University of Texas at San Antonio

Office of Environmental Health, Safety and Risk Management

Biological Safety Plan

i. Review & Signature Page

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

Printed Name	Signature	Title	Date
J. Brian Moroney		Director, EHSRM	June 7, 2017
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Replaces: June 1, 2011
Next Review Due: June 2020

This plan was revised on June 7, 2016 and replaces the 6/1/2011 version. Changes to this plan have been highlighted in “gray” and major changes are summarized below.

Page	Section	Brief description
4	Overview and Purpose	Updated links to CDC and NIH.
5	Responsibilities	Updated links to Manuals and HOP policy.
6	Principal Investigators	“Lab Specific Training” was added to paragraph.
6	Broken Glass	Information on cleaning broken glass.
10	Recombinant DNA	Experiments requiring prior approval.
12 - 16	Biosafety Levels	Biosafety level tables
17	Application for IBC Approval	Updated link to IBC webpage
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40	List of Select Agents and Toxins	Updated list of Select Agents as of 1/12/2017
45	Appendix V update	UTSA Contact Numbers

ii. Table of Contents

I. Overview and Purpose

This plan was prepared by the Environmental Health Safety and Risk Management (EHSRM) office after review of pertinent federal and state regulatory requirements from the Occupational Health and Safety Administration (OSHA), the Texas Department of State Health Services, the Texas Commission on Environmental Quality (TCEQ) as well as guidelines required by the Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/biosafety/publications/bmbl5/index.htm and National Institutes of Health-*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines. 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. It 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 EHSRM.

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 which 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, with a minimum frequency of every 3 years for relevance and regulatory updates. The online version of this plan will be reviewed periodically for updates on the EHSRM

website at: http://www.utsa.edu/safety/#/laboratory/manuals. Questions can be addressed to the Laboratory Safety Manager who also serves as the Institutional Biosafety Officer through EHSRM at 458-6101.

IV. Responsibilities

A. Environmental Health Safety and Risk Management (EHSRM) will:

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 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://utsa.edu/hop/chapter9/).

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, bloodborne pathogens including recombinant or synthetic nucleic acids, 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. Maintain a biological waste disposal program.

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 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 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 EHSRM.

4. Develop and train laboratory personnel on safety procedures and protocols that are specific for their lab(s). For more information on Laboratory-Specific Training go here.

5. Advise EHSRM of any significant protocol changes and prior to bringing new biologically hazardous agents onto campus including recombinant or synthetic nucleic acids.

6. Report any exposures, spills, thefts or other incidents involving biological agents, including recombinant or synthetic nucleic acids, to EHSRM 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 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 EHSRM if necessary, including those involving recombinant or synthetic nucleic acids.

4. Report to the supervisor or EHSRM 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 or 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 recombinant DNA guidelines.

4. Serve as an avenue of appeal in case of dispute between EHSRM and the PI.

E. The Laboratory Safety Committee will:

1. Assist in reviewing new safety issues involving laboratories.

2. Review facility safety issues involving laboratories.

3. Review continuing safety issues involving laboratories.

V. Biological Laboratory Safety Plan

A. Biosafety

Safety is very important in biological laboratories due to the microscopic nature of many of the organisms being studied, the high concentrations involved, and the infectious nature of many organisms. History has shown that workers in laboratories working with microorganisms can become infected by the organisms they have been working with for years. Such incidents continue to occur. These infections are known as Laboratory Acquired Infections (LAI). LAI's may follow a route of infection different from that 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. Safety guidelines

1. No mouth pipetting: use only pipetting devices.

2. No food or drink stored or consumed in the laboratory.

3. 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.

4. Remove gloves before touching common use items.

5. 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 or used 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 NEEDLES. ONCE DISCARDED, ITEMS MUST NOT BE REMOVED FROM THE SHARPS CONTAINER.**

   - Never bend, shear, break, remove disposable syringes or otherwise manipulate by hand needles prior to disposal.

➢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.

6. Broken Glass

Clean up broken glass as soon as possible to prevent injuries. If broken glass is contaminated with a potentially biohazardous substance (recombinant or synthetic nucleic acids), 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.

7. 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 bioaerosols 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, operating a flow cytometer, working with a cryostat, or operating a cell sorter.

