



The University of Texas Health Science Center at Houston

Institutional Biosafety Manual

Including
Bloodborne Pathogens Exposure Control Plan and
Tuberculosis Exposure Control Plan

September 2020

PREFACE

The objective of UTHealth's Environmental Health and Safety Biological Safety Program is to assist all levels of management in fulfilling the commitment to furnish a place of employment and learning that is as free as possible from recognized biological hazards that cause or are likely to cause harm to visitors, personnel, or the surrounding community. It is vital that faculty, staff and students have sufficient information available to aid them in the safe conduct of their daily work activities relating to biological agents and recombinant and synthetic nucleic acid molecules.

The purpose of the Institutional Biosafety Manual is to assist both personnel and management in complying with the objectives of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition (December 2009), *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (April 2019), the OSHA Bloodborne Pathogens Standard (29 CFR Part 1910.1030), the Select Agent Program Regulations (42 CFR Part 73, HHS Final Rule; 7 CFR 331 and 9 CFR 121, USDA Final Rule) and UTHealth's health and safety policies. Many of the items in this manual are addressed in the annual Basic Laboratory and Bloodborne Pathogens Safety training sessions provided by Environmental Health and Safety.

This manual is not intended to be an exhaustive or fully comprehensive reference, rather a guide for principal investigators and other technically qualified individuals. Further advice concerning hazards associated with specific biological agents, recombinant or synthetic nucleic acid molecules, and the development of new or unfamiliar activities should be obtained through consultation with the Institutional Biosafety Committee and Environmental Health and Safety's Biological Safety Program.

All users of biological agents and recombinant or synthetic nucleic acid molecules must be familiar with the requirements set forth in this manual and applicable guideline of the CDC, NIH, and OSHA, and must conduct their operations in accordance with them.

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1.0 INTRODUCTION

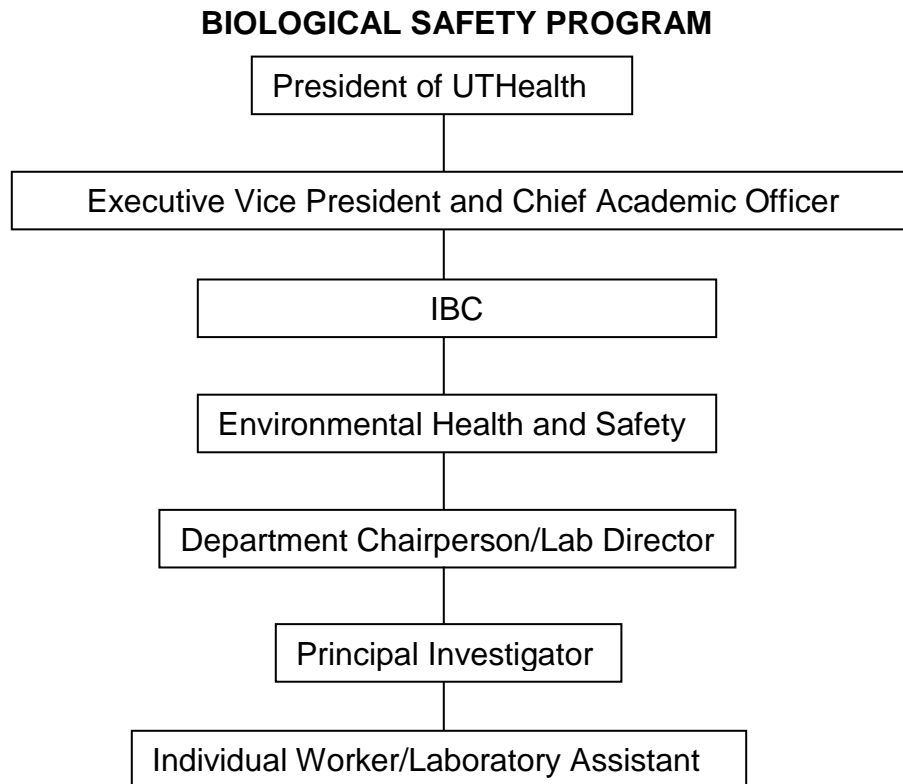
Any work performed at UTHealth involving agents of known or potential pathogenicity for humans, animals, or plants must be conducted in a manner that affords protection to workers, animals, and the surrounding community and environment. The Environmental Health and Safety Biological Safety Program at UTHealth was established to ensure that adequate administrative and operational protection measures are in place. The UTHealth Biological Safety Program, which consists of the Institutional Biosafety Committee (IBC), and Environmental Health and Safety (EH&S), provides this manual in order to outline the responsibilities of all parties involved in obtaining and using biological hazards, recombinant or synthetic nucleic acid molecules, or working in a patient care setting at UTHealth. The Biological Safety Program is also responsible for the following:

- State the training required by all individuals working with biological hazards.
- Advise all individuals working with hazardous biological agents of their rights and responsibilities under federal and state laws.
- Manage the Bloodborne Pathogens Exposure Control Plan and Tuberculosis Exposure Control Plan for UTHealth.
- Prescribe the use of medical surveillance and preventive procedures such as health histories and vaccinations.
- Provide the worker with a reference to assist in the safe handling of pathogenic agents.
- Provide information on zoonotic diseases transmissible from animal to man.
- Provide information on the proper treatment and disposal of wastes.
- State the steps to be taken in the case of spills or other emergencies.
- Provide guidance for the control and prevention of person-to-person or patient-to-healthcare worker infections in human clinical activities.

1.1 Organization/Policy

Whenever pathogenic agents are used at an institution, the safety of personnel and the general public becomes the primary consideration. The President of UTHealth has directed the development of a comprehensive Biological Safety Program with the Executive Vice President and Chief Academic Officer as the responsible administrator. The Institutional Biosafety Committee and EH&S are responsible for ensuring a quality Biological Safety Program for UTHealth. The Institutional Biosafety Committee (IBC) is authorized by the President to review and approve proposals and laboratory activities that utilize recombinant or synthetic nucleic acid molecules and biological hazards. EH&S is responsible for the daily Biological Safety Program's operations. The determination of an individuals' potential exposure to a biological hazard is conducted through the joint efforts of the UTHealth Employee/Student Health Services and EH&S. The organizational

structure of the Biological Safety Program is shown below. Each component of the organization is charged with specific responsibilities in order to achieve the best possible worker protection, while producing minimal interference with research and clinical activities.



Where unsafe practices involving the use of biological hazards or actions in violation of established guidelines are observed, EH&S has the authority to recommend suspension of the work until a thorough review can be made by the IBC. If the IBC, at any time, is not satisfied with the adequacy of the biological safety practices employed in a project, they may require all work involving the agent to be suspended until satisfactory procedures have been adopted.

1.2 Responsibilities

Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) reports to the Executive Vice President and Chief Academic Officer on matters related to the use of biological hazards and recombinant or synthetic nucleic acid molecules in research, clinical, and educational activities at UTHealth. Biological hazards are defined as potentially infectious microorganisms, human tissues, cells and body fluids, and agents carried by experimental animals that may pose significant disease or health risks to employees. EH&S is the monitoring and the enforcement arm of the IBC.

Specific committee charges include the following:

- To recommend to the Executive Vice President and Chief Academic Officer, policies and procedures to ensure the health and safety of all individuals within UTHealth, and to ensure compliance with all applicable federal, state and local statutes, regulations, and procedures and principles relating to the purchase, storage, use, and disposal of biological hazards and recombinant or synthetic nucleic acid molecules used in UTHealth research, clinical and educational programs.
- To review research protocols provided by principal investigators, clinical directors or laboratory instructors relating to the use of biological hazards and recombinant or synthetic nucleic acid molecules.
- To review EH&S determination of appropriate biosafety containment level of those laboratories, clinics and/or practices. All projects with recombinant or synthetic nucleic acid molecules must be reviewed by EH&S prior to initiation of work to ensure full committee approval by the IBC is obtained if necessary. Activities identified as Biosafety Level 2 and greater may not initiate without approval by the IBC.
- To recommend to the Executive Vice President and Chief Academic Officer, the need for general and specific training programs for research, clinical and teaching activities dealing with recombinant or synthetic nucleic acid molecules and biological agents, and to review the appropriateness and effectiveness of such UTHealth training programs.
- To submit reports at least annually, to the Executive Vice President and Chief Academic Officer, summarizing activities and reviewing the status of significant biological hazards and recombinant or synthetic nucleic acid molecules biological safety issues identified during the year.

Institutional Review Entity

The Institutional Biosafety Committee (IBC) serves as the Institutional Review Entity (IRE) and has the following responsibilities:

- Reviewing research projects that have been designated by the PI as potential DURC and conducting a risk assessment to determine if they are indeed DURC.
- Selecting *ad hoc* members for the IRE as necessary to be content experts during DURC review.
- Working with the PI to determine the benefits of the research and, in conjunction with the previously developed risk assessment, developing a risk mitigation plan for the research.
- Providing the draft risk mitigation plan to the USG funding agency and/or NIH within 90 calendar days of IRE determination of DURC.
- Ensuring implementation of the risk mitigation plan.
- Reviewing annually all active risk mitigation plans.

- Maintaining records of DURC reviews and risk mitigation plans for at least the term of the research grant/contract plus three years but not less than eight years.
- Providing education and training on DURC to research personnel.

Ensuring compliance with the policy among lab personnel. *The Infectious Diseases Review Panel*

The Infectious Diseases Review Panel (IDRP) is comprised of IBC committee members who have healthcare backgrounds. The IDRP seeks out expertise when necessary based on the case under review. The IDRP responsibilities include:

- Review instances of HIV, HBV, HCV or other bloodborne pathogens and TB and other serious infectious diseases in students, researchers, and health care workers, to identify exposure-prone procedures (below) and to determine those circumstances, if any, under which a student, researcher, or health care worker who is infected may perform such procedures. Exposure prone procedures (determined by the SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus, March 2010) include:
 - General surgery, including nephrectomy, small bowel resection, cholecystectomy, subtotal thyroidectomy other elective open abdominal surgery.
 - General oral surgery, including surgical extractions, hard and soft tissue biopsy (if more extensive and/or having difficult access for suturing), apicoectomy, root amputation, gingivectomy, periodontal curettage, mucogingival and osseous surgery, alveoplasty or alveoectomy, and endosseous implant surgery.
 - Cardiothoracic surgery, including valve replacement, coronary artery bypass grafting, other bypass surgery, heart transplantation, repair of congenital heart defects, thymectomy, and open-lung biopsy.
 - Open extensive head and neck surgery involving bones, including oncological procedures.
 - Neurosurgery, including craniotomy, other intracranial procedures, and open-spine surgery.
 - Non-elective procedures performed in the emergency department, including open resuscitation efforts, deep suturing to arrest hemorrhage, and internal cardiac massage.
 - Obstetrical/gynecological surgery, including cesarean delivery, hysterectomy, forceps delivery, episiotomy, cone biopsy, and ovarian cyst removal, and other transvaginal obstetrical and gynecological procedures involving hand-guided sharps.
 - Orthopedic procedures, including total knee arthroplasty, total hip arthroplasty, major joint replacement surgery, open spine surgery, and open pelvic surgery.
 - Extensive plastic surgery, including extensive cosmetic procedures (e.g., abdominoplasty and thoracoplasty).
 - Transplantation surgery (except skin and corneal transplantation).

- Trauma surgery, including open head injuries, facial and jaw fracture reductions, extensive soft-tissue trauma, and ophthalmic trauma.
 - Interactions with patients in situations during which the risk of the patient biting the physician is significant; for example, interactions with violent patients or patients experiencing an epileptic seizure.
 - Any open surgical procedure with a duration of more than 3 hours, probably necessitating glove change.
- To recommend to the Executive Vice President and Chief Academic Officer, infectious disease control policies and procedures to ensure the health and safety of all patients, staff and faculty of UTHealth.
 - To recommend to the Executive Vice President and Chief Academic Officer, policies and procedures to ensure UTHealth compliance with all federal, state, and local statutes, regulations, procedures and principles relating to TB, HIV, HBV, HCV, and other significant pathogens.
 - To identify tasks that carry the risk for transmission and the employees or occupational groups that are involved.
 - To review and contribute to the update of the Institutional Biosafety Manual, Bloodborne Pathogen Exposure Control Plan, and TB Exposure Control Plan annually, or as necessary.
 - To define and monitor compliance with the written plan and to monitor follow-up for those employees who test positive for any of the identified pathogens.

Any such events should be reported to the IDRP by contacting the chair of the IBC committee or EH&S Director.

Environmental Health and Safety Biological Safety Program

The Biological Safety Manager serves under the Assistant Vice President of Environmental Health and Safety. S/he manages the Biological Safety Program with the assistance of the technical staff and administrative staff.

The responsibilities of the Biological Safety Manager and EH&S include:

- Provide consulting services to any potential user of biological agents and provide advice on biological safety procedures.
- Ensure that all applicable regulations, standards and guidelines from the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Department of Transportation (DOT), Texas Commission on Environmental Quality (TCEQ), and the Texas Department of State Health Services (DSHS) are reasonably met.

- Review for concurrence/non-concurrence of all matriculations to use biological agents prior to being sent to the IBC.
- Provide general surveillance of all biological safety related activities, including providing assistance to all personnel in meeting their responsibilities.
- Assist in the receipt and shipment of all biological agents coming to or leaving the facility, including training of shipping regulations and packaging requirements.
- Instruct personnel in biological safety.
- Maintain a biological waste disposal program.
- Supervise decontamination activities in the event of accidental spills or leaks of biological hazards.
- Provide a program of environmental monitoring for contamination.
- Assist the IBC and the UTHealth Employee and Student Health Services in developing and reviewing an "exposure determination list," including the following:
 - A list of all job classifications in which *all* employees may have contact with blood or other potentially infectious materials on a routine basis
 - A list of job classifications in which *some* employees have potential occupational exposure
 - A list of all tasks and procedures or groups of closely related tasks and procedures in which the potential for occupational exposure exists and that are performed by employees in job classifications in which *some* employees have occupational exposure
- Investigate and evaluate the circumstances surrounding biological agent exposure incidents in conjunction with other relevant parties.
- Provide advice and assistance to Health Services in order to acquire personnel health histories, medical evaluations, vaccinations or other needed testing.
- Maintain centralized records pertinent to the Biological Safety Program.
- Develop and refine biological agent detection and identification methods and techniques.
- Administer the overall day-to-day operation of the Biological Safety Program at UTHealth.
- Serve as an ex-officio member of the IBC.
- Hire and train the staff of the EH&S Biological Safety Program.

- Provide and maintain information on biological agent protection, biological safety supplies and equipment, and applicable state and federal regulations and guidelines.
- Suspend any operation causing an excessive and/or unnecessary biological hazard as rapidly and as safely as possible, and subject the situation to expeditious resolution by the IBC.
- Develop a schedule for implementation of OSHA regulations governing exposure to bloodborne pathogens as described in Occupational Exposure to Bloodborne Pathogens (OSHA 29 CFR 1910.1030; see Appendix 3) and Texas Department of State Health Services equivalent regulation (25 TAC, Part 1, Chapter 96).
- Remain in compliance with the CDC Select Agent regulations as described in 42 CFR 73; and with other regulations as applicable.

Department Chairperson

The Chairperson is an integral part of the application process that each Principal Investigator must follow in order to obtain and use specified biological agents. The designated “Laboratory Director” is in charge of all activities involving the use of biological agents in his or her laboratories.

The responsibilities of the Department Chairperson or a designative representative are to:

- Ensure that staff members who desire to use known or suspected biological hazards contact EH&S for appropriate training and approvals, and also secure a copy of the Institutional Biosafety Manual.
- Have plans for all new buildings and modifications of existing structures where Biosafety Level 2 or higher work is to be performed, submitted for approval by the IBC through EH&S prior to construction or modification.
- Notify EH&S of any transfer of infectious agents to or from UTHealth.
- Have any areas where biological hazards were previously used be surveyed by EH&S before any modifications are performed.
- Inform EH&S of the final disposition of any biological hazards in the possession of a departing staff person.

Principal Investigator

The Principal Investigator (PI) is the individual who submits the application to employ biological agents in his or her work. This individual has the primary responsibility for adherence to all guidelines and regulations. The PI is also fully responsible for the safe

use of such agents by himself/herself and those under his or her direction. The PI must be a *faculty member and/or a full-time employee*.

