELECT AGENTS AND TOXINS

Abrin
*Bacillus cereus Biovar anthracis**
Botulinum neurotoxins*
Botulinum neurotoxin producing species of Clostridium*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)1
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus 3
Ebola virus*
Francisella tularensis*
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus 3
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**
OVERLAP SELECT AGENTS AND TOXINS
*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus 3

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus3
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum 3
Mycoplasma mycoides 3
Newcastle disease virus 2, 3
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ)
SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycinicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

1. C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

2. A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

3. Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, West African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13

APPENDIX II – EQUIPMENT AND LABORATORY CLEAN OUT / CLEARANCE PROCEDURES

A. Equipment Clean Out / Clearance Procedure

Laboratory personnel need to ensure the equipment is cleaned of all biological, chemical, and radioactive materials when lab equipment goes out for repair or disposal. The Laboratory Safety Division and Environmental, Health, Safety and Risk Management (EHSRM) must certify equipment to be cleared of hazards prior to repair, shipping for repair, sending to surplus or disposing of equipment.

1. All equipment, including chemical fume hoods, must be cleaned/decontaminated to remove any hazardous materials or residue including chemicals, potentially infectious biological agents, and radioactive materials.

    - **For biological agents**: An appropriate tuberculocidal grade disinfectant such as 1-10% dilution of household bleach (5.25-6% sodium hypochlorite solution) applied for a contact time of 10-20 minutes should be used. Alternately, a commercially available detergent-disinfectant solution such as Dispatch®, Clorox Clean-up®, Lysol IC®, etc. may be used following manufacturer's instructions. Caution – most disinfectants are also corrosive – proper PPE should be worn (gloves & face shield or goggles) and metal surfaces especially should be rinsed with water and wiped down after application.

    - **For chemicals**: An appropriate solvent for the chemical residues which may be present should be used, followed by a detergent cleaning.

    - **For radioactive material areas**: Wipe tests shall be completed prior to an appropriate detergent solution wipe down. If wipe tests confirm areas of contamination, then all decontamination materials must be kept for radioactive waste disposal. If applicable, final wipe tests shall be conducted to verify proper decontamination. All wipe tests and survey locations must be documented.

2. Some equipment will need specialized cleaning/decontamination. For example, biological safety cabinets will need to be decontaminated with formaldehyde, vaporized hydrogen peroxide or other materials. Currently this type of decontamination is not done in-house. Contact the Laboratory Safety Division for more information.

3. Laboratory Safety Division must be contacted to remove any remaining waste biological agents or hazardous chemicals for disposal. Laboratory Safety Division is the contact for this service.

4. If radioactive materials were used in the equipment, then Radiation Safety Personnel (RSP) must be contacted to clear the area. Once complete, RSP will complete and sign the radiation portion of the equipment clearance tag.

5. For biological or chemical clearance of equipment, Laboratory Safety Division can be contacted to do the review and fill out the equipment clearance tag.

6. Once the equipment clearance tag has been signed and posted by pertinent Laboratory Safety Division personnel, the equipment can be repaired or removed from the lab for service, surplus, or disposal.

Visit http://utsa.edu/safety/ for additional information.

APPENDIX III – EMERGENCY PROCEDURES FOR BLOODBORNE PATHOGENS EXPOSURE

Emergency Procedures for Bloodborne Pathogens Exposure

A. If you are exposed to blood or body fluids:

1. Remove gloves.
2. Wash your hands and any contact areas immediately and for at least 15 seconds with soap and running water. If not available, use waterless hand sanitizer.
3. Rinse well.
4. Rinse areas such as your eyes, nose, or inside your mouth, if those areas were splashed or splattered with blood or body fluids. Rinse with water for at least 15-20 mins.
5. Dry your hands and contact areas by patting with paper towels.
6. Notify your supervisor.
7. Seek medical treatment within two hours of your exposure with a physician familiar with occupational medicine (contact the Workers Compensation Coordinator for appropriate paperwork and assistance with choosing a physician, or use the WCI Preferred Providers List Link).
8. Complete the Workers Compensation Insurance Packet.
9. Call EHSRM at extension 5250 to report the incident and for information about counseling and education related to your exposure.

B. If a spill or contamination to a work surface occurs:

1. Put on gloves and any other appropriate PPE.
2. Decontaminate work surface following spill kit instructions or use an appropriate disinfectant and allow a minimum of 15 minutes contact time.
3. Wipe up spillage with paper towels.
4. Use other appropriate equipment such as a brush, scooper, tongs, forceps and/or dust pan to pick up decontaminated material or broken glassware to prevent direct contact.
5. Dispose of used PPE and clean-up materials in appropriate biohazard container.
6. Report spills and contamination to your supervisor and EHSRM.
7. Submit Biological Waste Pick-up Request found on the EHSRM website.

Do not use, repair, or put back into service any equipment that was contaminated with blood or other potentially infectious materials (OPIM) until it has been appropriately decontaminated.

APPENDIX IV – UTSA CONTACT INFORMATION

Emergency: (UTSA Police) 210-458-4911

Non-Emergency: (UTSA Police) 210-458-4242

Office of Business Continuity and Emergency Management: 210-458-6851

- UTSA Emergency Response Guide: CLICK HERE
- LiveSafe App Download: CLICK HERE

Environmental Health Safety and Risk Management (EHSRM): 210-458-5250

Lab Safety Manager: 210-458-8515

- Exposure control (Academic and research settings), Chemical, Biological, Radiation, Laser Safety

Risk and Life Safety Manager: 210-458-4420

- Emergency response, Life Safety

Occupational Health Program (OHP): 210-458-5304

- Hepatitis B vaccination administration

Workers Compensation: 210-458-8178

- Exposure control (Non-academic settings)

Environmental and Construction Safety Manager: 210-458-5808

- Biological, Chemical Waste Management

Facilities Work Control: 210-458-4262

Visit http://utsa.edu/safety/ for additional information.