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

C. rDNA—Recombinant DNA

DNA in which one or more segments or genes have been inserted, either naturally or by laboratory manipulation, from a different molecule or from another part of the same molecule, resulting in a new genetic combination. Work with rDNA must be approved by the Institutional Biosafety Committee unless it is exempt under the NIH guidelines (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). A listing of exempt experiments is listed below. If you have consulted the NIH guidelines and the listing below and still have questions, contact the Institutional Biosafety Officer in EHSRM. Be aware that some experiments considered exempt by NIH will require a protocol submission to the UTSA IBC per UTSA policy.

1. Exempt experiments

    1. The rDNA is never going to be in an organism or virus.

    2. The rDNA is solely from a single non-chromosomal or viral source.

    3. The rDNA is solely from a prokaryotic host and propagated in the same host or transferred to another host by well established physiological means.

    4. The rDNA is from a eukaryotic host and is propagated in the same host.

    5. The rDNA is from a species that naturally exchanges DNA by known physiological processes. A list of species are available at the NIH website.

    6. The rDNA is of a type which does not present a significant risk to health or the environment, as determined by the NIH Director*.

    *The NIH has determined that rDNA from infectious agents of BSL-2 or above is not exempt and must receive IBC approval. Additionally, certain cloning vectors, such as Adeno or Sindbis based vectors, or amphotrophic Moloney Murine Leukemia Virus, LentiVirus (CRISPR) based vectors, are some examples that are non-exempt.

2. Experiments Requiring Prior Approval

    The following experiments require prior approval from the NIH, Recombinant DNA Advisory Committee (RAC), Food and Drug Administration (FDA), or the IBC or the IRB.

    1. Gene transfer experiments in humans.

2. Genes for toxins lethal for vertebrates.

3. Release of genetically engineered organisms to the environment.

4. Those using human or animal pathogens (biosafety level 2 and higher) as host-vector systems: including adenovirus vectors and murine retroviruses that infect human cells.

5. Cloning DNA from human or animal pathogens (biosafety level 2 and higher) into a non-pathogen host-vector system.

6. Cultures of more than 10 liters.

7. Experiments involving whole plants or animals, including transgenic organisms.

3. Experiments Requiring IBC Notice Simultaneous with Initiation

Some recombinant DNA work requires IBC review and approval, but prior approval is not required, and may be conducted at BSL-1 containment, i.e.

- Recombinant DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (with some restrictions) propagated and maintained in cells in tissue culture. It must be demonstrated that the cells lack helper virus for the specific families of defective viruses being used.

Some plant experiments do not require prior approval. Work with recombinant DNA in plants or any work with plant pathogens must also comply with USDA and EPA regulations.

D. Working with Potentially Infectious Agents

Infectious agents are viable microorganisms or their toxins, which cause or may cause disease in humans or animals. Examples of infectious agents include bacteria, viruses, fungi, parasites, and prions. Prions are infectious proteins.

Infectious agents are classified into four Risk Groups (RG) according to the severity of their effects on human health. Appendix I gives examples of agents in each risk group.

1. Risk Groups:

a. Risk Group 1- Agents that are not associated with disease in healthy adults.

b. Risk Group 2 – Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

c. Risk Group 3 – Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk, low community risk)

d. Risk Group 4 – Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

2. Biological Safety Levels:

Biological Safety Level (BSL) or Biosafety Level (BL) refers to the actions, precautions, or equipment needed to protect people and the environment from biological agents being worked with in the laboratory.

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**	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:***	• Adequate illumination. • Eyewash inside the laboratory. • Laboratory pressure negative to the hallway.

Biosafety Level (BSL)	Requirements/Special Practices	Facility Requirements
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.	• 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 or reusing needles or syringes and never use your hands to pick up broken glass.	• 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 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**	All BSL-1, 2 and 3 Plus: • A Class A positive pressure suit must be worn for entry into the laboratory. ***Special Practices:***	All requirements for BSL1, 2 and 3 Plus: • A dedicated supply, exhaust, vacuum and decontamination system. • Double door autoclaves.

Biosafety Level (BSL)	Requirements/Special Practices	Facility Requirements
cure. There are very few laboratories in the U.S. that operate at this level. UTSA does not have a laboratory of this type.	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.	• 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. • An emergency generator and an emergency exit.