Responsibilities of the PI:

- Limit personnel, student, employee, and visitor exposure to biological hazards to the lowest practical level.
- Provide for special safety considerations for any individuals under 18 years of age in the lab. (EH&S or UT Employee Health Services can be contacted for special instructions and extra precautions.)
- Select and apply the recommended biosafety level for the work to be conducted.
- Be familiar with the required medical surveillance for each type of infectious agent, and formally request these services for all exposed laboratory personnel.
- Develop laboratory safety procedures specific to that lab or protocol(s), placing a priority on engineering controls and work practice (e.g. biosafety cabinets and containment levels) to eliminate or minimize employee exposure.
- Personally train or arrange for the training of all employees and students within 10 days of employment with regard to the specific safety techniques and practices to be used in the laboratory. Each person's proficiency with these tasks must be demonstrated to the PI prior to working with any infectious agent. The PI is also responsible for verifying each person's continued proficiency in applicable biological safety practices.
- Arrangement and documentation for the training of students and employees regarding:
 - General procedures for lab personnel
 - Operating procedures for laboratory equipment
 - Emergency procedures
- Follow correct procedures for procurement of biological agents.
- Maintain accurate records reflecting the various agents that are used in the laboratory.
- Provide current posting and labeling of laboratories, stock materials, and associated equipment that may be contaminated.
- Prohibit eating, drinking, smoking, and the application of contacts or cosmetics in the lab.
- Forbid the storage of food and drink in areas where biological hazards agents are used.

- Require adherence to good laboratory work practices, including the minimization of aerosol formation and use of manual pipetting devices. Mouth pipetting shall be strictly forbidden.
- Provide for the safe transportation of any biological agent by using containers which prevent or contain leakage.
- Provide adequate personal protective equipment and instruction on its proper use.
- Ensure that biological wastes are properly prepared for disposal.
- Report immediately to laboratory supervisor and/or EH&S any hazardous spills, suspected exposures, theft of material, or other incidents regarding biosafety.
- Ensure that the workplace is maintained in a clean and sanitary condition.

Individual Worker

The individual worker is the person who deals with the biological agents on a regular basis. This is the person who should be most familiar with the potential hazards associated with the agent, as well as the requisite safety procedures.

Responsibilities of the individual include:

- Keep his or her exposure to the infectious agent as low as practical.
- Assist the PI in keeping all postings and labels of laboratories, materials, and equipment current.
- Follow good laboratory practices including regular hand washing, minimization of aerosol formation, and the use of manual pipetting devices. Mouth pipetting shall be strictly forbidden.
- Properly dispose of all infectious wastes and maintain accurate disposal records.
- Report immediately to EH&S all hazardous spills, suspected exposures, theft of material, and any other biological agent related accidents.
- Have a working knowledge of the emergency and decontamination procedures.
- Familiarization with the biological safety precautions in the specific areas of:
 - Procedures for lab personnel
 - Operating procedures for equipment

1.3 Training

Instruction concerning individual laboratory operating procedures and the development of a laboratory safety plan are the responsibility of the PI. Training regarding basic laboratory and bloodborne pathogens safety and refresher training is provided by EH&S. Basic laboratory and bloodborne pathogens safety initial and refresher training is required for all principle investigators as well as all staff in the laboratory. Several EH&S courses are offered during the calendar year and are available online through the Learn 2 Succeed platform. Specifics on any of these resources may be obtained by contacting EH&S at 713-500-8100 or visiting our website at <https://www.uth.edu/safety/index.htm>.

1.4 Application for Approval to Use Hazardous Biological Agents

The NIH has mandated that all organizations that come under NIH regulations have an Institutional Biosafety Committee (IBC). To ensure compliance with the various administrative control measures, UTHealth has established formalized procedures for obtaining approval to use recombinant or synthetic nucleic acid molecules and potentially infectious agents. PI's are required to develop protocols and ensure that laboratory safety procedures are followed in the workplace. Before the use of any biological agents or recombinant or synthetic nucleic acids can begin, an IBC approved protocol must be in place.

Use of Infectious Microorganisms: A completed Protocol Application (for application instructions see Appendix 2) must be submitted to the IBC for any planned work with recombinant or synthetic nucleic acid molecules or require Biosafety Level 2 (BSL-2) containment or greater. Applications must be approved by the IBC prior to introducing the organism into the workplace. Protocols can be submitted with a valid UT username and password, using the online protocol submission form found at the following link: <https://safety-assistant.uth.edu/EHSAQuestionnaire/EHSAWebisapi.dll?protocol=BIO>.

NIH Use of Recombinant or Synthetic Nucleic Acid Molecules: Molecules considered to be exempt (III-F) by the National Institutes of Health Department of Health and Human Services *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)* (see Appendix 3) are exempt from the *NIH Guidelines* and registration with the Institutional Biosafety Committee is not required. In contrast, the **use of "non-exempt" molecules** requires the submission of a protocol application to the IBC for review and approval. Studies in category III-A, III-B, III-C or III-D require committee approval before work is initiated. Studies in category III-E require committee notification by submitting a protocol application simultaneously with work initiation and must subsequently undergo full committee review. The Biological Safety Program is available to help classify your work with recombinant or synthetic nucleic acid molecules. For protocol application instructions see Appendix 2. Protocols can be submitted with a valid UT username and password, using the online protocol submission form found at the following link: <https://safety-assistant.uth.edu/EHSAQuestionnaire/EHSAWebisapi.dll?protocol=BIO>.

Use of Human Tissues and Body Fluids: An approved protocol is required for all work involving human and non-human primate tissues, body fluids, and cells. According to Appendix H of the CDC/NIH *Biosafety in Microbiological and Microbiological Laboratories, 5th Edition* (2009), the use of tissue, fluids, and cells of human and non-human primate origin should be conducted at the BSL-2 level due to the potential for bloodborne pathogen exposure. Also involved are the OSHA regulations governing exposure to bloodborne pathogens, which are described in Occupational Exposure to Bloodborne Pathogens (OSHA 29 CFR Part 1910.1030). State regulations governing bloodborne pathogens can be found in the Texas Department of State Health Services bloodborne pathogen control regulation (25 TAC, Part 1, Chapter 96).

Use of Experimental Animals: Laboratory animals may carry diseases which are infectious to humans and, therefore, safe work practices and laboratory procedures should be developed with the assistance of the Executive Director, Center for Laboratory Animal Medicine and Care for all projects that use animals. A protocol application must be submitted to the IBC for approval for the following types of work: **transplantation or injection of human tissues into animals, use of nonhuman primates, use of human and nonhuman primate tissues, use/creation of transgenic animals excluding transgenic rodents, except those that contain a transgene encoding more than fifty percent of an exogenous eukaryotic virus, and those in which the transgene is under the control of a gammaretroviral promoter , or the use of retroviruses and other infectious organisms from any species in animals**, along with appropriate approval from the Animal Welfare Committee.

Use of CDC/USDA Select Agents: Any work to be conducted with a listed CDC/USDA Select Agent must be approved by the IBC and one of the Responsible Officials within Environmental Health & Safety prior to acquiring or working with the select agent. The PI and EH&S must meet *prior* to work commencement to set-up and equip the laboratory to meet the requirements of the select agent regulations. A registration with the CDC or USDA is also required for select agent work prior to beginning any research projects. A list of select agents can be found in section 4.6 of the manual and on the [CDC Select Agent website](#).

Protocol Approval

All protocol applications are reviewed by the Biological Safety Manager or designated representative prior to being submitted to the IBC. In some instances, the Biosafety Manager or designated representative *is authorized to* grant temporary approval to a PI pending review and final approval by the IBC. Expedited review of an application can be granted by the Committee Chair of the IBC. Expedited review is not an option for work involving recombinant and synthetic nucleic acid molecules; however, accommodations will be made to review the protocol in a timely manner.

Approval of any proposed use of a biological agent will be based on the adequacy of the safety measures to be exercised. Three principle factors are considered by the IBC in evaluating the adequacy of the safety provisions in a proposed usage. First, the ability and experience of the applicant to work with the hazards involved in the application will be reviewed. Secondly, the adequacy of the facilities and equipment for containment of

the proposed usage will be verified. Third, the thoroughness and attention given to the safety precautions applied to the proposed experimental or clinical procedures.

The Committee may specify further recommendations for certain types of operations and particular projects. To assist in observing safety precautions and to assure that adequate measures of safety are being practiced, the IBC directs the EH&S to serve as a liaison between the Committee and the individual projects.

The approved protocol application and accompanying memorandum of understanding (MUA) are approved for a five-year period with annual review forms to document continuation of the approved work. Changes to the existing safety plans, experimental protocols, or personnel must be submitted via the online protocol system. An investigator may amend the protocol at any time. The proposed changes will be evaluated and approved by the committee if necessary.

2.0 GENERAL INFORMATION & PROCEDURES

2.1 Biological Agents Definition

A biological agent is considered to be a biological hazard if exposure may result in a real or potential risk to the well-being of humans, animals, or plants. Infectious agents include, but are not limited to conventional pathogens, non-exempt recombinant or synthetic nucleic acid molecules protocols involving pathogenic vectors, agents carried in human tissues, and inherent and experimental infections of laboratory animals.

2.2 Warning Signs and Postings

The universally accepted biological hazard warning symbol shall be used throughout the institution to notify workers about the presence of infectious agents. It is the responsibility of the PI and EH&S to ensure that all necessary postings are installed and properly maintained. The warning symbol must be removed when the hazardous agent is no longer in use or present.

The biohazard symbol on the postings should be orange or red in color with a contrasting background.



Figure 1: Biohazard Warning Symbol

As a general rule, the location of the posting is predicated by how access is gained to the area where biological hazards are used. In most cases, the door to any laboratory containing an infectious agent should have a biohazard warning symbol posted. In addition, postings should also be displayed in other areas such as biological safety cabinets, freezers, or other specially designated work and storage areas or equipment where potentially infectious agents are used or stored. All individual containers of biological agents should also be labeled to identify the content and any special precautionary measures that should be taken.

Universal biohazard labels must be affixed to containers of regulated waste, and refrigerators/ freezers containing blood or other infectious materials. Labels must be affixed to other containers used to store, transport, or ship blood/other potentially infectious materials. Acceptable color-coded (red or orange) bags or containers may be substituted for labeling requirement.

2.3 Infectious Agent Hazard Classification

Four risk groups of biological agents have been established by the Centers for Disease Control and Prevention (CDC)/National Institute of Health (NIH): Risk Group (RG) 1, 2, 3, and 4 with RG1 being the least hazardous.

RG1: Agents that are not associated with disease in healthy adult humans.

RG2: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

RG 3: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk). RG 3 agents are generally transmitted via aerosols.

RG4: 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). Currently, UTHealth does not have a facility to accommodate work with RG 4 agents.

The [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(April 2019\)](#) contain a broad list of agents classified by Risk Group. For additional information, also see [Biosafety in Microbiological and Biomedical Laboratories](#). The Biological Safety Program is also available to help classify the appropriate risk group for the agent with which you are working.

2.4 Biosafety Levels

Four biological safety levels have been designated in the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) document. The levels have been established based on the risk group of the infectious agent and the activities to be performed. Each biosafety level consists of a combination of facilities, prescribed laboratory procedures and safety equipment:

Biosafety Level 1: The practices and equipment utilized in a Biosafety Level 1 facility are appropriate for work with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Examples of these types of microorganisms include *E. coli* K12 derivatives, *Saccharomyces cerevisiae*, and others.

Biosafety Level 2: The equipment, practices, and facilities used in Biosafety Level 2 laboratories are established for a broad range of indigenous moderate risk group 2 agents. Examples include *Salmonella* sp., and *Toxoplasma* sp. The primary hazards to workers associated with these agents are accidental auto-inoculation, ingestion, and skin and mucous membrane exposure. Procedures with the ability to produce aerosols must be conducted in primary containment devices such as a biological safety cabinet.

Biosafety Level 3: Biosafety Level 3 facilities are established for the use of indigenous or exotic agents that possess the potential for infection by aerosol, and the results of such infection may have serious or lethal consequences. Typical examples of agents designated as requiring Biosafety Level 3 facilities include *Mycobacterium tuberculosis*, St. Louis encephalitis virus, and *Coxiella burnetii*.

Biosafety Level 4: Level 4 facilities are designed for work with dangerous and exotic agents that pose a high risk to individuals to contract a life-threatening disease. In these facilities, all manipulations are considered to be of high risk, and the procedures and safety equipment are designed to prevent exposure.

The BMBL describes in detail the requirements for each of the four biosafety levels.

Table 1 Summary of laboratory facilities BSL 1-4

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not associated with disease in healthy adults	Standard Microbiological Practices	As needed to allow for good microbiological practices	Open bench top Sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practices plus: Limited access Biohazard warning signs “Sharps” precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: Class I or II BSC or other physical containment devices used for all manipulations of agents that can cause splash or aerosol of infectious materials. PPE: laboratory coats, gloves; face protection as needed	BSL-1 facilities plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol disease transmission; disease may have serious or lethal consequences	BSL-2 practices plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering	Primary barriers: Class I or II BSC or other physical containment devices used for all manipulations of agents PPE: laboratory coats, gloves; face protection; respiratory protection as needed	BSL-2 facilities plus: Physical separation from access corridors Self-closing, double door access Exhausted air not recirculated Negative airflow into laboratory
4	Dangerous/exotic agents with pose high risk of life-threatening disease, aerosol transmitted lab infectious, or related agents with unknown risk of transmission	BSL-3 practices plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility	Primary barriers: All procedures conducted in Class III BSC, or Class I or II BSC in combination with full body, air supplied positive pressure personnel suit	BSL-2 facilities plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum and decon systems Other requirements as outlined in the text of the BMBL

Four levels have also been described for activities involving infectious disease activities with experimental animals. The four levels, designated as Animal Biosafety Levels (ABSL) 1, 2, 3 and 4 are also described in the BMBL.

It is important to note that the PI is responsible for selecting and applying the recommended biosafety level for the work conducted in adherence with the BMBL and NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)*. The investigator's unique knowledge and judgment of the agent to be used is critical in assessing the associated risks of exposure. The Biological Safety Program is available to assist in determining the appropriate biosafety level for your work.

3.0 ENGINEERING AND WORK PRACTICE CONTROLS

3.1 Laboratory Safety Procedures

Written laboratory safety procedures will be included in laboratory protocols for each research and teaching laboratory wherein employees and students may be exposed to biological agents, including exposures that could result from work with infectious microorganisms, recombinant or synthetic nucleic acid molecules involving pathogenic vectors, human tissues and body fluids, and experimental animals. The laboratory safety procedures will address routine specific safety precautions for the laboratory, and specify correct responses to accidents that might occur in the area. The Principal Investigator is responsible for the safety of workers and visitors in the laboratory and, therefore, is responsible for development of the plan and for ensuring compliance with safe practices.

The laboratory safety procedures should be written with reference to the following documents: CDC/NIH BMBL, NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)* and the Occupational Safety and Health Administration (OSHA) regulations governing exposures to bloodborne pathogens (see Appendix 3). It will also include requirements for health monitoring, tests, and immunizations. Standard UTHealth procedures for needlestick and other injuries, animal bites/scratches, and occupational illness will be incorporated into individual procedures, as needed. The individual laboratory safety procedures will be reviewed periodically by the Biological Safety Program and/or the IBC.

All employees and students working in a research or teaching laboratory with potential exposure to biological agents will be appropriately trained within 10 days of initial employment and annually thereafter as necessary for workers potentially exposed to bloodborne pathogens. The PI is responsible for providing this training, or to ensure attendance by the worker at appropriate safety training sessions provided by EH&S. The PI will document training by maintaining records of attendance.

Employees and students that work in laboratories where non-human primates, *Mycobacterium tuberculosis*, or *Bacillus anthracis* are handled, must be enrolled in the occupational health program. In addition, all employees that are employed by the Center for Laboratory Animals Medicine and Care (CLAMC) and directly handle animals will also be enrolled in the occupational health program (see section on Health Services).

When preparing standard procedures for augmenting the Institutional Biosafety Manual, the faculty member should consult with:

- EH&S, IBC, or Departmental Chairperson to obtain additional information or references.
- The staff of the UT Employee Health Services for information on health monitoring, tests, immunizations, and occupational injuries/illnesses.

- A member of the Center for Laboratory Animal Medicine and Care (CLAMC) professional staff to discuss safety aspects of animal exposure.
- In addition to any items required by the individuals listed above, the following procedures should be included in the Laboratory Safety Procedures:
 - All laboratory employees/students working with potentially infectious materials are required to wear laboratory coats or disposable gowns. Laboratory clothing should not be worn in non-laboratory areas and should remain in the laboratory, or change room, at the end of the day. Laboratory clothing should be laundered by a contractor that is informed of potential contamination and is experienced in the safe handling of contaminated clothing.
 - Safety goggles/glasses, face shields, or other protective devices should be utilized when necessary to protect the eyes and face from splashes and impacting objects. Examples of procedures that may produce aerosols include mixing, vortexing, and decanting.
 - When working with potentially infectious material, disposable, well-fitting latex (or a suitable substitute that provides protection from potential, concurrent chemical and physical hazard exposure risks) gloves should be worn. Double gloving should be used when working with sharp instruments (needles, etc.) and materials known to be infected with HBV, HCV, or HIV. If a glove is torn/cut, the individual must remove the gloves and wash his/her hands. Gloves should be removed aseptically and autoclaved with other laboratory wastes before disposal. Employees with open cuts or abraded skin are required to keep these surfaces covered with a dressing. Employees with wounds that are weeping, purulent (pus-exuding) should not work in laboratory, animal care areas, or patient care settings without appropriate precautions as designate by Health Services.
 - Employees are required to keep their hair at an appropriate length, covered, or tied in such a manner so that it does not become contaminated.
 - Plasticware should be substituted for glassware whenever possible.
 - Eating, drinking, smoking, storing food, applying cosmetics, and handling contact lenses is not permitted in the laboratory or animal work area.
 - Employees will not use work surfaces as seats.
 - All technical procedures will be performed in a manner that minimizes the creation of aerosols. All biological specimens should be covered, capped, corked, or plugged at all times except at the time of collection, separation, pouring, or analysis. If the potential exists for production of aerosols, the work must be conducted in a currently certified biological safety cabinet.