3. Animal Biosafety Levels:
The recommendations detailed below describe four combinations of practices, safety equipment, and facilities for experiments with animals infected with agents that cause, or may cause, human infection. These four combinations, designated Animal Biosafety Levels (ABSL) 1-4, provide increasing levels of protection to personnel and to the environment, and are recommended as minimal standards for activities involving infected laboratory animals. The four ABSLs describe animal facilities and practices applicable to work with animals infected with agents assigned to Biosafety Levels 1-4, respectively.

Animal Biosafety Level (ABSL)	Requirements/Special Practices	Facility Requirements
Animal Biosafety Level 1 (ABSL-1): **Is 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): **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.**	Mimics BSL-2 except for facility requirement additions.	ABSL-1 Plus: • Must have a mechanical cage washer capable of operating at 180°F. • Autoclave must be available within the facility. • Hand washing sink must be in the room.

Animal Biosafety Level (ABSL)	Requirements/Special Practices	Facility Requirements
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.

4. There are also 4 biosafety levels for plants (BL1-4-P) listed 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 and 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.**

5. There are BSL's for large-scale work. Large scale work is defined as any work involving ten liters or more Prior to performing large scale work at UTSA, the Institutional Biosafety Officer must be consulted, and the IBC must approve the protocols.

E. Hazards of tissue culture—human and primate tissue:

Work with human and non-human primate tissues and cell lines must be carried out at BSL-2. These tissues and cell lines can harbor human pathogens that require precautions when working with them. They can also become contaminated with pathogens in the laboratory. Questions about individual cases should be addressed to the Biosafety Officer.

Tissue cultures from humans and other animals can contain infectious agents, such as oncogenic viruses. Precautions should always be taken when working with tissue culture.

Fixed tissue is less likely to contain infectious agents. However infectious agents such as prions can remain active after the fixation process.

F. IBC—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. For applications to be considered, they must be submitted by the 15th of the previous month.

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-ibcne/w

Only fill out the portion of the application pertaining to your research. The application should be submitted by the deadline posted on the IBC website for the meeting during which review is desired. For more information use the website to contact the IBC chair or the Institutional Biosafety Officer.

G. Bloodborne Pathogens Policies and Procedures

Laws and Regulations

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. 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 Institutional Biosafety Officer or EHSRM Laboratory Safety Division Personnel will provide and post the signs and labels for the lab.

I. Select Agents

Select agents are biological agents or toxins that could pose a severe threat to public health and safety; to animal or plant health/products. A current listing of select agents and toxins can be found at the CDC website under the Select Agent Program. The most current list at the time of this plan's update is available in Appendix III.

It is illegal to possess select agents without registration with the federal government. If you have any select agents which have not been registered, contact the Laboratory Safety Manager (LSM) immediately. If you plan to begin work with select agents, the application process should be started as early as possible. The process for approval for select agent work can take several months

and requires additional security clearance procedures as well as approval of the Responsible Official for the UTSA Select Agent Program. Contact the LSM as soon as possible to begin the process.

J. Decontamination methods

There are different levels of “decontamination”.

1. Sterilization is a method which destroys all microbial life, including bacterial spores. Autoclaving (dry or steam) is one method of sterilization.

2. Disinfection is a method which reduces all forms of disease causing organisms on inanimate surfaces.

3. Decontamination is a method which reduces the numbers of organisms to acceptable levels.

4. Antisepsis is a method which reduces the number of organisms on living tissues.

5. Use of heat, radiation, and chemicals are three decontamination methods which 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 some items therefore alternatives are needed. 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.

K. Transportation and Shipping

Biological agents being shipped, fall into two categories:

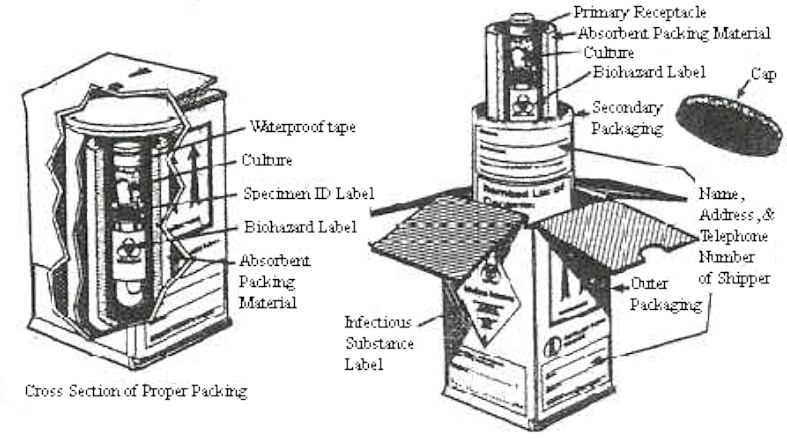
- Category A: Infectious Substances (UN 2814 or UN 2900).