- When a biological safety cabinet is used for containment, ensure that the cabinet is functioning properly with sash in place and air flow not impeded. Cabinets will be certified annually (and following relocation) for safety and efficacy.
- Specimens containing infectious materials to be centrifuged should be covered, preferably with a screw cap or a cap that fits over the rim. A safety centrifuge cup or a sealed safety centrifuge rotor shall be used for infectious materials. If there is any spill or breakage in the centrifuge, turn the machine off and wait 5-10 minutes for any possible aerosols to settle. Notify the laboratory supervisor. The unit should then be cleaned immediately and thoroughly using an approved and effective disinfectant.
- Mouth pipetting will not be permitted for any materials or reagents. Mechanical pipetting devices shall be utilized.
- Hypodermic needles and syringes will be used only for parenteral injection and aspiration of fluids from patients, laboratory animals, and bottles sealed with a diaphragm. Hypodermic needles and syringes should not be used as a substitute for automatic pipetting devices in the manipulation of potentially infectious fluids. Needles used in collection of potentially infectious material will not be recapped after use. All syringes, needles, and other sharps will be placed into red plastic puncture resistant containers labeled as containing "sharps" and "infectious material." The container should also be labeled with the universal biohazard symbol. Whenever possible safety engineered sharps devices or needless devices shall be used in lieu of traditional needles and sharps.
- All liquid or solid materials containing potentially infectious material should be decontaminated before disposal. Contaminated materials that are to be treated outside of the laboratory will be placed in durable, leak proof containers with the outer container bearing the universal biohazard symbol. The container will be closed and disinfected on the exterior surface before being removed from the laboratory. EH&S should be contacted for waste pick-up and disposal by calling 713-500-5837.
- Work surfaces which may have contact with potentially infectious material should be decontaminated with an approved disinfectant (e.g., 10% dilution of household bleach for a minimum contact time of 15 minutes). Soak up the disinfectant and contaminated material with an absorbent material (such as paper towels) and dispose of these materials in a biohazard bag or sealed container. Gloves and other necessary personal protective equipment should be worn for clean-up.
- All spills and other accidents, with overt or potential exposure to infectious materials, will be reported immediately to the laboratory supervisor and Environmental Health & Safety. A written record (Supervisor's First Report of

Injury) of such incidents must be completed and submitted to the Workers' Compensation Insurance program.

- Animals not involved in the work being performed shall not be in the laboratory.
- Animal carcasses for disposal will be placed in rigid, leak-proof containers and delivered to the walk-in cooler located in the MSB basement by laboratory personnel or frozen in a laboratory freezer. The bag will have the appropriate label filled out and attached. Technicians will dispose of the carcasses by incineration.
- Only persons who have been advised of potential hazards and who meet specific entry requirements (e.g., training, occupational medical clearance, immunization) should be allowed to enter the laboratory working area. Children are not permitted in laboratory work areas. Laboratory doors should be kept closed. Access to animal facilities is restricted to authorized personnel.
- Employees should wash their hands after all procedures involving animals and potentially contaminated materials. Employees are encouraged to shower and change clothes after working with animals.

3.2 HIV and HBV Research Laboratories and Production Facilities

Individuals in research laboratories and production facilities engaged in the culture, production, concentration, experimentation, or manipulation of HIV, HBV, and HCV are responsible for the following requirements in addition to the other requirements of this manual:

- All waste will be treated (e.g. autoclaved) prior to disposal.
- Access to the work area will be limited to authorized personnel only.
- Laboratory doors shall be kept closed when work is in progress. A biological hazard warning sign will be posted on all access doors.
- All work will be conducted in biological safety cabinets or other physical-containment devices when using potential aerosol generating procedures.
- Samples containing HIV, HBV, or HCV may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.
- Personal protective clothing will be worn in the work area and animal rooms and will be removed prior to leaving the laboratory. Personal protective equipment shall be decontaminated prior to laundering.
- Extreme caution shall be used when handling needles and syringes. ***Do not recap any used needles.*** Place used needles and syringes in approved sharps containers.

- Each laboratory shall have available hand washing and eye wash facilities.
- In addition to training requirements listed in this manual, employees shall demonstrate proficiency in standard microbiological practices and techniques and in the practices and operation specific to the facility before being allowed to work with HIV, HBV or HCV. Employees must have prior experience in the handling of human pathogens or tissue cultures before working with these agents.
- The PI shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents and only until after employee has demonstrated proficiency can work with infectious agents commence.

3.3 Biological Safety Cabinets

Biological safety cabinets are used for the protection of personnel from aerosols produced by experimental procedures involving biological agents, in addition to protecting experimental products from contamination. When used along with proper microbiological techniques, they provide an effective containment system for the manipulation of agents in Biosafety Level 1, 2 3, and 4 laboratories. Although biological safety cabinets are designed to prevent the escape of aerosols, personnel must have appropriate training in their safe use. Rapid movements in front of the cabinet, opening and closing of doors, or brisk walking can drastically change the air flow patterns, resulting in the escape of aerosols.

Biological Safety Cabinet selection should be based on:

- Hazard classification/risk group
- Amount of protection needed for research products or personnel
- Amount and type of hazardous aerosols generated

There are three main classes of Biological Safety Cabinets: Class I, II and III.

Class I: This cabinet provides partial containment of aerosols, but no protection from contamination for the material in the cabinet or experiment. Although the cabinet provides adequate personnel protection, cross contamination may result from unfiltered air flowing over the work area. The front opening of the cabinet should be approximately 8 inches in height. Air velocity should be a minimum of 75 linear feet per minute (lfpm).

Class II: Both the worker and the material in a class II cabinet are protected. Class II cabinets have the following benefits:

- High efficiency particulate air filter (HEPA) on the intake and exhaust

- Downward clean air flow

Etiologic agents of low to moderate risk group of infectious vectors associated with recombinant or synthetic nucleic acid molecules research, and moderate risk oncogenic viruses may be manipulated safely in Class II cabinets.

There are two subtypes of Class II cabinets, type A and type B. These subtypes have the following characteristics:

Class II Type A1 cabinets (formerly designated Type A)

- maintain minimum average inflow velocity of 75 ft/min (0.38 m/s) through the work access opening
- have HEPA filtered downflow air that is a portion of the mixed downflow and inflow air from a common plenum (i.e., a plenum from which a portion of the air is exhausted from the cabinet and the remainder supplied to the work area)
- may exhaust HEPA filtered air back into the laboratory or to the environment through an exhaust canopy
- may have positive pressure contaminated ducts and plenums that are not surrounded by negative pressure plenums

Class II Type A1 cabinets are not suitable for work with volatile toxic chemicals and volatile radionuclides.

Class II Type A2 cabinets (formerly designated Type B3)

- maintain a minimum average inflow velocity of 100 ft/min (0.5 m/s) through the work access opening
- have HEPA filtered downflow air that is a portion of the mixed downflow and inflow air from a common exhaust plenum
- may exhaust HEPA filtered air back into the laboratory or to the environment through an exhaust canopy
- have all biologically contaminated ducts and plenums under negative pressure or surrounded by negative pressure ducts and plenums

Class II Type A2 cabinets used for work with minute quantities of volatile toxic chemicals and tracer amounts of volatile radionuclides required, as an adjunct to microbiological studies, must be exhausted through properly functioning exhaust canopies.

Class II Type B1 cabinets

- maintain a minimum average inflow velocity of 100 ft/min (0.5 m/s) through the work access opening
- have HEPA filtered downflow air composed largely of uncontaminated recirculated inflow air
- exhaust most of the contaminated downflow air through a dedicated duct exhausted to the environment after passing through a HEPA filter
- have all biologically contaminated ducts and plenums under negative pressure or surrounded by negative pressure ducts and plenums

Class II Type B1 cabinets may be used for work treated with minute quantities of volatile toxic chemicals and tracer amounts of volatile radionuclides required as an adjunct to microbiological studies if work is done in the direct exhausted portion of the cabinet, or if the chemicals or radionuclides will not interfere with the work when recirculated in the downflow air.

Class II Type B2 cabinets (sometimes referred to as "total exhaust")

- maintain a minimum average inflow velocity of 100 ft/min (0.5 m/s) through the work access opening
- have HEPA filtered downflow air drawn from the laboratory or the outside air (i.e., downflow air is not recirculated from the cabinet exhaust air)
- exhaust all inflow and downflow air to the atmosphere after filtration through a HEPA filter without recirculation in the cabinet or return to the laboratory
- have all contaminated ducts and plenums under negative pressure or surrounded by directly exhausted (non-recirculated through the work area) negative pressure ducts and plenums

Class II Type B2 cabinets may be used for work with volatile toxic chemicals and volatile radionuclides required as adjuncts to microbiological studies.

Class III: Class III cabinets provide the highest level of personnel protection. The entire unit is enclosed, thereby preventing agent from contacting the worker. Class III cabinets are self-contained, closed front, stainless steel, and are operated at negative pressure. Manipulations are performed with arm length rubber gloves sealed to the front of the unit. Highly infectious agents, generally risk group 4 agents, can be manipulated safely in Class III cabinets. Importantly, anaerobic chambers should not be mistaken as Class III biosafety cabinets.

When potentially infectious materials are to be used in a biological safety cabinet, the unit must be certified by a qualified individual on an annual basis. Cabinets require certification when:

- the unit is initially installed,
- annually thereafter,
- after moving the cabinet, and
- after HEPA filter replacement.

If a cabinet is not certified or the user does not plan to use potentially infectious material in the biosafety cabinet, a notice should be affixed to the cabinet indicating: *Cabinet not certified. Do not use pathogens.*

Guidelines for the use of biological safety cabinets

- Do not cover the rear exhaust or front air intake grilles.
- Wear gloves and long sleeve lab coat.

- Wash hands before and after experiment.
- Disinfect work area with 70% ethyl or isopropyl alcohol.
- Bunsen burners or other open flames are not allowed for use inside cabinet.
- Fans should be run for 15 minutes prior to and after work to allow removal of contaminants. It is preferable to leave the biosafety cabinet running at all times.
- Should not be used as a storage cabinet.

Clean air horizontal laminar flow work benches do not operate like biological safety cabinets. The primary purpose of a clean air work bench is to protect the material in the air stream, not the worker. Filtered air is blown horizontally across the material in the hood, towards the worker. Clean air hoods should never be used to manipulate potentially infectious agents, human tissues, or animal tissues.

3.4 Sterilization and Disinfection

Sterilization is a method or process to remove all viable microorganisms from an object or material. The process must consistently produce objects that are negative to chemical and biological indicators of contamination. Achieving sterility of the finished product depends on the number and type of organisms present, the temperature, and the length of contact time.

Steam sterilization (autoclaving) will kill most microorganisms when steam under pressure is applied at 121°C for a minimum of 15 minutes. It is important to remember that sterilization will not be complete if steam does not reach all surfaces of the object. This is of particular concern for items that have a high soil load and densely packed materials. Spore strips (*G. stearothermophilus*) can be placed at the center of the pack as a biological indicator of sterility. Autoclave tape is not an indicator of sterility; it simply indicates that the proper temperature has been achieved on the surface.

Sterilization is not practical for tables, cabinets, and some equipment, so disinfection must be utilized. The term disinfection implies the use of antimicrobial chemicals on inanimate objects with the purpose of destroying all non-spore forming organisms of pathogenic nature or which would compromise the integrity of the experiment. Note that disinfection does not mean the destruction of all organisms. Disinfectants destroy microorganisms by coagulating or denaturing proteins, injuring the cell membrane, and stopping normal enzymatic reactions.

The range of susceptibility of microorganisms to disinfectants is relatively broad. The vegetative bacteria, fungi, and lipid containing viruses are highly susceptible to inactivating agents. Non-lipid containing viruses are moderately resistant to these agents. Spore forms are the most resistant, as are prions. Use only disinfectants approved for use with a particular organism.

There are many chemical disinfectants on the market, with the main constituent being one of the following: chlorine, quaternary ammonium compounds, alcohol, formaldehyde, iodine, phenolics, or glutaraldehyde.

Chlorine Compounds

- 5000 ppm concentration needed
- Contact time: 10 to 30 minutes
- Wide spectrum germicidal
- Sanitizing properties
- No residue
- Low toxicity
- Bronchial irritant and skin irritation from extended contact
- Good for disinfecting surfaces
- Solution must be made fresh (at least monthly)
- Light contact (accelerates decomposition) prevented by using opaque containers

Quaternary Ammonium Compounds

- 0.1 to 2% concentration of active ingredient needed
- Contact time: 10 to 30 minutes
- Soluble in water
- Excellent for vegetative bacteria (gram +), lipo viruses, and HIV
- Good detergent properties
- Relatively non-toxic
- Not effective with spores and poor response with *Pseudomonas*
- Best for routine disinfecting of surfaces

Alcohol (ethyl or isopropyl)

- 60-95% concentration needed
- Contact time 10 to 30 minutes
- Effective on vegetative bacteria
- No residue formation
- Non-toxic (generally)

Formaldehyde

- 4-8% formaldehyde in 70% alcohol
- Contact time: 10 to 30 minutes
- Wide spectrum germicide
- Active in organic matter
- Can cause allergic dermatitis and is a suspected carcinogen
- Not recommended for routine use

Iodophor Compounds

- 0.47% concentration of iodine needed
- Contact time: 10 to 30 minutes
- Relatively non-toxic
- Wide spectrum germicide
- Fairly safe to use
- Not stable above 54°C

Phenolics

- 0.2 to 3.0% concentration effective
- Contact time: 10 to 30 minutes
- Wide spectrum antimicrobial agent
- Excellent sanitizing agent
- Toxic compound and a poor sporicidal agent

Glutaraldehyde

- Mode of action is alkylation
- Used in a 2% dilution
- Contact time: 10 to 60 minutes
- A chemo-sterilizer and high-level disinfectant
- Typically used for medical equipment such as endoscopes

3.5 Transportation and Shipment of Biological Agents

Any movement or transport of biological agents within a laboratory or building should be done in sturdy secondary containment as to prevent any spilling and/or leakage. The exterior of the secondary containment should be disinfected using a 10% dilution of household bleach with a contact time of 15 minutes. If the material to be transported could puncture the primary container, a secondary, puncture-resistant container should be used. Any equipment that is suspected of being contaminated must also be contained or decontaminated prior to movement or service work.

When transported, infectious substances and diagnostic/clinical specimens are classified as dangerous goods and must be shipped in accordance with federal and international regulations.

For the purposes of shipping, biological materials may be classified as either infectious substances (Category A or B), exempt patient specimens, genetically modified organisms, or biological products.

Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease in humans or animals when exposure to the occurs. Category A infectious substances are shipped as infectious substances, affecting humans (UN2814), or infectious substances affecting animals (UN2900). Indicative examples of Category A infectious substances (i.e. *Bacillus anthracis*, African Swine Fever Virus, etc.) can be found listed in the IATA Dangerous Goods Regulations.

Category B infectious substances are materials that are infectious, but do not meet the standard for inclusion in Category A. Category B infectious substances (i.e. unscreened human blood or human tissue) are shipped with the proper shipping name “biological substance, category B” and are assigned to UN3373.

An **exempt human specimen** that has minimal likelihood of containing pathogens is exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and must be based on the patient’s medical history, symptoms, local conditions, and individual circumstances. If there is more than minimal likelihood that a patient specimen contains pathogens, it must be shipped as an infectious substance (either Category A under UN2814 or UN2900, or Category B under UN3373).

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

Category A Infectious Substances

Requirements:

- Triple layer packaging
- Materials used for transport must be tested to ensure the sample will not leak
- Absorbent material
- Itemized contents list
- Outer package must bear Class 6.2 Infectious Substance label
- Additional labeling and marking requirements
- Shipper’s Declaration required

Category B Infectious Substances

Requirements:

- Triple layer packaging
- Materials used for transport must be tested to ensure sample will not leak
- Outer package and air waybill must bear “UN3373” and “Biological substance, category B” statement
- No Shipper’s Declaration required

Infectious substance or patient specimen shipments with dry ice

The following requirements are required in addition to the above requirements for Infectious substances or patient specimens shipped with dry ice.

Requirements:

- Never place dry ice in a sealed air tight container!
- Outer package must be approved to hold dry ice, otherwise use an overpack
- UN 1845 Dry Ice label, including estimated weight of dry ice
- Class 9 Dangerous Goods label

Laboratory personnel must be properly trained on transportation and shipment regulations **before** shipping an infectious substance. Infectious Substance Shipping will

need to be repeated every two years or as often as the regulations change. EH&S performs training sessions for those interested in receiving shipping training. Please contact the Biological Safety Program at 713-500-8170 for a training schedule and/or for assistance with shipping, or visit our website at <https://www.uth.edu/safety/biological-safety/transportation-shipment-ISS.htm>

3.6 Personal Protective Equipment

Personal protective equipment (PPE) shall be worn in instances where engineering controls are not feasible and should not be used as a substitute for engineering and administrative controls. Individuals will be encouraged to use appropriate personal protective equipment as indicated by the PI and/or EH&S. Adequate PPE is provided at no cost by the PI to the employee and should be readily accessible at the worksite. This includes, but is not limited to the following: gloves, gowns, laboratory coats, face shields or masks, head covers and eye protection as necessary. Accommodations will be made for individuals determined to be unable to use certain protective devices.

Gloves must be worn when an employee may have contact with blood, other potentially infectious materials, mucous membranes, non-intact skin and when handling or touching contaminated items or surfaces. Disposable single use gloves shall be replaced as soon as possible when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised. Hands should be washed each time gloves are removed. Disposable gloves shall never be washed or disinfected for reuse. Utility gloves may be disinfected for reuse if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibiting any sign of deterioration.

Masks and eye protection shall be worn whenever splashes, spray, droplets, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or mouth contamination.

Laboratory coats, gowns, aprons, clinic jackets, or similar outer garment must be worn in situations where there is a potential for exposure to infectious agents.

All PPE shall be removed immediately upon leaving the work area or as soon as possible if overtly contaminated, and placed in an appropriately designated area for decontamination or disposal.

The PI is responsible for the cleaning, laundering, and disposal of PPE and ensuring that it is being used appropriately.

3.7 Housekeeping

If an area becomes contaminated with blood or body fluids, the fluid shall be absorbed with disposable absorbent material and placed in a biohazard container or bag. Decontamination of contaminated materials must be performed using an approved disinfectant. Gloves must be worn throughout the entire procedure. All equipment and working surfaces will be cleaned and decontaminated upon completion of procedures,

spills, or after contact with blood or other potentially infectious materials using an approved disinfectant. Protective coverings, such as absorbent paper, are to be removed and replaced when overtly contaminated or at completion of procedures. All receptacles intended for reuse, such as bins, pails, or cans that may be contaminated should be inspected and decontaminated on a regular basis. Broken glassware will be cleaned up using mechanical means, such as brush, broom, dust pans, tongs, forceps, etc. Equipment that may become contaminated with blood or other potentially infectious materials shall be checked routinely and prior to servicing or shipping and shall be decontaminated as necessary.

Areas where designated infectious agents are used shall be cleaned on a regular basis by laboratory personnel with an approved disinfectant.

3.8 Biological Waste Disposal Procedures

Biological or potentially infectious waste is waste that has pathogens or biologically active material present in sufficient concentration or quantity so that exposure of a susceptible host could result in disease. The State of Texas categorizes this waste as Special Waste from Health Care Related Facilities and defines it as a solid waste which if improperly treated or handled may serve to transmit an infectious disease and is comprised of the following:

- **Animal Waste**
Carcasses, body parts, whole bulk blood and blood products, serum, plasma, and other blood components, and bedding of animals intentionally exposed to pathogens
- **Bulk Blood, bulk human blood products, and bulk human body fluids**
Semen, vaginal secretions, body fluid containing visible blood, saliva in dental settings, amniotic fluid, cerebrospinal fluid, peritoneal fluid, pleural fluid, pericardial, and synovial fluid.
- **Microbiological Waste**
Discarded cultures and stocks of infectious agents and associated biological materials, discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial and industrial laboratories, discarded live and attenuated vaccines, discarded used disposable culture dishes, discarded used disposal devices used to transfer, inoculate, or mix cultures.
- **Recombinant or synthetic DNA**
Discard all recombinant or synthetic DNA stocks, cultures, organisms, and associated biological materials as biohazard waste.
- **Pathological waste**
Body parts, tissues, recognizable human tissues, organs, bulk blood and body fluids.
- **Sharps**

Contaminated scalpel blades, razor blades, suture needles, disposable razors, disposable scissors, intravenous stylets and rigid intruders, glass pipettes, specimen tubes, blood, culture bottles, microscope slides, broken glass from laboratories.

These types of waste should always be handled in accordance with practices that minimize exposure to waste handlers and to ensure that the waste will ultimately receive the proper treatment.

This can be accomplished by adhering to the following general guidelines of:

- Minimizing the potential number of persons exposed to the waste.
- Maintaining the integrity of the waste containers during handling and treatment.
- Using personal protective equipment as needed.
- Conducting waste management practices that will avoid spills and accidents.

ON-SITE WASTE TREATMENT AND DISPOSAL

Infectious waste may be treated onsite so as to render it noninfectious. Treatment techniques approved by the Texas Department of State Health Services (25 TAC § 1.131-1.137) are:

- Chemical disinfection
- Steam sterilization
- Incineration
- Thermal inactivation
- Chlorine disinfection maceration
- Encapsulation (only for sharps in containers)
- Moist heat disinfection

The two most common methods utilized at UTHealth are steam sterilization and chemical disinfection. Each method requires strict adherence to Texas state rules and regulations in order to be an effective means of treating the waste.

Steam Sterilization (Autoclave)

Steam sterilization utilizes pressurized steam (15 psi) at 250 to 270°F (121 to 132°C) to kill pathogenic organisms that are present in the infectious waste. It is important to note that the steam sterilization process does not destroy the waste itself; however, since it has been rendered noninfectious, it can be disposed of in the regular trash provided it is placed in an opaque, black or grey trash bag. Standard operating procedures are required for each autoclave utilized to treat infectious wastes, and locations that treat over 50 pounds of waste per month must include the following criteria:

- The proper bags must be utilized.

- The temperature of the autoclave must be at least 121°C (250°F).
- The pressure must be at least 15 psi.
- Waste must be treated for a minimum of 30 minutes.
- Routine biological monitoring using the appropriate *Geobacillus stearothermophilus* species should be conducted and documented.
- A log of the type of waste treated, date treated, person performing the treatment, amount treated, and treatment parameters must be kept.

Once the waste has been treated, it should be double bagged in thick black or grey opaque liners and placed in designated containers located in each autoclave room. These containers can be obtained by contacting the EH&S Environmental Protection Program at 713-500-5837. Treated waste can then be disposed by housekeeping into a municipal solid waste landfill.

Biological Monitoring

Autoclave parameters for waste treatment waste should be monitored with the appropriate biological species indicator to test the efficacy of the treatment. Biological indicators can be in the form of either a biological indicator ampoule containing the spores of *Geobacillus stearothermophilus* or a chemical test strip which simulates *Geobacillus stearothermophilus* spores. All autoclaves should be tested according to the amount of waste treated per month.

Table 1. Autoclave performance testing schedule.

Routine Performance Testing Requirements 30 TAC §330.1219	
<u>Pounds Treated per Month</u>	<u>Testing Frequency</u>
Less than 50	N/A
50 – 100	Monthly
100 – 200	Biweekly
Greater than 200	Weekly

Biological indicator ampoules, (self-contained biological indicators) should be placed in the autoclave with the waste during a treatment cycle. After the cycle is complete, and the waste has cooled, remove the ampule and store in the autoclave room for removal by EH&S Environmental Protection Program (EPP). Biological indicators for routine testing of autoclaves used to treat biological wastes are provided by the EH&S EPP.

For those autoclaves in which a continuous readout of operating parameters is available, routine parameter monitoring with chemical indicator strips can be substituted for biological monitoring. Please place the chemical indicator strip in the autoclave with the

waste during a treatment cycle. After the cycle is complete, and the waste has cooled, remove the chemical test strip and verify the appropriate color change has occurred. Document the performance test by completing the efficacy log and attaching the chemical test strip in the space provided.

In addition to routine monitoring, every load should be monitored with a temperature indicator strip or tape that turns color when the proper temperature is achieved.

Chemical Disinfection

Aqueous or solid biohazard waste that does not contain hazardous materials can be disposed of through the sanitary sewer provided it is treated prior to doing so. In order for this waste to be disposed on in the proper manner, the following criteria must be met:

- The waste must be treated with a chemical agent registered with the EPA as a registered disinfectant and in accordance with the manufacturers' instructions. Disinfectants used must have been shown to be effective against the microorganisms present.
- The waste must be immersed for a minimum fifteen minutes in a freshly prepared solution of 10% bleach solution, 70% isopropanol solution or other acceptable disinfectant.

Records

Records are an essential part of documenting waste management programs. All departments that treat waste are required by State regulations to keep records that include the following:

- Date of treatment
- Method/Conditions of treatment
- Quantity of waste treated (pounds)
- Verification of operating parameters or biological monitoring
- Written procedures for the operation and testing of equipment used
- Printed name and initials of person treating the waste

These records can be recorded on autoclave use and efficacy forms included with these procedures. Autoclave use log books are located in each of the autoclave rooms utilized for onsite treatment of infectious wastes. The EH&S Environmental Protection Program will periodically collect these records for retention at OCB.

OFF-SITE WASTE TREATMENT AND DISPOSAL

For those departments that do not have the proper equipment to effectively treat waste, an off-site treatment option is available. This entails collecting and shipping infectious wastes to an offsite vendor for incineration, steam sterilization, or other approved treatment method. Untreated wastes require additional handling and packaging and should be handled as little as possible. Infectious wastes should be disposed of directly

into the designated transport container to minimize unnecessary sorting, handling, and repackaging.

Collection

In order to facilitate safe and compliant waste disposal, waste must be placed in biohazard bags and containers approved by the Texas Department of State Health Services. These containers include corrugated fiber boxes or hard plastic containers designated for biohazard waste. These containers are available by contacting the EH&S Environmental Protection Program or by calling the Hazardous Waste Line at 713-500-5837. Boxes or hard plastic containers should be closed and labeled with a complete biological waste tag.

Infectious Wastes generated at the School of Dentistry, School of Nursing, Denton A. Cooley Building, Institute of Molecular Medicine, and School of Public Health are transported by research or clinical staff to an onsite biological waste storage area for collection. Biological waste storage areas, as well as, replacement boxes, red liners, and sharps containers are located in the following rooms:

SOD: 1266
IMM: 120
SPH: B01a
SON: 510
BBSB: 1406

Waste generated at other locations at UTHealth; when the waste container is 3/4 full, a call should be made to the Hazardous Waste Line (713-500-5837). Please leave a message for the respective waste pick-up extension listed in the automated call. The waste is collected every Monday, Wednesday and Friday.

GENERAL GUIDELINES

Storage

Infectious waste should not be allowed to accumulate and should be inactivated and/or disposed of daily or on a regular basis as needed. If the storage of infectious material is necessary, it should be stored in a rigid, leak-proof container and bear the universal biohazard symbol. Infectious waste may be stored at room temperature until the storage container is full, but no longer than 30 days from the date of generation. Frozen waste may be kept up to 90 days from the date of generation. If infectious waste becomes putrescent during storage, it should be removed off site within 24 hours for processing and disposal. Storage of waste should be in a manner that affords protection from theft, vandalism, human or animal exposure, rain, water, and wind. Infectious waste should be stored separate from chemical and radioactive waste.

Transporting biohazard waste through the hallways or between buildings should be conducted with the use of secondary containment, or in fully enclosed carts, to prevent spills or exposure to other personnel. The outside of the container should be decontaminated prior to transport.

Sharps

Typical sharps encountered in a medical research or clinical settings include **hypodermic needles, syringes, Pasteur pipettes, broken glass, and scalpel blades**. All discarded sharps that are used in patient care or research studies should be classified and managed as infectious waste because of the possibility of an undiagnosed bloodborne disease or pathogen. Even those sharps that are not contaminated carry the risk of physical injury due to puncture wounds, cuts, or scratches, and must be handled with extreme care.

Sharps must be placed in a **labeled or color-coded, puncture resistant, rigid container** designed for sharps. **Glass bottles, plastic bottles and coffee cans are not acceptable containers!** Sharps containers are available by contacting the EH&S Environmental Protection program or by leaving a message on the Hazardous Waste Line (713-500-5837). Once the containers are 3/4 filled, a call should be made to the Hazardous Waste Line (713-500-5837) for pickup. The container will be collected and a replacement container will be supplied.

Containers should be easily accessible to personnel and located as close as feasible to the work area. Containers should remain upright and not be overfilled. **Used needles shall not be recapped or sheared, but should be deposited whole into the appropriate sharps containers.** Uncontaminated broken glass and pipettes (glass and plastic) should be disposed of into either a broken glass container or a cardboard box labeled with the words "Broken Glass". This container should be properly sealed and placed by the regular trash for disposal.

Quality Control

EH&S conducts regular surveys of the laboratories to ensure compliance with any applicable regulation or policy. In addition, routine biological or parameter monitoring of the autoclaves is conducted utilizing *Geobacillus stearothermophilus biological indicators or chemical test strips*. Any non-compliance issues are immediately addressed in an effort to protect the health and safety of personnel.

Contact EH&S Environmental Protection program 713-500-8100 or leave a message on the Waste Line at 713-500-5837 for questions regarding proper waste disposal.

3.9 Biological Spill Clean-Up Procedures

The following procedures are provided as a guideline to cleanup of biological spills.

For biological spills inside the biological safety cabinet:

1. Wear laboratory coat, eye protection and gloves during clean-up.
2. Allow cabinet to continue to run during clean-up.

3. Apply an approved disinfectant and allow a minimum of 15 minutes contact time.
4. Wipe up spillage with disposable disinfectant-soaked cloth or tissue.
5. Wipe the walls, work surface and any equipment in the cabinet with a disinfectant soaked cloth.
6. Discard contaminated disposable materials in appropriate hazardous biological waste container(s) and autoclave before discarding as waste.
7. Place contaminated reusable items in biohazard bags or in autoclavable pans with lids before autoclaving and cleanup.
8. Expose non-autoclavable materials to disinfectant and allow 15 minutes contact time before removing from the biological safety cabinet.
9. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving if necessary.
10. Run cabinet at least 15 minutes after cleanup before resuming work or turning cabinet off.

For hazardous biological spills in the laboratory, outside the biological safety cabinet:

1. Clear area of all personnel. Wait approximately 30 minutes for the aerosols to settle before entering spill area.
2. Remove any contaminated clothing and place in biohazard bag to be autoclaved.
3. Wear a disposable gown, shoe covers, eye protection and gloves. In a Biosafety Level 3 (BSL-3) facility, respiratory protection is usually required. (see facility specific protocols).
4. Initiate cleanup with disinfectant as follows:
 - a. Soak paper towels in disinfectant and place over spill.
 - b. Encircle the spill with additional disinfectant being careful to minimize aerosolization during pouring while assuring adequate contact. Start from the periphery and work toward the center.
 - c. Decontaminate all items within the spill the area.
 - d. Allow 15 minutes contact time to ensure germicidal action of disinfectant before passing items to clean area.
 - e. Place disposable contaminated spill materials in appropriate biological hazardous waste container(s) for treatment.
 - f. Place contaminated reusable items in autoclavable containers.

For hazardous biological spills inside the centrifuge:

1. Clear the immediate area of all personnel. Wait 30 minutes for aerosols to settle before attempting to clean up spill. Keep centrifuge closed.
2. Wear a laboratory coat, eye protection and gloves during cleanup.
3. Remove rotors and buckets to nearest biological safety cabinet for clean-up.
4. Thoroughly disinfect inside of centrifuge.
5. After thorough disinfection of rotor or rotor cups, remove contaminated debris and place in appropriate hazardous biological waste container(s) and autoclave before disposing as infectious waste.

For hazardous biological spills outside laboratory, during transport:

1. Transport hazardous biological materials in an unbreakable sealed primary container, placed inside a secondary container with a lid. Label the outer container with the biohazard symbol if material is Risk Group 2 or higher.
2. Should a spill occur in a public area, do not attempt to clean it up without appropriate personal protective equipment. Call EH&S for assistance at 713-500-5832.
3. As an interim measure, wear gloves and place paper towels, preferably soaked in disinfectant, directly on spilled materials to prevent spread of contamination. To ensure adequate contact, surround the spill with disinfectant, if available, taking care to minimize aerosols.

IF YOU ARE NOT SURE ABOUT THE PROPER PROCEDURES OR NEED ASSISTANCE, CALL EH&S at 713-500-8100. FOR AFTER HOURS SPILLS CALL 713-500-5832 or 911.

4.0 REQUIREMENTS FOR WORK WITH SPECIFIC INFECTIOUS AGENTS

4.1 Infectious Microorganisms

"Infectious Microorganisms or Agents" are defined as those pathogenic bacteria, viruses, fungal organisms, parasites, and prions that can be transmitted to a person or animal, directly or indirectly, and are capable of causing disease in the new host.