- 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 for 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.

2. Example label and packaging for a category A – Infectious Substance



Cross Section of Proper Packing

VI. Personal protective equipment (PPE)

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/UV protection. Safety glasses with side shields provide adequate impact resistance with limited splash protection. Chemical splash goggles (with no perforations around the goggles) provide adequate impact resistance, splash protection, 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.

2. Wear chemical splash goggles for maximum protection, especially if you wear corrective lenses (glasses or contacts).

B. Hand protection

Gloves protect your skin from the biological agents you work with. Disposable latex/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 EHSRM 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 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 to launder.

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 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 initially and annually thereafter.

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 also disrupt the laminar flow of the air and can 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 Institutional Biosafety Officer.

BSCs must be installed and certified (annually) by a certified professional. EHSRM arranges the annual certification. BSCs which have been moved must be recertified before use. Contact EHSRM to arrange recertification.

1. Classes of BSCs

Class I BSCs -These offer HEPA-filtered exhaust air; however, the supply air is not HEPA-filtered ("dirty room air" 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, 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.

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.

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. Effective April 15, 2016 (NSF/ANSI 49) all Type A cabinets cannot be direct-connected or canopy connected without exhaust flow alarms.

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.

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 work stations, 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.

5. Proper techniques for working in BSC's:

   - Always enter straight into cabinet with no sweeping motions.
   - Work from "Clean to Dirty" side to prevent contamination.
   - Place materials well within cabinet.
   - Place the discard pan within cabinet.
   - Watch for disruptions of the laminar flow.
   - Decontaminate materials before removal from the cabinet.
   - Protect vacuum lines with HEPA filters or traps.

B. 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. They must be chained by the thickest part of the cylinder (2/3 of the height of the cylinder) not the cylinder collar.

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 an appropriate dolly with a securing strap.

4. Cylinder and delivery valves should 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 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.

C. 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 breakages or spills.

5. Ensure that the proper rotor is used for the centrifuge and the conditions of centrifugation.

6. If a tube breaks in the centrifuge, let it sit for 20 minutes so aerosols can settle before opening centrifuge to decontaminate.

D. 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.

E. Autoclaves

Autoclaves operate at high temperature and pressure. The autoclaves can also 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.

VIII. Waste management

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

IX. Training

Different training courses are needed based upon the hazards in the workplace. UTSA offers the following safety training for laboratory personnel:

Researcher Biological Safety and Bloodborne Pathogens (SA 483)	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.
Annual Refresher Researcher Biological Safety /Bloodborne Pathogens (SA 483r)	This course is designed to meet mandated requirements for an annual training refresher.

Hazard Communication and Laboratory Safety (SA 443.01)	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.
Hazardous Waste Generator (SA 401)	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.
Laser Safety Training (SA 465)	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, laser generated air contaminant hazards. This course also covers the basic required documentation and regulations for laser users.
Radiation Safety Training (SA 433)	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.

X. Emergency procedures and equipment

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 Plan.

A. Biological spills

Response to biological spills (i.e. blood, tissue, recombinant or synthetic 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 (i.e blood, tissue, recombinant or synthetic nucleic acids). If biological aerosols result from the spill, evacuation should follow. Contact EHSRM immediately (if unavailable contact Campus Police at 458-4911 or non-emergency 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 EHSRM 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

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

➢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.

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

➢Seek medical attention.

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

➢Always keep the area under an emergency shower unobstructed.

2. Eyewashes

➢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 behind the eyeball where agents could be trapped.

➢Seek medical attention.

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

➢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.

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

XI. Laboratory Deactivation and Equipment Disposal

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

Equipment to be disposed of (or surplused) 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, EHSRM should be contacted to check the equipment. EHSRM 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 III for details.

EHSRM should be contacted before a laboratory deactivation begins. Pertinent personnel from EHSRM will come by the

laboratory to review what items need to be dealt with. For instance, laboratory safety personnel will review what areas and equipment need to be cleaned due to possible biological (i.e. blood, tissue, recombinant or synthetic nucleic acids) or chemical contamination.