Written laboratory safety procedures or standard operating procedures (SOPs) will be prepared by the PI for each laboratory in which infectious agents are used for teaching or research purposes. The faculty member responsible for the laboratory will prepare the procedures and ensure compliance by all workers and students. Safety procedures that are indicated in the Safety Review Forms must be *approved* by the Institutional Biosafety Committee prior to introduction of the agents into the laboratory.

The individual laboratory safety plan or SOPs should include information from the following: 1) the UTHealth Institutional Biosafety Manual, 2) the National Research Council *Biosafety in the Laboratory*, 3) the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, 4) the OSHA *Occupational Exposure to Bloodborne Pathogens (29 CFR Part 1910.1030)*, 5) the IATA *Dangerous Goods Regulations for Shipping Infectious Substances*, and 6) the *CFR 42 Part 73; Select Agents*. These, and other documents, are available online or by calling EH&S at 713-500-8100.

Training of employees and students is an extremely important safety factor in the laboratory. The responsible faculty member will provide training and then closely supervise the new laboratory worker to ensure that procedures are being properly conducted.

Employees and students should be familiar with signs and symptoms of illness caused by the agent(s) under investigation. A laboratory worker that develops illness that could be of laboratory origin should inform his/her supervisor, complete a Supervisor's First Report of Injury form, and report to the UT Employee/Student Health Services. If the employee or student prefers to see another physician, he/she should advise the other physician of a potential laboratory infection so that the UT Employee/Student Health Services physician can be contacted for consultation.

A health history will be evaluated for each employee or student exposed to infectious microorganisms. A consultation will be provided to individuals based on this health history and the Laboratory Safety Plan, by the UTHealth Employee/Student Health Services physician. All employees and students that will work with, or will be in the laboratory where infectious microorganisms are in use, will be immunized against those agents if a vaccine is available. A baseline serum sample will be collected and frozen if recommended by the UT Employee/Student Health Services.

Short-term students and visitors to the laboratory should not be exposed to potentially infectious material unless they are trained in safe procedures and familiarized with the

safety plan of the laboratory. All personnel, including short-term students and visitors, must be enrolled in the UT Employee/Student Health Services medical surveillance program as indicated by the level of hazard present in the laboratory, or if recommended by the Institutional Biosafety Committee. Non-essential visitors and children should not be allowed access to a laboratory where infectious agents may be present. Consult HOOP policy #164 “Minor’s in the Workplace” for more information.

OSHA defines an occupational exposure as “reasonably anticipated skin, eye, mucous membrane, or parenteral contact with infectious or potentially infectious material that may result from an employee’s duties”. UTHealth will use this definition as reference for exposures or suspected exposures to infectious organisms, and shall be inclusive of the route of inhalation.

4.2 Recombinant or Synthetic Nucleic Acid Molecules

It is the policy of UTHealth that research and teaching programs utilizing recombinant or synthetic nucleic acid molecules technology will be conducted in full compliance with federal and state laws and regulations, irrespective of the source of funding for the research. Primary consideration will be given to (1) protection of the health of employees, students, and the public, (2) protection of domestic and feral animal populations, and (3) protection of all aspects of the environment.

Pursuant to the National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)* (the *NIH Guidelines*; see Appendix 3) UTHealth must:

- Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecules research where it poses health and environmental risk concerns.
- Establish an Institutional Biosafety Committee (IBC) as specified in the *NIH Guidelines*.
- Appoint a Biosafety Officer, if the institution is engaged in recombinant or synthetic nucleic acid molecules research at the Biosafety Level 3 or 4 containment level. The Biosafety Officer at UTHealth is the Assistant Vice President of EH&S.
- Require that investigators responsible for research covered by the *NIH Guidelines* comply with the appropriate sections of the *NIH Guidelines* and assist investigators to do so.
- Ensure appropriate training for the IBC Chairperson and members, the Biosafety Officer and laboratory staff regarding the *NIH Guidelines*, their implementation, and laboratory safety. Responsibility for training laboratory staff may be carried out through the PI. The institution is responsible for ensuring that the PI is adequately trained and may delegate that responsibility to the IBC.
- Determine the required biosafety level for the project and the need for any health surveillance for research personnel.

- Significant safety problems with recombinant or synthetic nucleic acid molecules projects will be reported immediately to the chairperson of the IBC. That official will then be responsible for investigating the incidents and reporting appropriate details to the NIH Office of Science Policy. See section 4.3 of this manual for reporting instructions.

The IBC will function as defined by the *NIH Guidelines*. The committee will represent the University in ensuring compliance with relevant regulations and this policy. The IBC will:

- Review non-exempt recombinant or synthetic nucleic acid molecules research for compliance with *NIH Guidelines* as specified and approve projects found to be in conformity. The IBC will independently assess containment levels required by these Guidelines and will assess facilities, procedures, practices, personnel training, and personnel expertise, as appropriate.
- Set containment levels for specified experiments including those involving whole animals or plants.
- Review, periodically, recombinant or synthetic nucleic acid molecules research being conducted to ensure fulfillment of the requirements of the *NIH Guidelines* (see Appendix B).
- Adopt emergency plans covering accidental spills and personnel contamination. Maintain copies of these plans for ready access in the event of an accident.
- Report significant problems to the appropriate institutional official immediately. Investigate all incidents, and jointly with the PI and report appropriate information to the NIH Office of Science Policy within 30 days. See section 4.3 of this manual for reporting instructions.
- The IBC may not authorize initiation of experiments not explicitly covered by the *NIH Guidelines* until authorized to do so by the NIH.

The Assistant Vice President of EH&S and Biosafety Officer shall be a member of the IBC and his/her duties will include:

- Ensure through periodic inspection (at least annually for Biosafety Level 2 and monthly for Biosafety Level 3 & 4) that laboratory standards are rigorously followed.
- Report significant problems, violations of the *NIH Guidelines*, significant research related accidents and illnesses to the Chairperson of the IBC. The Chair of the IBC will investigate all incidents and violations with results reported to the Executive Vice President and Chief Academic Officer. If appropriate, the details will be reported to the NIH Office of Science Policy. See section 4.3 for reporting instructions.

- Develop emergency plans for dealing with accidental spills, personnel contamination and investigating laboratory accidents with assistance and consultation of members of the IBC.
- Provide advice on laboratory security and research safety.

On behalf of the institution, the PI is responsible for complying fully with the *NIH Guidelines* in conducting recombinant or synthetic nucleic acid molecules research. The PI will be fully informed of his/her responsibilities under the *NIH Guidelines* and will be knowledgeable regarding containment and safety as detailed in the *Laboratory Safety Monograph*, a supplement to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)*, U.S. Department of Health, Education, and Welfare (available from EH&S).

The Principal Investigator will:

- Not initiate or modify recombinant or synthetic nucleic acid molecules research requiring IBC approval, until the research or proposed modification has been approved by the IBC.
- Make the initial determination of the required levels of containment in accordance with the *NIH Guidelines* and the select microbiological practices and laboratory techniques to be used. Request consultation from the IBC, if needed, to assist with planning of project safety and occupational health.
- Submit the initial research proposal (and subsequent changes) to the IBC for review and approval/disapproval if the protocol is covered under sections III-A through III-D of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)* (see Appendix 3 of this manual).
- Remain in communication with the IBC throughout the conduct of the project.
- Prior to initiation of the investigation, provide the laboratory staff copies of the safety protocols that describe potential hazards and precautions to be taken routinely and in the event of an accident. Ensure that a copy of the safety protocol is maintained in the laboratory.
- Instruct and train the staff in practices and techniques required to ensure safety and procedures for dealing with accidents. Document the training by maintaining a record of date, time, attendees, and discussion content.
- Inform the staff of reasons and provisions for precautionary medical practices (e.g. vaccinations, serum collection) advised or requested.
- Report significant problems and violations of the *NIH Guidelines* to the IBC immediately. The Committee will investigate the problem, and with the PI, will report appropriate details to the NIH Office of Science Policy within 30 days. See section 4.3 of this manual for reporting instructions.

- Report new information bearing on the *NIH Guidelines* to the IBC and NIH.
- Be adequately trained in proper microbiological techniques, if inexperienced in safe methods of conducting recombinant or synthetic nucleic acid molecules research. EH&S will provide individual or group training upon request.
- Comply with shipping requirements for infectious vectors used in recombinant or synthetic nucleic acid molecules research.
- Adhere to IBC approved emergency plans in the event of accidental spills and/or personal contamination.
- Submit information to NIH if required by the *NIH Guidelines*. Obtain IBC concurrence if direct communication to NIH is required.

4.3 Reporting of Incidents Involving Recombinant or Synthetic Nucleic Acid

Molecules

Lab incidents or illness involving recombinant or synthetic nucleic acid molecules or noncompliance with the *NIH Guidelines* may be brought forward by any person, and should be promptly reported to EH&S (713-500-8100) for investigation and reporting of the incident to the National Institutes of Health Office of Science Policy and the Institutional Biosafety Committee if required.

UTHealth must report any significant problems or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH within 30 days. Examples include needlesticks or mucous membrane exposure to material containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet.

Spills and accidents which result in either 1) overt exposures to risk group 2 (RG2) organisms or 2) overt or potential exposures to risk group 3 (RG3) organisms containing recombinant or synthetic nucleic acid molecules must be immediately reported to EH&S (713-500-8100) for investigation and reporting of the incident to the National Institutes of Health Office of Science Policy, and the Institutional Biosafety Committee, if required. Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained.

Adverse Events Involving Recombinant or Synthetic Nucleic Acid Molecules in Human Gene Transfer

Human gene transfer experiments involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or nucleic acid molecules derived from recombinant or synthetic nucleic acid molecules, into human research participants. Researchers should contact the EH&S Biosafety Program (713-500-8170) prior to beginning human gene

transfer experiments and should consult Section III-C of the *NIH Guidelines* for pertinent requirements to conduct this research.

For projects involving human gene therapy, a “serious adverse event” is any event occurring at any dose that results in any of the following outcomes: death, a life-threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization also may be considered a serious adverse event when, upon the basis of appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An adverse event is “associated with the use of a gene transfer product” when there is a reasonable possibility that the event may have been caused by the use of that product.

An “unexpected serious adverse event” is any serious adverse event for which the specificity or severity is not consistent with the risk information available in the current investigator’s brochure.

Contact the EH&S Biosafety Program (713-500-8170) immediately if any of the above occurs for investigation and reporting.

4.4 Human Tissues and Body Fluids

A major provision of the OSHA standard that governs occupational exposures to human blood and body fluids (29 CFR Part 1910.1030) is the *Exposure Determination*. The Exposure Determination is a listing of all positions within UTHealth that may have involvement with human blood and body fluids.

For the areas under the direction of the IBC, the following Exposure Determination has been developed:

Departments and areas where all employees are expected to have exposures to human blood and body fluids:

Environmental Health and Safety: All technical employees in this office are potentially exposed to human blood and body fluids as a result of their work managing the Biological Safety Program. The predominant sources of exposure are the medical waste collected and processed by this office and their frequent involvement in the clinical and research lab areas. These positions have been specifically identified as:

Director
Safety Manager
Safety Specialist

Departments and areas where some employees are expected to have exposure to human blood and body fluids:

Services/Branch Operations: All technical staff working at the Medical School, Dental Branch, School of Public Health, Mental Sciences Institute, Institute of Molecular Medicine, Harris County Psychiatric Center, University Center Tower, and Graduate School of Biomedical Sciences are designated as having possible infrequent exposures as a result of their maintenance and repair work in the clinical and research laboratories. These positions have been specifically identified as:

- Mechanical Engineer
- Utilities Operations Supervisor
- Utilities Operator
- Electrician
- Electrical Engineer
- Maintenance Supervisor
- Maintenance Leader
- Maintenance Worker
- Refrigeration Mechanic
- Plumber
- Carpenter Supervisor
- Carpenter
- Painter
- Project Specialist

Plant operations personnel within UTHealth are not expected to be exposed. However, appropriate actions, including training and immunizations will be provided if notification is received regarding any job tasks where exposures can occur.

Housekeeping: All housekeeping staff working in UTHealth, UTPhysicians, or HCPC clinical settings are designated as having possible infrequent exposures as a result of their housekeeping tasks in the clinical and research labs and patient-care areas. These positions have been specifically identified as the following:

- Housekeeper
- Housekeeping Team Leader
- Housekeeping Supervisor

Only selected other housekeeping personnel at UTHealth may be exposed. Tasks at UTHealth involving exposure include housekeepers with assignments to laboratory or clinical areas who may periodically encounter blood spills from accidents. All other housekeeping personnel at UTHealth are not expected to be exposed. However, appropriate actions, including training and immunizations will be provided if notification is received regarding any job tasks where exposures can occur.

Clinical and Research Laboratory Departments: Clinical and Research Laboratory staff members that interact with human blood and body fluids include

employees with duties in such related work areas. These positions have been specifically identified as:

Physician
Physician Assistant
Nurse
Nurse Anesthetist
Occupational Therapist
Physical Therapist
Dental Hygienist
Dental Technician
Dental Assistant
Dental Dispensary Assistant
Phlebotomist
Research Technician
Child Care Specialist
Hospital Aide
Health Care Assistant
Cytologist
Histology Technician
Medical Technician
Medical Technologist
Radiological Physicist
Radiologic Technologist
Infection Control Practitioner

Other departmental staff members are not expected to be exposed specifically to human blood and body fluids, but are covered under other specific provisions of the IBC.

University Police: All public safety officers and employees whose jobs involve interaction with suspects and/or responding to emergencies are designated as having possible infrequent exposures as a result of their contact with these individuals:

Chief of Police
Assistant Chief of Police
University Police Officer
University Security Guard
Police Cadet

Other auxiliary personnel, such as secretaries and office clerks within the University Police are not expected to be exposed. However, appropriate actions including training and immunizations will be provided if notification is received regarding any job tasks where exposures can occur.

All other individuals in this organization are not expected to be exposed. However, appropriate actions, including training and immunizations will be provided if notification is received regarding any job tasks where exposures can occur.

Departmental Research and Teaching Labs: Instructors, technicians and assistants in research and teaching laboratories are designated as having possible exposures to human blood and body fluids if, as a result of their work, these types of materials are encountered. The responsibility for recognizing and reporting individual work situations where possible exposures to human blood and body fluids may occur rests with the individual supervisors. These positions have been specifically identified as:

- Professor
- Associate Professor
- Assistant Professor
- Research Scientist
- Research Associate
- Research Assistant
- Research Technician
- Research Instructor
- Graduate Assistant
- Postdoctoral Fellow
- Resident
- Laboratory Assistant

With such a diverse and dynamic population of workers at UTHealth, it is impossible for EH&S to constantly inventory the training, immunization and safety status of each worker. The responsibility for recognizing and reporting situations where occupational exposures to human blood and body fluids may occur rests with the *individual supervisor*.

A MUA form will be completed for each laboratory wherein human tissues (blood, etc.) are handled for teaching or research and clinical study purposes. The faculty member responsible for the laboratory will include with the form a safety plan and will ensure compliance by all workers and students. A copy of the plan will be reviewed by the Biosafety Program Manager or a designated EH&S representative.

Information from this manual, the CDC *Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and other Bloodborne Pathogens in Health Care Settings*, CDC *Recommendations for Prevention of HIV Transmission in Health Care Setting*, and OSHA *Occupational Exposure to Bloodborne Pathogens (29 CFR Part 1910.1030)* will be incorporated into each laboratory safety procedures. These documents are available from EH&S.

All employees and students who have occupational exposure to human blood and other tissues will be offered the hepatitis B vaccination series free of charge. The vaccination will be made available after the employee has received the training required and within 10 working days of initial assignment unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee

is immune, or the vaccine is contraindicated for medical reasons. Employees who decline to accept the hepatitis B vaccination must sign a mandatory waiver form.

In an effort to reduce potential exposure of employees and students to blood infected with hepatitis and human immunodeficiency viruses, blood for research and teaching laboratories will, when possible, be obtained from stocks that have been tested and found negative for those pathogens.

Tissues collected from employees, students, patients, or autopsy cases of unknown pathogen status are assumed to be infected and should be handled with appropriate universal precautions.

Training of employees and students is an extremely important safety factor in the laboratory. The PI must provide training and then closely supervise the new laboratory worker until confident that procedures are being properly conducted. Training must be documented by maintaining a record of time, attendees, and content of the discussions or lectures.

Short-term students and visitors to the laboratory should not be exposed to potentially infectious material unless they are trained in safe procedures and familiarized with the safety plan of the laboratory. All personnel, including short term students and visitors must be enrolled in laboratory safety training classes indicated by the level of hazard present in the laboratory, or if recommended by the IBC.

4.5 Experimental Animals

It is the policy of UTHealth that employee and student exposure to infectious hazards associated with animal and animal tissue contact will be minimized. Natural infections will be controlled by use of pathogen free animals, where possible, and by a broad program of optimum veterinary care for all animal subjects. Both experimental and natural infections will be controlled by appropriate experimental design, technical methods, containment equipment, and building engineering systems. EH&S Basic Laboratory and Bloodborne Pathogens Safety training course is an integral part of the employee safety program at UTHealth.