The Radiation Safety Officer (RSO), Radiation & Laser Safety Coordinator or other EHSRM 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, EHSRM 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.

XII. References

A. Chapter 502 of the Health and Safety Code. Texas Hazard Communication Act, Revised 1993. Texas Department of State Health Services, Division of Regulatory Services, Enforcement Unit.

B. Handbook of Laboratory Safety. Chemical Rubber Company, Third Edition, 1990.

C. Biosafety in Microbiological and Biomedical Laboratories. The Centers for Disease Control and Prevention and the National Institutes of Health, Fifth Edition, Revised December 2009.

1. Appendix A - Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.

D. Biological Safety in the Laboratory: A Guide for Biological Safety and Handling Biological Agents. The University of Texas Health Science Center at San Antonio, Department of Institutional Safety, 1995.

E. NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules. National Institutes of Health, April 2016.

F. American Biological Safety Association. Risk Group Classification for Infectious Agents.

XIII. Appendices

Appendix I Classification of Infectious Agents on the Basis of Hazard

Appendix II List of Select Agents and Toxins

Appendix III Equipment and Laboratory Clean out/Clearance Procedures

Appendix IV Emergency Procedures for Bloodborne Pathogen Exposure

Appendix V Contact Information

Appendix I. Classification of Infectious Agents by Hazard Group

Risk Group	Bacterial Agents	Fungal Agents	Parasitic Agents	Viral, Rickettsial, Chlamydial and other Agents
Risk Group 1	All bacterial, parasitic, fungal, viral, rickettsial and chlamydial agents not associated with disease in adults. Agents not included in higher classes are not by default in Risk Group 1.			
Risk Group 2	*K1 antigen *Acinetobacter calcoaceticus *Klebsiella-spp. Andserotypes *Actinobacillus-spp. *Legionella pneumophila *Aeromonas hydrofoil *Leptospira interrogans-spp *Arizona hinshawii-all serotypes *Listeria-spp. *Bacillus anthracis *Moraxella-spp. *Bordetella-spp. *Mycobacterium-spp. (except those listed in Risk Group 3)	*Actinomycetales (including Actinomyces spp. and Arachnia propionica) *Blastomyces dermatitdis *Cryptococcus neoformans *Paracoccidioides brasiliensis	*Entamoeba histolytica *Leishmania-spp. *Naegleria gruberi, *N. fowleri *Schistosoma mansoni *Toxoplasma gondii *Toxocara canis *Trichinella spiralis *Trypanosoma cruzi	*Adenoviruses, human—all types *Cache Valley virus *Corona viruses *Coxsackie A and B viruses *Cytomegaloviruses *Echoviruses—all types *Encephalormyocarditis virus (EMC) *Flanders virus *Hart Park virus *Hepatitis-associated antigen material *Herpesvirus - associated antigen material *Herpesviruses (except Herpesvirus simiae—Monkey B virus—which is Risk Group 4) *hTLV I/II *Human Immunodeficiency virus (except large volumes or high concentrations that require BL3) *Influenza viruses—all types except A/PR8/34, which is Risk Group 1 *Langat virus *Measles virus *Mumps virus *Parainfluenza viruses—all types except *Parainfluenza virus 4, SF 4 strain, which is Risk Group 1 *Polio viruses—all types, wild and attenuated *Pox viruses—all types, except Alastrim, Smallpox and Whitepox, which are forbidden; and Monkey pox, which, depending on the experiment, is Risk Group 3 or 4

	*Borrelia recurrentis, *B. vincentii *Neissaria gonorrhoea, *N. meningitides *Campylobacter fetus *Pasteurella-spp.(except those listed inRisk Group3) *Campylobacter jejuni *Salmonella-spp. and all serotypes *Chlamydia psittaci *Shigella-spp. and all serotypes *Chlamydia trachomatis *Sphaerophorus necrophorus *Clostridium botulinum *Staphylococcus aureus *Cl. chuvoei, *Streptobacillus moniliformis *Cl. haemolyticum, *Streptococcus pneumonia *Cl. histolyticum, *S. pyogenes			*Rabies virus—all strains except Rabies street virus, which is Risk Group 3 or 4 *Reoviruses — all types *Respiratory syncytial virus *Rhinoviruses—all types *Rochalimaea vinsonii *Rubella virus *Simian viruses—all types except Herpesvirus simiae (Monkey B virus) and Marburg virus, which are Risk Group 4 *Sindbis virus *Tensaw virus *Turlock virus *Vaccinia virus *Varicella virus *Vesicular stomtitis virus *Yellow fever virus, 17d vaccine strain