The UT Employee Health Services located in the University Center Tower Suite 1620 provides physical examinations, tests, and immunizations to individuals exposed to experimental animals.

4.6 Select Agents and Toxins

The Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) implemented a final rule on March 18, 2005 setting forth requirements regarding the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents or toxins. A select agent is defined as a biological agent or toxin that has the potential for misuse, whether inadvertent or the result of terrorist acts, against the United States homeland, or for any other potential criminal act or threat to public health and safety. The requirements are designed to implement provisions of the Public Health Security and Bioterrorism

Preparedness and Response Act of 2002 (Public Law 107-188). The following is a list of all select agents and toxins that fall under the requirements of the law:

Table 2: Select Agents and Toxins

HHS Select Agents and Toxins	Overlap Select Agents and Toxins
1. Abrin	36. <i>Bacillus anthracis</i> *
2. <i>Bacillus cereus</i> Biovar <i>anthracis</i> *	37. <i>Bacillus anthracis</i> Pasteur Strain
3. Botulinum neurotoxins*	38. <i>Brucella abortus</i>
4. Botulinum neurotoxin producing species of <i>Clostridium</i> *	39. <i>Brucella melitensis</i>
5. Conotoxins (Short. Paralytic alpha conotoxins containing the following sequence X ₁ CCX ₂ PACGX ₃ X ₄ X ₅ X ₆ CX ₇)	40. <i>Brucella suis</i>
6. <i>Coxiella burnetii</i>	41. <i>Burkholderia mallei</i> *
7. Crimean-Congo haemorrhagic fever virus	42. <i>Burkholderia pseudomallei</i> *
8. Diacetoxyscirpenol	43. Hendra virus
9. Eastern Equine Encephalitis virus	44. Nipah virus
10. Ebola virus*	45. Rift Valley fever virus
11. <i>Francisella tularensis</i> *	46. Venezuelan equine encephalitis virus
12. Lassa fever virus	
13. Lujo virus	USDA Select Agents and Toxins
14. Marburg virus*	47. African horse sickness virus
15. Monkey pox virus	48. African swine fever virus
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstituted 1918 influenza virus)	49. Avian influenza virus
17. Ricin	50. Classical swine fever virus
18. <i>Rickettsia prowazekii</i>	51. Foot-and-mouth disease virus*
19. SARS-associated coronavirus (SARS-CoV)	52. Goat pox virus
20. Saxitoxin	53. Lumpy skin disease virus
South American Haemorrhagic Fever viruses:	54. <i>Mycoplasma capricolum</i>
21. Chapare	
22. Guanarito	55. <i>Mycoplasma mycoides</i>
23. Junjin	56. Newcastle disease virus
24. Machupo	57. Peste de petits ruminant virus
25. Sabia	58. Rinderpest virus*
26. Staphylococcal enterotoxins (A, B, C, D, E subtypes)	59. Sheep pox virus
27. T-2 toxin	60. Swine vesicular disease virus
28. Tetrodotoxin	
Tick-borne encephalitis complex (flavi) viruses:	USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins
29. Far Eastern subtype	61. <i>Coniothyrium glycines</i> (formerly <i>Phoma glycinicola</i>)
30. Siberian subtype	62. <i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)
31. Kyasanur Forest disease virus	63. <i>Ralstonia solanacearum</i>
32. Omsk hemorrhagic fever virus	64. <i>Rathayibacter toxicus</i>
33. Variola major virus (Small pox virus) *	65. <i>Sclerophthora rayssiae</i>
34. Variola minor virus (Alastrim)*	66. <i>Synchytrium endobioticum</i>
35. <i>Yersinia pestis</i> *	67. <i>Xanthomonas oryzae</i>
* Denotes Tier 1 Agent	

Anyone at UTHealth who possesses, or intends to possess, any of the listed select agents or toxins must contact Environmental Health and Safety (713-500-8100) before commencement of work. UTHealth must register your laboratory since an entity may not use or possess any select agent or toxin unless it has been granted a certificate of registration by the CDC and/or USDA. For additional information on the select agent and toxin program, please visit CDC's website at <http://www.selectagents.gov/> or contact the Biological Safety Program.

For select agents and toxins, the CDC/USDA has defined an occupational exposure as "any event which results in any person in a registered entity facility or lab not being appropriately protected in the presence of an agent or toxin". This may include reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potential infectious materials that may result from the performance of a person's duties. For example, a sharps injury from a needle being used in select agent or toxin work would be considered an occupational exposure." These exposures should be reported immediately to EH&S for reporting to the CDC/USDA as required by law.

4.7 Dual Use Research of Concern

A subset of research, as defined by the Federal government, which has the greatest potential for generating information that could be readily misused to threaten public health and national security, has been termed "Dual Use Research of Concern, or DURC.

DURC is defined as "life sciences research that, based on current understanding, can be reasonably anticipated 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, agricultural crops and other plants, animals, the environment, material, or national security".

These definitions could potentially encompass some of the current and/or future life sciences research projects at UTHealth; however, the current scope of the policy has been limited to the following 15 biological agents and toxins that are considered select agents. Additionally, there are 7 categories of experiments. Research must involve both a listed agent/toxin and a listed category to be deemed DURC.

Agents and Toxins:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any amount)
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 influenza virus
- Rinderpest virus
- Toxin-producing strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

Categories of Experiments:

- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed above

Work with these agents/toxins under these circumstances requires identification by the PI and additional review by the Institutional Review Entity (IRE). Contact the Biosafety Program if you are planning any work that could be considered to fall under DURC.

5.0 LABORATORY SAFETY EVALUATIONS

5.1 Routine Surveys

The staff of EH&S will conduct routine surveys of all work areas using biological hazards. These routine surveys are intended to serve as review of the practices and procedures, and equipment that should be used in the workplace. The frequency of these surveys will be established based on the level of hazard and the quantity of material being used. Work areas that are found to be non-compliant with the measures set forth in this manual may be evaluated more frequently in order to verify that safety measures are being implemented. Safety discrepancies discovered during routine surveys will be addressed according to the following procedure.

5.2 Response to Non-Compliance

Discrepancies discovered during routine inspection will be addressed in the following manner.

Verbal Notification:

If, during a routine evaluation or inspection, a problem involving biological safety procedures is observed, a verbal recommendation will be provided. If upon receipt of a verbal recommendation, the laboratory staff takes immediate steps to correct the problem, then no further response regarding the discrepancy will be requested.

Written Notification:

Step One:

Following the survey, a written summary of the findings and recommendations including corrections during the survey will be sent to the PI responsible for the laboratory. The PI will then be requested to take corrective action within 30 days. Verbal, e-mail, or written response is requested.

Step Two:

If, a second observation reveals that the same discrepancy exists, notification of this situation may be sent to both the PI and the Department Chair. A **written response**, including specific steps taken to ensure correction of the discrepancy will be sent to EH&S. Discrepancies may be presented to the IBC at the discretion of the Assistant Vice President of EH&S.

Step Three:

If the problem continues, both the PI and the Department Chair will be given a written account of the situation. The entire case history of the event will also be presented to the IBC.

Any operation causing a high or unacceptable risk to employees or personnel exposure to any biological hazard will be suspended immediately by the EH&S without regard to the above procedure. In the event of this action, the situation will be promptly reviewed by the Assistant Vice President of EH&S and the IBC.

6.0 UT EMPLOYEE/STUDENT HEALTH SERVICES

The UT Employee Health Services, located in the University Center Tower, Suite 1620, and UT Student Health Services, located in the UT Professional Building Suite 130, serve as vital components of the Biological Safety Program by helping to protect the health and safety of employees, students and authorized visitors in clinics, research and teaching laboratories. The primary objective of the program is prevention, and early detection of work-related health effects achieved through training, periodic evaluations and immunizations. The major services provided include: pre-placement examinations for designated personnel, immunizations, periodic monitoring evaluations, exit evaluations, maintenance of employee occupational health records, response to exposures, epidemiology, and considerations for other special medical situations.

6.1 Pre-Placement Physical Exams

Pre-placement physical examinations are used to identify any medical condition that might place workers at an increased risk to themselves or others as a result of certain job exposures or activities. If such a condition is identified, the appropriate accommodation will be made. Pre-placement exams are also used to provide a baseline assessment of health status for comparisons to future testing. Some jobs may require that blood serum be collected and stored. In the event of an unusual illness after employment, the baseline serum can be compared to a sample at the time of illness to assist with diagnosing and possibly determining the time of onset of the illness. Currently personnel designated for pre-placement examinations include members of EH&S, CLAMC, Facilities Planning and Engineering.

Pre-placement physical examinations may include the following:

- New employees, students, and authorized visitors are given either basic or comprehensive Health History Forms to complete and return to UT Employee/Student Health Services.
- A UT Employee/Student Health Services healthcare provider (a nurse practitioner or physician) interviews the individual and reviews the Health History Forms with the person to verify and clarify the information.
- A set of tests are established for each type of exposure situation the employee may encounter based on their job description. These exams may include:
 - Laboratory tests including complete hematology, urinalysis, and serum chemistry.
 - Pulmonary function (FEV₁, FVC, FEV₁/FVC)
 - Hearing (500, 1000, 2000, 3000, 4000, 6000, 8000 Hz)
 - Visual Acuity (Near & Far)
- A physical examination
- Information obtained from the above procedures is reviewed by the UT Employee/Student Health Services nurse practitioner or physician who discusses any positive findings with the individual. Persons with evidence of an immunodeficiency process or who are taking immunosuppressive medication will be counseled regarding potential health risks of exposure to infectious material including experimental animals, human tissues, and known pathogens.

- Recommendations for job assignment and accommodations, if necessary, are made to designated persons.
- Currently, serum banking is not performed at UTHealth. Contact UT Employee/Student Health Services to discuss serum banking on a case by case basis, as needed.

6.2 Immunizations and Tuberculosis Surveillance

Employees, students and authorized visitors will be offered immunizations and/or skin tests as indicated for the situation, including:

- Tuberculin skin testing (PPD) repeated annually or as recommended for the situation (i.e. work exposure to TB). Skin tests will be interpreted and managed following the most current CDC guidelines.
- Tetanus vaccine will be administered every 10 years or post-injury if needed per CDC Guidelines.
- Administration of rabies vaccine, if indicated, by possible animal contact.
- Administration of the Hepatitis B vaccine, if indicated, by exposure to human tissues or body fluids.
- Administration of the varicella vaccine, if indicated, by immunization status in relation to possible occupational exposure.

6.3 Periodic Surveillance

Periodic surveillance exams are designed to:

- Detect changes in an individual's health that might indicate the need for a change in job placement or in the work process.
- Educate individuals with regard to health promotion and disease prevention.
- Detect evidence of exposure to infectious agents, and/or exposures to chemical toxins or other physical hazards.

Typical surveillance exams may include the following:

- Annual review and update of health histories
- Annual review and update of immunizations and TB skin tests, as needed
- Repeat of physical exams, as indicated by job, or exposure, and age category
- Completion of laboratory tests, if indicated, by history or new duties
- Collection and storage of serum samples, as indicated

6.4 Exit Evaluations

Exit evaluations may be performed at the termination of employment, schooling or authorized visitation as a basis for comparison to Pre-placement exams. Exit evaluations may include:

- Updating of health history
- Completion of a physical exam unless the employee has undergone a pre-placement or periodic evaluation within 6 months
- Collection of a serum sample for storage to be retained for 10 years

6.5 Employee Health Records

Health records obtained from employees, students and authorized visitors will be kept confidential and maintained in a secure location by the UT Employee/Student Health Services. Access to records will be limited to authorized personnel per state and federal law. Records will not be released to anyone without the individual's written consent, except in situations required by law. All medical and exposure records will be maintained for the duration of the individual's stay, plus 30 years.

6.6 Response to Exposures

Personnel exposures to infectious agents can arise from a variety of incidents, including aerosols, splashes of liquid into mucous membranes or broken skin, percutaneous injury and animal scratches or bites. In the event of any incident of this type involving infectious materials, the immediate response should be directed towards lifesaving. Any bleeding should be controlled, and if possible, the wound(s) should be thoroughly cleaned with hot soapy water and a disinfectant solution.

Any exposure incident involving infectious materials should be reported to the UT Employee/Student Health Services. If exposure occurs after 5:00 p.m. or on a weekend, or holiday, the employee should go to the Memorial Hermann Hospital Emergency Room, if indicated, for wound care or tetanus update. The employee/faculty member should report to UT Health Services as soon as possible on the next working day. A UT Health Services provider can be reached by calling 713-500-3267 or by calling the needlestick hotline at 1-800-770-9206. A Supervisor's First Report of Injury Form must also be completed for reporting to Worker's Compensation and Insurance. All students who sustain an exposure should call the 24-hour Exposure Hotline at 713-500-OUCH.

For select agents and toxins, the CDC/USDA has defined an occupational exposure as: "Any event which results in any person in a registered entity facility or lab not being appropriately protected in the presence of an agent or toxin. This may include reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potential infectious materials that may result from the performance of a person's duties. For example, a sharps injury from a needle being used in select agent or toxin work would be considered an occupational exposure." These exposures should be reported immediately to EH&S for reporting to the CDC/USDA as required by law.

6.7 Other Special Medical Considerations

Allergies:

Individuals with histories of allergies, specifically animal allergies, will be evaluated and advised of the potential health risk of animal exposure.

Reproductive Concern (Pregnancy):

Employees and authorized visitors will be advised to inform UT Employee/Student Health Services staff if they are pregnant or are considering pregnancy, so that they can be counseled on possible work-related risks. It is encouraged for all pregnant employees/authorized visitors to self-report their pregnancy to avoid exposure to specific hazards by considering modified work tasks during the pregnancy.

Disease Outbreak Evaluations:

In the event of a disease outbreak:

- Exposure will be documented.
- Physical examinations will be done as indicated.
- Serum samples will be collected and stored as indicated.
- Lab tests will be done as indicated.
- Appropriate treatment will be given or referral made as needed.

7.0 OCCUPATIONAL HEALTH SERVICES FOR AGENT CATEGORIES

The UT Employee/Student Health Services may require for any specific employee, student or authorized visitor to indicate what agent he/she will be in contact with based on five general categories of infectious materials encountered at UTHealth: infectious microorganisms and/ or vectors used in recombinant or synthetic nucleic acid molecules research, human tissues and body fluids, and experimental animals. In some instances, additional occupational medical services may be necessary in order to provide adequate surveillance. Additional medical surveillance and services may be administered at the discretion of the UT Employee/Student Health Services, with the knowledge and consent of the individual. Confidentiality requirements of medical records or information of the affected person involved must be observed.

7.1 Exposure to Infectious Microorganisms

The UT Employee/Student Health Services routinely provides the following to individuals exposed to infectious microorganisms:

For Risk Group 1 and Risk Group 2 Agents:

- **Health history examinations:** Completion of Basic Health History Form
- **Immunizations and screening:** Tetanus immunization, Hepatitis B vaccine, TB screening
- **Periodic surveillance evaluations:** Annual update of Basic Health History Form
- **Employee health records:** Basic Health History Forms and immunization, screening and serum records maintained in Employee Health Services
- **Response to exposures:** Clean exposed area with soap and water for at least 15 minutes and/or flush mucous membranes with water or saline for at least 15 minutes. Fill out a "Supervisor's First Report of Injury" form. Report to UT Employee Health Services at UCT 1620 (713-500-3267, or after hours at 800-770-9206) for employees, or UT Professional Building Suite 130 (713-500-5171, or after hours at 713-500-OUCH (6824)) for students. A physical examination will be conducted in the event of suspected work-related illness (which may take the form of frequent and /or unusual colds or ailments)).
- **Other considerations:** Basic Health History Form should also be updated to reflect significant changes in health status and be maintained as a confidential medical record. Serum banking may be performed only when recommended by a UT Employee Health Services physician. Currently, serum banking is not performed at UTHealth

For Risk Group 3 Agents, Human Hepatitis (all agents), and Retroviruses from Humans, Nonhuman Primates, Rodents, and Other Vertebrate Species:

The UT Employee Health Services routinely provides the following to individuals exposed to human tissues and body fluids:

- **Health history examinations:** Completion of Comprehensive Health History Form and complete physical examination
- **Immunizations and screening:** Tetanus immunization, Hepatitis B vaccine, TB screening
- **Periodic surveillance evaluations:** Annual update of Comprehensive Health History Form
- **Employee health records:** Comprehensive Health History Form, results of physical examination, and immunization, screening and serum records maintained in UT Employee Health Services
- **Response to exposures:** Clean exposed area with soap and water for at least 15 minutes and/or flush mucous membranes with water or saline for at least 15 minutes. Fill out a “Supervisor's First Report of Injury” form. Report to UT Employee Health Services at UCT 1620 (713-500-3267, or after hours at 800-770-9206) for employees, or UT Professional Building Suite 130 (713-500-5171, or after hours at 713-500-OUCH (6824)) for students. A physical examination will be conducted in the event of suspected work-related illness (which may take the form of frequent and /or unusual colds or ailments). Hepatitis B antibody and HIV antibody testing after counseling with informed consent.
- **Other considerations:** Comprehensive Health History Form should also be updated to reflect significant changes in health status. Serum banking may be performed only when recommended by a UT Employee Health Services physician. Currently, serum banking is not performed at UTHealth

7.2 Exposure to Human Tissues and Body Fluids

The UT Employee Health Services routinely provides the following to individuals exposed to human tissues and body fluids:

- **Health history examinations:** Completion of Basic Health History Form
- **Immunizations and screening:** Tetanus immunization, Hepatitis B vaccine, TB screening
- **Periodic surveillance evaluations:** Annual update of Basic Health History Form

- **Employee health records:** Basic Health History Form, results of any physical examination, and immunization, screening and serum records maintained in UT Employee Health Services
- **Response to exposures:** Clean exposed area with soap and water for at least 15 minutes and/or flush mucous membranes with water or saline for at least 15 minutes. Fill out a “Supervisor's First Report of Injury” form. Report to UT Employee Health Services at UCT 1620 (713-500-3267, or after hours at 800-770-9206) for employees, or UT Professional Building Suite 130 (713-500-5171, or after hours at 713-500-OUCH (6824)) for students. A physical examination will be conducted in the event of suspected work-related illness (which may take the form of frequent and /or unusual colds or ailments). Hepatitis B antibody and HIV antibody testing after counseling with informed consent.
- **Other considerations:** Basic Health History Form should also be updated to reflect significant changes in health status. Confidentiality of medical records must be maintained.

7.3 Exposure to Experimental Animals

The UT Employee/Student Health Services routinely provides the following to individuals exposed to experimental animals:

- **Health history examinations:** Physical examinations will include completion of a Comprehensive Health History Form and physical examination.
- **Immunizations and screening:** Tetanus, measles (if indicated by immunization history), Rabies (if indicated), Hepatitis B (if indicated by exposure to human tissues) immunizations, TB screening.
- **Periodic surveillance evaluations:** Annual update of Comprehensive Health History Form. Tuberculin test annually (semi-annually if indicated) with chest radiograph for positive reactors. Repeat of complete physical examination annually for all Center for Laboratory Animal Medicine and Care (CLAMC) personnel with direct animal contact.
- **Employee health records:** Update of history annually with directed physical and/or laboratory examination if indicated.
- **Response to exposures:** Report to UT Employee/Student Health Services. Complete physical examination if indicated by illness or exposure and at termination of employment. Animals frequently carry significant pathogens as flora of the oral cavity.
- **Other considerations:** Complete Comprehensive Health History Form should also be updated to reflect significant changes in health status. Serum banking is performed only when recommended by a UT Employee/Student Health Services physician. Currently, serum banking is not performed at UTHealth.

8.0 BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

8.1 Purpose

While Texas law allows mandatory testing of a source patient in the event of an accidental exposure, it requires institutions to have written procedures that protect the rights of both source patients and exposed health care workers.

8.2 Definitions

Hazardous Body Fluids: Hazardous body fluids include blood, bloody fluids, and other body fluids which are known or assumed to be associated with the transmission of bloodborne pathogens.

Source Patient: The source patient is from whom the health care worker sustained an exposure of hazardous body fluids.

8.3 Exposure Risk Classifications

Blood Exposure

High Risk: Includes exposure to both large volumes of blood and blood with a known high titer of a bloodborne pathogen.

Increased Risk: Includes exposure to either large volumes of blood or blood with a known high titer of a bloodborne pathogen.

No Risk: Includes neither exposure to large volumes of blood or blood with a known high titer of a bloodborne pathogen.

Skin Exposure

Increased Risk: Exposure involving a known high titer of a bloodborne pathogen, prolonged contact over an extensive area, and/or an area in which skin integrity is visibly compromised.

8.4 Treatment of Exposed Health Care Worker

Immediate Treatment

Immediate treatment is provided to the health care worker at the site where the injury occurred. Immediate treatment consists of the following:

1. Clean exposed area with soap and water for at least 15 minutes.
2. Flush mucous membranes with water or saline for at least 15 minutes.

Notification Procedures for Exposed Health Care Worker

After immediate treatment is completed, the exposed health care worker should call 713-500-3267 (after hours at 800-770-9206) for employees/faculty members or 713-500-5171, (after hours at 713-500-OUCH (6824)) for students/residents to speak with the UTHealth Exposure Coordinator, who will counsel the health care worker and refer him/her for appropriate care.

Early Treatment of Exposures

The exposed health care worker must fill out a "Supervisor's First Report of Injury" form and blood samples are to be obtained prior to administration of any treatment. A blood sample for baseline surveillance should be obtained and sent to the lab prior to being given immune globulin.

Confidentiality of Lab Results

Lab work drawn on an exposed health care worker is identified by an encoded number and not his or her name. The encoded numbers are known only to the exposed health care worker and the designated Exposure Coordinator.

Costs for Lab Studies

The exposed health care worker is not responsible for the laboratory bills related to the accidental exposure occurring during work duties. Employee and Student services will work with the affected individual to cover any associated costs.

9.0 TUBERCULOSIS EXPOSURE CONTROL PLAN

9.1 Purpose

The purpose of the Tuberculosis Control Plan is to reduce the potential of transmission of pulmonary *Mycobacterium tuberculosis* from person to person and to detect tuberculosis exposures (and possible disease contractions) to staff by utilizing a screening process set forth in recommendations by the Center for Disease Control and Prevention in the report, ["Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019"](#). These 2019 Guidelines replace the 2005 Guidelines and address recent changes in health care practice and settings, re-evaluate the risk assessment process, and establish screening and testing procedures for tuberculosis.

9.2 Hierarchy of Control Measures

1. Use of administrative measures to reduce the risk of exposure to persons with suspected or confirmed infectious TB.
2. Use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei.
3. Use of personal respiratory protective equipment.

9.3 Scope

The plan covers all patients, classified employees, staff, faculty, medical staff and educational appointees (including students and volunteers) of UTHealth.

9.4 Risk Assessment for Health Care Workers

An initial risk assessment to evaluate the risk of TB transmission will be done by UT Employee Health Services with the assistance of the IBC and EH&S. This will cover all parts of the facility. This will include all clinics where TB patients may receive care or cough-inducing procedures may be performed, and individual groups of health care workers that work throughout the facility.

The purpose of this assessment is to provide guidance on controls to be taken, and frequency of staff screening for exposure to tuberculosis. Each specific area and occupational category will be classified as low, medium or potential ongoing transmission (high) risk based on factors outlined above. Reference 2019 CDC Guidelines for all occupational categories that will be included in the risk assessment. Risk assessments and health care worker exposure will be reviewed annually.

Low Risk

Applies to settings in which persons with TB disease are not expected to be encountered, and therefore, exposure to *M. tuberculosis* is unlikely. Health care workers will never be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.

Medium Risk

Applies to settings in which the risk assessment has determined HWCs will or will possibly be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.

Potential Ongoing Transmission Risk (High Risk)

Applies to any setting (or group of HCWs) where there is evidence that suggests person-to-person (e.g., patient-to-patient, patient-to-HCW, HCW-to-patient, HCW-to-HCW) transmission of *M. tuberculosis* in a setting during the preceding year. Evidence of person-to-person transmission of *M. tuberculosis* includes 1) clusters of TST or BAMT conversions, 2) HCW confirmed TB disease, 3) increased rates of TST or BAMT conversions, 4) unrecognized TB disease in patients or HCWs, or 5) recognition of an identical strain of *M. tuberculosis* in patients or HCWs with TB disease identified by DNA fingerprinting.

The frequency of risk assessment and skin testing will be determined on the basis of the most recent risk assessment. Low risk groups will be assessed upon employment and reassessed only if exposure occurs, medium risk groups every 12 months, and potential ongoing (high) risk groups as often as necessary.

Representatives of the IBC will inspect the facility, review data, and make recommendations regarding changes in the TB Exposure Control Plan at least annually or as necessary to update the plan in response to documented nosocomial transmission of TB.

Following each risk assessment, the IBC, in conjunction with other appropriate health care workers will review all TB Control policies to assure that they are effective and meet current needs.

Analysis of Health Care Workers TB Skin Test Screening Data:

Results of employee TB (PPD testing will be kept by the Occupational Health Program in a retrievable aggregate database

PPD conversion rate will be calculated as follows:

A = # health care worker with new positive skin tests in each area or group

B = # health care workers with negative skin tests in each area or group

$$\% \text{ Conversion} = \frac{A}{A+B} \times 100$$

To identify areas where the risk of occupational PPD test conversion may be increasing, PPD test conversion rates for each area will be compared to rates in areas without occupational exposure to active TB and to previous rates in the same area.

- Any time a cluster of PPD test conversions is noted, further evaluation is indicated.
- The frequency of PPD testing is determined by the risk assessment.
- Areas in which cough-inducing procedures are performed on patients who may have active TB will, at the minimum, be considered intermediate risk.

Review of Patient Medical Records:

The medical records of patients diagnosed with active TB will be reviewed for the risk assessment and to determine whether any employee exposures occurred.

Case Surveillance:

Data on the number of active TB cases among patients and health care workers will be collected, reviewed and used to:

- Identify the number of isolation rooms required.
- Recognize clusters of nosocomial transmission.
- Assess the level of potential occupational risk.
- Monitor drug susceptibility characteristics of *M. tuberculosis* isolates.

Observation of Infection Control Practices:

1. Compliance is considered to be a standard of performance and will be included in the annual performance evaluation for all employees with potential for exposure.
2. Recommended practices are stated in this plan, copies of which are located in each department in the safety manual.
3. Strategies for monitoring of compliance:
 - a. Follow-up on the report of an employee's failure to comply with the required protective measures will be the responsibility of the employee's supervisory staff.
 - b. Follow-up of problems identified through informal reports, complaints from staff, quality assurance or safety reports, minutes from committees, employee questionnaires, staff logs, and comments received during evaluation of education and training programs will be the responsibility of the affected department's supervisory staff. Significant issues will be forwarded to the IBC.

Noncompliance will be reported to an employee's immediate supervisor for evaluation and follow-up.

9.5 Administrative Controls

1. Initial assessment:

Patients will be assessed for possible infectious TB at the site of initial presentation (Emergency Center, Outpatient clinics, Observation areas, etc.) following the procedure for handling suspected TB patients. Health care workers who are the first points of contact should ask the following questions, which will help recognize and detect patients with signs and symptoms suggestive of TB:

- a. Have you had a cough of two or more weeks duration?
- b. Has this cough been productive of sputum? Is it blood stained?
- c. Have you had fever, night sweats, unintentional weight loss, lethargy or weakness?
- d. Do you or any of your family have TB now, or a history of TB?

At this time, it should be determined if a patient is a member of a high-risk group.

For those patients whose assessments indicate suspected infectious TB, follow established TB protocol for proper actions.

2. Physician Referral:

Referring physicians or facilities should be questioned as to the patient's possible TB status, in order to facilitate the patient's admission into appropriate isolation and care.

3. Bacteriologic Screening:

Harris County TB Control will be notified of all positive AFB direct smears and cultures.

4. Management of Pediatric Patients with Known or Suspected Infectious TB:

1. Pediatric patients with suspected or confirmed TB should be evaluated for potential infectiousness on the basis of symptoms: sputum AFB smears, radiologic findings, and other criteria. Those with cavitary pulmonary or laryngeal TB should be placed in Airborne Infection Precautions until they are determined to be non-infectious.
2. Parents and relatives of pediatric patients suspected of having TB should be assessed as soon as possible for the presence of TB and should be asked to wear an N95 respirator at all times when in the facility until their status is known.
3. Parents should have chest x-rays and PPD tests placed and it should be documented that they are not considered to be infectious before they may discontinue use of a N95 respirator.

5. Management of Patients with Suspected Tuberculosis in Ambulatory Care Settings and Emergency Centers:

1. Refer to Administrative Controls initial assessment section.
2. Place patient with suspected infectious TB in Airborne Infection Isolation in separate negative pressure room or demistifier tent if available. If separate waiting/exam room is

unavailable or if patient requires transportation to ancillary departments, patient should wear a N95 respirator.

3. Schedule patient to minimize exposure to other patients.
4. Patients should be instructed to use cough etiquette by covering their mouth with tissues if it is necessary for them to clear respiratory secretions, and to then reapply the N95 respirator. Patients should also be told how to dispose of the tissues in appropriate waste receptacle.
5. If patients are known to be non-compliant with TB medications, institute Airborne Infection Precautions until they are documented to be non-infectious.
6. Patients with previously diagnosed TB infections should be considered to be infectious until the physician determines otherwise.

6. PPD Tuberculin Skin Testing:

1. Administration of tuberculin test (Mantoux):
 - a. 0.1 ml of PPD will be injected into either the volar or dorsal surface of the arm. (Anergy panels should be ordered in addition to PPD testing for immunocompromised patients where TB is suspected.)
 - b. Tuberculin is injected just beneath the surface of the skin.
 - c. Discrete, pale elevation of the skin 6-10 mm should be produced.
2. Reading of the skin test
 - a. Trained personnel will read the test between 48-72 hours and record results on the appropriate form, which will then be placed in the patient's chart.
 - b. Presence or absence of induration is to be assessed, (not redness or erythema), and should be recorded in millimeters.

7. Treatment Guidelines:

Patients who have confirmed active TB or are considered highly likely to have active TB should be started on appropriate treatment promptly, according to current guidelines.

While the patient is in the hospital, anti-tuberculosis drugs will be administered by directly observed therapy, in which a health care worker observes the patient ingesting the medications. All patients should be discharged on outpatient directly observed therapy. Arrangements for this will be made in collaboration with the Harris County TB Control Department at 713-439-6215.

8. Cough-Inducing Procedures:

1. Cough-inducing procedures should not be performed on patients who may have infectious TB unless absolutely necessary. These cough-inducing procedures include endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (including pentamidine therapy), and bronchoscopy. Other procedures that may generate aerosols, e.g. irrigation of TB abscesses, homogenizing or lyophilizing tissue, are also included in these recommendations.

2. All cough inducing procedures performed on patients who may have infectious TB should be performed using local exhaust ventilation devices, e.g. booths, or if that is not feasible, in a negative air flow room that meets TB ventilation requirements (i.e. airborne infection isolation rooms).
3. Health care workers should wear a N95 respirator present in rooms where cough-inducing procedures are being performed on patients who have, or are at high risk of having infectious TB.
4. After completion of cough-inducing procedures, patients with known or suspected TB should remain in the airborne infection isolation room or enclosure and not return to common waiting areas until coughing subsides. They should be given tissues and instructed to cover their mouth and nose when coughing. If they must recover from their sedatives or anesthesia following procedures such as bronchoscopy, they should be monitored in a separate airborne infection isolation room, and not in recovery rooms with other patients.
5. Before the booth, enclosure, or room is used for another patient, adequate time should be allowed to pass so that any droplet nuclei that have been expelled into the air are removed. This time will vary according to the efficiency of the ventilation or filtration used, but is generally 20 minutes.
6. If performing bronchoscopy in positive pressure rooms, such as operating rooms, if unavoidable, TB infection should be ruled out before the procedure. If bronchoscopy is being performed for diagnosis of pulmonary disease on patients that may have infectious TB, it should be performed in a room that meets TB isolation ventilation requirements.
7. Before prophylactic aerosolized pentamidine therapy is initiated, all patients should be screened for active TB. Screening should include medical history, PPD, and chest x-ray.
8. Before each subsequent aerosolized pentamidine treatment, patients should be screened for symptoms suggestive of TB. If such symptoms are elicited, a diagnostic evaluation for TB should be initiated.
9. For patients with suspected or confirmed active TB, it is preferable to use oral instead of aerosolized, prophylaxis for pneumocystic pneumonia if clinically practical.
10. Harris County TB Control Center should be notified (713-599-3600) for contact investigation prior to discharge; especially when children are in the household.

Any required infection control measures must be followed to ensure compliance with the OSHA standards and/or current guidelines for preventing the transmission of *M. tuberculosis*.

9.6 Engineering Controls

1. Prevention of nosocomial transmission. Patient rooms and areas where patients with suspected or confirmed TB are treated should be at negative pressure to adjacent areas, have at least 6 air changes per hour, be directly exhausted to the outside or have air recirculated through a HEPA filtration system with 99.7% filtration. Patient isolation rooms are required to have negative pressure relative to the surrounding areas.

2. Monitoring of isolation rooms for negative pressure when used for TB isolation should be done routinely, per current guidelines or standards.
3. HEPA filters should be monitored and changed routinely, per current guidelines or standards.
4. The need for supplemental ventilation or air cleaning will be periodically reassessed as a part of the risk assessment.