	*Cl. novyi, *Cl. septicum, *Cl. tetani *Treponema crateum *Corynebacterium diptheriae, *C. equi, *T. pallidum *C. haemolyticum, *C. pseudotuberculosis, *T. pertenue *C. pyogenes, *C. renale *V. parahaemolyticus *Edwardsiella tarda *Vibrio cholerae, *Erysipelothrix insidiosa *Yersinia enterocolitica *Escherichia coli—all entero pathogenic, entero toxigenic, entero invasive strains			

	*Haemophilus ducreyi, *H. influenzae *Mycoplasma-spp. (except Mycoplasma mycoides and M. agalactiae, which are forbidden).			
Risk Group	**Bacterial Agents**	**Fungal Agents**	**Parasitic Agents**	**Viral, Rickettsial, Chlamydial and other Agents**
Risk Group 3	*Bartonella -spp. *Brucella -spp. *Francisella tularensis *Mycobacterium avium complex. * M. bovis * M. tuberculosis *Pasteurella multocida type B ("buffalo" and other foreign virulent strains) *Yersinia pestis	*Coccidioides immitis *Histoplasma capsulatum *Histoplasma capsulatum var. duboisii	None	*Arboviruses—all strains except those in Risk Group 2 and 4 *Coxiella burnettii *Ehrlichia-spp. *Lymphocytic choriomeningitis virus (LMC) *Monkey pox virus, when used in vitro *Rabies street virus *Rickettsia-spp. (except R. ruminantium) *WestNile and Semliki Forrest viruses, depending on conditions of use and geographical location of the laboratory

				*Yellow fever virus, wild, when used in vitro *Most Prions such as Creutzfeldt-Jacob, BSE, Scrapie,and Kuru
Risk Group 4	None	None	None	*Ebola fever virus *Hemorrhagic fever agents, including Crimean hemorrhagic fever, Congo, Junin and Machupo viruses *Herpesvirus simiae (Monkey B virus) *Lassa fever virus (Mastomys natalensis) *Marburg virus (Cercopithecus spp.) *Monkey pox, when used for transmission or animal inoculation experiments *Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever and Central European encephalitis viruses *Venezuelan equine encephalitis virus—epidemic strains, when used for transmission or animal inoculation experiments *Yellow fever virus—wild, when used for transmission or animal inoculation experiments

Low-Risk Oncogenic Viruses		Moderate-Risk Oncogenic Viruses	
*AD7-SV40	*Adenovirus	*Ad2-SV40	*EBV
*Avian leukosis	*Bovine leukemia	*FeLV	*FeSV
*Bovine papilloma	*CELO	*GaLV	*HVateles
*Dog sarcoma	*Guinea pig herpes	*HV Saimiri	*SSV-1
*Hamster leukemia	*HTLV I/II	*Yaba	
*Lucke (frog)	*Marek's		
*Mason-Pfizer monkey virus	*Mouse mammary tumor		
*Murine leukemia	*Murine sarcoma		
*Polyoma	*Rat leukemia		
*Rat mammary tumor	*Rous sarcoma		
*Shope fibroma	*Shope papilloma		
*SV-40			

Appendix II. 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 $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[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 virus[3]
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 III. EQUIPMENT AND LABORATORY CLEAN OUT / CLEARANCE PROCEDURES

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. 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.

➢ 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 & faceshield 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.

➢ 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.

➢ EHSRM must be contacted to remove any remaining waste biological agents (blood, tissue, recombinant or synthetic nucleic acids) or hazardous chemicals for disposal. Environmental Safety Division is the contact for this service.

➢ 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.

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

➢ Once the equipment clearance tag has been signed and posted by pertinent EHSRM 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 IV. 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 20 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. These should be done 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 dustpan 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.

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

Appendix V. UTSA CONTACT INFORMATION

UTSA CONTACT INFORMATION

Emergency: (UTSA Police) 210-458-4911

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

Office of Business Continuity and Emergency Management: 210-458-6756

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

- General inquiries

Lab Safety Manager: 210-458-6101

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