9.7 Respiratory Protection

1. In the following circumstances, health care workers should wear a NIOSH approved high efficiency particulate air (HEPA) respirator or an approved N-95 respirator:
 - a. When entering rooms housing patients with suspected or confirmed infectious TB
 - b. When performing high risk procedures on patients who have suspected or confirmed infectious TB. Examples of these include administration of aerosolized medications, bronchoscopy, sputum induction, endotracheal intubation and suctioning procedures, and autopsies.
 - c. Emergency medical response personnel or others who must transport, in a closed vehicle, an individual with suspected or confirmed infectious TB.
2. Qualitative or quantitative fit testing must be performed for each respirator wearer. The results of such fit testing must be maintained in a retrievable aggregate database.
3. Medical surveillance will be performed on all potential HEPA respirator wearers.
4. Disposable HEPA respirators should be discarded per hospital policy current guidelines.
5. Multi-user reusable HEPA respirators should be cleaned and filters checked and/or changed per hospital policy or current guidelines.
6. Designated user reusable HEPA respirators should be cleaned and filters checked and/or changed per hospital policy or current guidelines.
7. HEPA respiratory wearers should perform check to insure proper fit prior to each use.
8. Facial hair that interferes with the seal of the mask must be removed.

9.8 Health Care Workers Tuberculosis Screening Program

Health care workers should have a two-step Tuberculin Skin Test or a single BAMT infection with *M. tuberculosis* upon employment and at appropriate intervals as determined by UT Employee/Student Health Services. The 2019 Guidelines introduce the term “tuberculin skin

tests” (TSTs) which is used to include optional testing systems in addition to the purified protein derivative (PPD). The additional test system is the use of whole-blood interferon gamma release assay (IGRA), QuantiFERON® TB Gold test (QFTG) (Cellestis Limited, Carnegie, Victoria, Australia), which is a Food and Drug Administration (FDA) approved in vitro cytokine-based assay for cell-mediated immune reactivity to *M. tuberculosis* and may be used instead of TST in TB screening programs for HCWs. This IGRA is an example of a blood assay for *M. tuberculosis* (BAMT). BAMT does not require two-step testing and is more specific than skin testing. BAMT that uses *M. tuberculosis* specific antigens (e.g., QFT-G) are not expected to result in false-positive results in persons vaccinated with BCG. Baseline test results should be documented, preferably within 10 days of HCWs starting employment.

9.9 Health Care Workers with TB Infection or Active Disease

Health care workers with baseline positive or newly positive TST or BAMT result should receive one chest radiograph to exclude a diagnosis of TB disease. Such HCWs should be excluded from the workplace and should be allowed to return to work when the following criteria have been met: 1) three consecutive sputum samples collected in 8–24-hour intervals that are negative, with at least one sample from an early morning specimen (because respiratory secretions pool overnight); 2) the person has responded to anti-tuberculosis treatment that will probably be effective (can be based on susceptibility results); and 3) the person is determined to be non-infectious by a physician knowledgeable and experienced in managing TB disease.

If TB disease is excluded, offer HCW treatment for LTBI in accordance with published guidelines. HCWs receiving treatment for LTBI can return to work immediately.

Health care workers with infectious TB should notify UT Employee/Student Health Services and be excluded from work until documented to be noninfectious and substantial improvement in symptoms. Clearance from Student and Employee Health is required to return to work. UT Employee/Student Health Services will monitor compliance with medications. Noncompliant health-care workers should be excluded from work until therapy is re-instituted and the individual assessed to be noninfectious.

Health care workers with TB at sites other than the lung or larynx usually do not need to be excluded from work if concurrent pulmonary TB has been excluded (except exuding skin lesions).

All information provided by health care workers regarding their health status will be treated confidentially.

10.0 NONHUMAN PRIMATE EXPOSURE PROCEDURES

Standard Operating Procedure for Employee Injury Resulting from Monkey Bites, Scratches, Sticks with Contaminated Needles, or Other Wounds.

All employees and trainees working with macaques and/or any workers who have the potential for exposure to *Macacine herpesvirus -1* (herpes B virus, B virus, cercopithecine herpesvirus 1) will be educated about the exposure risks and response protocol associated with B virus.

If you are injured as a result of a monkey bite, scratch, other wound, or a monkey cage associated injury proceed with the following procedures. These procedures are also outlined in a NHP response take away sheet that is in all Macaque Exposure Kits.

Procedure for Macaque Exposures (Herpes B Precautions in Event of Macaque Bite or Scratch, Injury from NHP Cage, or any contact of macaque secretions on exposed skin or membranes):

1. Stop what you are doing and immediately locate the Macaque Exposure Kit.
2. For **eye splash or splash to mucus membranes** immediately flush exposed area with spray saline found in the Macaque Exposure Kit until you are able to locate an eye wash station. Flush eyes for a total of **at least 15** minutes.
3. Scrub the wound for a **minimum of 15 minutes total time**. Start with the powdered "Tide with Bleach" container labeled "Step 1". Work the powder into the wound, rinsing frequently, for at least five minutes to denature the virus. Then proceed to the dedicated Betadine scrub sponge that is labeled "Step 2" and scrub vigorously for an additional ten minutes. Culture the wound with a Collection-Eze swab after the scrub is finished or call someone to do it for you. (Please note: The scrubbing of Step 1 and Step 2 are self-evident and can be completed before consulting the written procedure if necessary.)
4. Notify Occupational Health of the exposure at 713-500-3267, (or after hours at 800-770-9206) and proceed to 7000 Fannin, UCT Suite 1620, Houston TX 77030 for post-exposure care, prophylaxis, and blood draw. Memorial Hermann Hospital is the designated after-hours emergency room location for treatment. Proceed to the MHH ER after contacting the Occupational Health on-call provider to inform them of the incident.
5. Notify the CLAMC veterinary staff and your supervisor of the exposure. Call 713-500-7728 to notify a veterinarian to assess status of the macaque involved.

Procedure for Post Exposure Sample collection:

1. Occupational Health will collect a blood sample from the exposed person immediately following the incident. Follow above described procedures.
2. CLAMC will collect a blood sample from the NHP involved in the incident.

Macaque Exposure Kit Contents

1. **Concise Instructions:** Step by step numerical instructions individualized for each institution
2. **Container for "Tide with Bleach"** prominently marked "Step 1" with shortened directions for 5-minute scrub
3. **Betadine Scrub Sponge** prominently marked "Step 2" with shortened directions for additional 10-minute scrub
4. **Ketamine:** 1 bottle or single dose drawn up in syringe for adequate macaque restraint
5. **Culture Swabs:** A minimum of 6 Collection-Eze or similar swab for viral culture (3 for macaque cultures, 2 for human wound cultures plus 1 extra).
6. **Syringes and Needles:**
 - a. Syringe and needle for Ketamine injection of primate
 - b. Syringe and needle for primate blood collection
 - c. Syringe and needle for human blood collection
 - d. Extra syringes and needles in case needed
7. **Alcohol Wipes:** Individually packaged wipes for venipuncture site preparation
8. **Blood Tubes:** A minimum of 3 serum separator tubes (1 for macaque, 1 for human plus 1 extra), also 2 non-breakable serum tubes for shipment.
9. **Permanent Marker** for tube labels and pen for submission form.
10. **Shipping Labels** and waterproof plastic envelope for enclosure of submission form with shipment.
11. **Styrofoam Shipping Container** with ice pack or dry ice (ice packs should be in a designated freezer)



Due to the possibility of time constraints such as a submission deadline, kit supplies should be located so as to expedite the collection and shipping of the samples.

REMEMBER, HUMAN BLOOD IS TREATED AS A BIOLOGICAL HAZARD. REPLENISH MACAQUE EXPOSURE KIT AFTER USE.

**SUBMISSION [FORM](#) FOR *HERPESVIRUS SIMIAE* DIAGNOSIS
(CENTER FOR LABORATORY ANIMAL MEDICINE AND CARE)**

APPENDIX 1: Environmental Health and Safety Policies and Guidelines

SAFETY HEALTH ENVIRONMENT AND RISK MANAGEMENT

BIOLOGICAL SAFETY PROGRAM

THE HANDBOOK OF OPERATING PROCEDURES (HOOP) POLICIES RELATED TO SAFETY AND HEALTH

2	<u>Campus Security</u>
79	<u>Purchase of Drugs, Pharmaceuticals and Controlled Substances</u>
85	<u>Controlled Access Status for Emergency, Disaster or Severe Weather</u>
86	<u>Medical Emergencies, Minor Injuries/Illnesses</u>
87	<u>Reporting Criminal Activity to Campus Police</u>
88	<u>Building Pathways Use</u>
89	<u>Environmental Management and Hazardous Waste Disposal</u>
90	<u>Safe Use of Potentially Hazardous Materials in the Laboratory</u>
95	<u>Research Training</u>
141	<u>Emergency Management and Business Continuity Plans</u>
157	<u>Tuberculosis Infection Control</u>
158	<u>Bloodborne Pathogen Infection Control</u>
164	<u>Minors in the Workplace</u>
173	<u>Substance Abuse</u>

EH&S HEALTH AND SAFETY RELATED GUIDELINES

[Institutional Biosafety Committee Policy](#)
[PI Responsibilities with rDNA](#)
[Dual Use Research of Concern Policy](#)
[Biosafety Cabinet Guidance Document](#)
[IBC Protocol Application Guidance](#)
[NIH Guidelines for PIs at a Glance](#)
[Chemical Hygiene Plan](#)
[Hazardous Waste Disposal Procedures](#)
[Radiation Safety Manual](#)

APPENDIX 2: IBC Protocol Application Instructions

INSTITUTIONAL BIOSAFETY COMMITTEE PROTOCOL APPLICATION FORM INSTRUCTIONS

Any use of microbiological/infectious agents and/or recombinant or synthetic nucleic acid molecules in research, must be reviewed and approved or exempted by the Institutional Biosafety Committee (IBC) before the procedure is initiated. The CDC/NIH manual entitled "[Biosafety in Microbiological and Biomedical Laboratories, 5th edition](#)" contains safe practices and laboratory requirements for research using microbiological agents. The NIH "[Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(April 2019\)](#)" contains requirements for protocol review and safe practices for work involving recombinant or synthetic nucleic acid molecules.

The [UTHealth Environmental Health & Safety's \(EH&S\) Biological Safety Program](#) is available to help with completion of these forms or to answer any question you may have. You can reach the Environmental Health & Safety Biological Safety Program at 713-500-8170.

USING THE ONLINE PROTOCOL SUBMISSION FORM:

Provide as much information as possible where requested. Determine what biosafety level the protocol calls for (BSL-1, 2, or 3). Note that microbiological agents classified as BSL-1 are exempt from committee review. Assistance with determining your biosafety level can be obtained by contacting the EH&S Biological Safety Program. All levels of Recombinant or Synthetic Nucleic Acid Molecules work require notification and/or approval to the Institutional Biosafety Committee. Complete the necessary information as best you can and contact the Biological Safety Program (713-500-8170) with any questions.

REQUIRED MATERIALS:

1. Completed Protocol Application.
2. A copy of the research protocol or standard operating procedures (SOPs) which should include practices to ensure safety and health in the laboratory. These can be attached in the online submission system.
3. Copies or citations of any relevant articles. These can be attached in the online submission system.

A memorandum of understanding and agreement (MUA) form will be generated by EH&S following submission of above materials and prior to submission to the IBC committee.

IBC MEETING DATES: Second Thursday of every month. Contact EH&S for time and location.

SUBMISSION DEADLINE: 1st week of the month to ensure committee review the following month to facilitate review and preparation. For example: Submit by June 5th to ensure review by the IBC at the July meeting. We will work with investigators to meet any and all grant deadlines whenever feasible.

ONLINE PROTOCOL SUBMISSION LINK: <https://safety-assistant.uth.edu/EHSAQuestionnaire/EHSAWebisapi.dll?protocol=BIO>

ONCE APPROVED: Protocols are granted approval for a period of five years, but will be reviewed on an annual basis. An annual protocol review form will be distributed to you each August.

CHANGES IN METHODS, MICROBIOLOGICAL AGENT/ RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES, OR PERSONNEL: Protocol changes may be submitted to EH&S at any time. Apply through the online protocol submission system, referencing the Institutional Biosafety Safety Committee registration number. If changes are extensive, include a new set of forms.

IMPORTANT NOTICE TO PRINCIPAL INVESTIGATOR APPLICANTS

The Principal Investigator (PI) is the individual who submits the application to employ biological agents or recombinant or synthetic nucleic acid molecules in his or her work. This individual is responsible for

adherence to all guidelines and regulations. The PI is also fully responsible for the safe use of such agents by themselves and those under his or her direction. Other specific responsibilities of the PI are described in the UTHealth Biological Safety Manual and HOOP policies.

Dual use organisms or select agents/toxins will require additional information and review. Please refer to the dual use research of concern guidance document.

Agents:

- ✓ Avian influenza virus (highly pathogenic)
- ✓ *Bacillus anthracis*
- ✓ Botulinum neurotoxin (in any amount, exempt quantities from 42 CFR Part 73 are not recognized by this policy)
- ✓ *Burkholderia mallei*
- ✓ *Burkholderia pseudomallei*
- ✓ Ebola virus
- ✓ Foot-and-mouth disease virus
- ✓ *Francisella tularensis*
- ✓ Marburg virus
- ✓ Reconstructed 1918 influenza virus
- ✓ Rinderpest virus
- ✓ Toxin-producing strains of *Clostridium botulinum*
- ✓ Variola major virus
- ✓ Variola minor virus
- ✓ *Yersinia pestis*

Categories of Experiments:

- ✓ Enhances the harmful consequences of the agent or toxin
- ✓ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- ✓ Confers to the agent or toxin resistance to clinically and/or agriculturally useful
- ✓ Prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- ✓ Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- ✓ Alters the host range or tropism of the agent or toxin
- ✓ Enhances the susceptibility of a host population to the agent or toxin
- ✓ Generates or reconstitutes an eradicated or extinct agent or toxin listed above

REPORTING LABORATORY INCIDENTS INVOLVING rDNA OR NONCOMPLIANCE WITH THE NIH GUIDELINES:

Lab incidents or illness involving recombinant or synthetic nucleic acid molecules or noncompliance with the *NIH Guidelines* may be brought forward by any person, and should be promptly reported to E&HS (713-500-8100) for investigation and reporting of the incident to the National Institutes of Health Office of Science Policy and the Institutional Biosafety Committee if required.

UTHealth must report any significant problems or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH within 30 days. Examples include needlesticks or mucous membrane exposure to material containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet.

Spills and accidents which result in either 1) overt exposures to risk group 2 (RG2) organisms or 2) overt or potential exposures to risk group 3 (RG3) organisms containing recombinant or synthetic nucleic acid molecules must be immediately reported to EH&S (713-500-8100) for investigation and reporting of the incident to the National Institutes of Health Office of Science Policy, and the Institutional Biosafety Committee, if required. Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained.

APPENDIX 3: Relevant Documents and Websites (NIH Guidelines, CDC/BMBL, etc.)

RELEVANT DOCUMENTS

The following documents can be accessed via the internet at the websites below or by calling EH&S at 713-500-8100.

National Institutes of Health, [Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(April 2019\)](https://osp.od.nih.gov/biotechnology/nih-guidelines/)

Website address: <https://osp.od.nih.gov/biotechnology/nih-guidelines/>

Biosafety in Microbiology and Biomedical Laboratories, 5th Edition, (December 2009).

Website address: <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>

SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus. Infection Control and Hospital Epidemiology. March 2010, 31(3).

Website address: <https://www.shea-online.org/index.php/practice-resources/2015-04-25-18-30-42/guidelines-under-review/412-guideline-for-management-of-healthcare-workers-who-are-infected-with-hepatitis-b-virus-hepatitis-c-virus-and-or-human-immunodeficiency-virus>

OSHA Bloodborne Pathogen Standard, 29 CFR, Part 1910.1030

Website address:

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS

TAC Bloodborne Pathogen Standard, Title 25, Part 1, Chapter 96

Website address:

[https://texreg.sos.state.tx.us/public/readtac\\$ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=96](https://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=96)

RELEVANT WEBSITES

Federal Select Agent Program

Website address: <https://www.selectagents.gov/index.html>

TX-DSHS Bloodborne Pathogens

Website address:

https://www.dshs.texas.gov/idcu/health/infection_control/bloodborne_pathogens/plan/

APPENDIX 4: Environmental Health and Safety Numbers

Environmental Health & Safety, OCB 1.330

Environmental Health & Safety Main Office and
Institutional Biosafety Committee Administration 713-500-8100

Environmental Health & Safety Office Fax 713-500-8111

Biological Safety Program, CYF G.102

Biological Safety Main Office 713-500-8170

Biological Safety Office Fax 713-500-5841

Chemical Safety Program, CYF G.102

Chemical Safety Main Office 713-500-5832

Chemical Safety Office Fax 713-500-5841

Environmental Protection Program, OCB 1.330

Environmental Protection Main Office 713-500-8100

Hazardous Waste Pick-up Voice Mail Box 713-500-5837

Radiation Safety Program, CYF G.102

Radiation Safety Main Office 713-500-5840

Radiation Safety Office Fax 713-500-5841

Occupational Safety and Fire Protection, OCB 1.330

OSFP Main Office 713-500-8100

OSFP Office Fax 713-500-8111

After Hours Emergencies (24 hour) 713-792-2890 or 911