



THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON

INSTITUTIONAL BIOSAFETY MANUAL

including
Bloodborne Pathogens Exposure Control Plan
and Tuberculosis Exposure Control Plan

September 2007

PREFACE

The objective of The University of Texas Health Science Center at Houston'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 DNA.

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 (4th edition), the NIH Guidelines for Research Involving Recombinant DNA Molecules (April 2002), 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 The University of Texas Health Science Center at Houston's health and safety policies. Many of the items in this manual are addressed in the periodic Basic Laboratory and Clinic 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 DNA, 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 DNA must be familiar with the requirements set forth in this manual and applicable guidelines of the CDC, NIH, and OSHA, and must conduct their operations in accordance with them.

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- Appendix 1: Environmental Health and Safety Directives
- Appendix 2: Institutional Biosafety Committee Application Forms
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1.0 INTRODUCTION

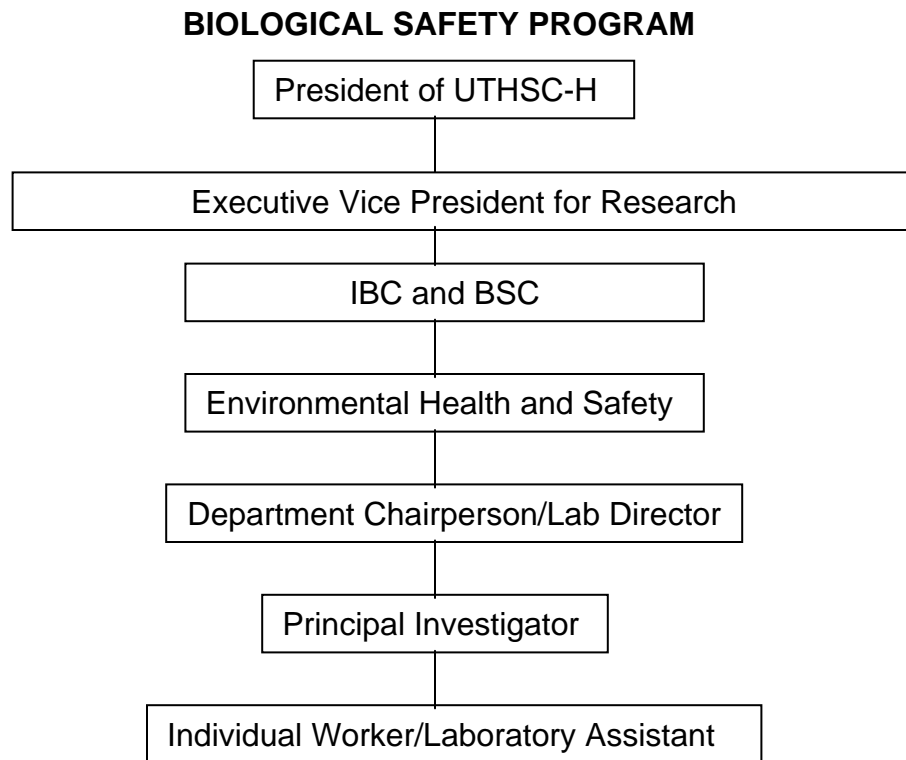
Any work performed at The University of Texas Health Science Center at Houston (UTHSC-H) involving agents of known or potential pathogenicity for humans, animals, or plants must be conducted in a manner that affords protection to workers, animals, and the surrounding community and environment. The Environmental Health & Safety Biological Safety Program at UTHSC-H was established to ensure that adequate administrative and operational protection measures are in place. The UTHSC-H Biological Safety Program, which consists of the Institutional Biosafety Committee (IBC) and Biological Safety Committee (BSC), 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 DNA, or working in a patient care setting at UTHSC-H. 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.
- Serve as the Bloodborne Pathogens Exposure Control Plan and Tuberculosis Exposure Control Plan for UTHSC-H.
- Prescribe the use of medical surveillance and preventive procedures such as health histories and vaccinations.
- Provide the worker with a reference so as 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 UTHSC-H has directed the development of a comprehensive Biological Safety Program with the Executive Vice President for Research as the responsible administrator. The Institutional Biosafety Committee, Biological Safety Committee, and EH&S are responsible for ensuring a quality Biological Safety Program for UTHSC-H. The Institutional Biosafety Committee and Biological Safety Committee are authorized by the President to review and approve proposals and laboratory activities that utilize rDNA

and biological hazards. EH&S provides 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 UTHSC-H 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 Institutional Biosafety Committee or Biological Safety Committee. If the Committee, 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 reports to the Executive Vice President for Research on matters related to the use of recombinant DNA in research, clinical, and educational activities at UTHSC-H. EH&S is the monitoring and the enforcement arm of the Institutional Biosafety Committee (IBC).

Specific committee charges include the following:

To recommend to the Executive Vice President for Research policies and procedures to ensure the health and safety of all individuals within UTHSC-H, and to ensure compliance with all applicable federal, state and local statutes, regulations, procedures and principles relating to the purchase, storage, use, and disposal of rDNA biological agents used in UTHSC-H research, clinical and educational programs.

To review the protocols provided by principal investigators, clinical directors or laboratory instructors relating to the use of rDNA biological agents. To review the activities of EH&S in certifying the appropriate biosafety containment level of those laboratories, clinics and/or practices. Activities identified as Biosafety Level 2 and greater may not initiate without written consent of the IBC.

To recommend to the Executive Vice President for Research the need for general and specific training programs for research, clinical and teaching activities dealing with rDNA biological agents, and to review the appropriateness and effectiveness of such UTHSC-H training programs.

To submit reports at least annually, to the Executive Vice President for Research summarizing activities and reviewing the status of significant rDNA biological safety issues identified during the year.

Biological Safety Committee

The Biological Safety Committee reports to the Executive Vice President for Research on matters related to the use of biological hazards in research, clinical, and educational activities at UTHSC-H. Biological hazards are defined as potentially infectious microorganisms, human tissues 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 effector arm of the Biological Safety Committee (BSC).

Specific committee charges include the following:

To recommend to the Executive Vice President for Research policies and procedures that ensure the health and safety of all individuals within UTHSC-H, and to ensure compliance with all applicable federal, state and local statutes, regulations, procedures and principles relating to the purchase, storage, use, and disposal of biological hazards used in UTHSC-H research, clinical and educational programs.

To review the protocols provided by principal investigators, clinical directors or laboratory instructors relating to the use of biological hazards and to review the activities of EH&S in certifying the appropriate biosafety containment level of those laboratories, clinics and/or practices. Activities identified as Biosafety Level 2 and greater may not initiate without written consent of the BSC.

To recommend to the Executive Vice President for Research the need for general and specific training programs for research, clinical and teaching activities dealing with biological hazards, and to review the appropriateness and effectiveness of such UTHSC-H training programs.

To submit reports at least annually, to the Executive Vice President for Research summarizing activities and reviewing the status of significant biological safety issues identified during the year.

The Infectious Diseases Review Panel

The BSC has assumed the responsibilities formerly held by the Infectious Diseases Review Panel which 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 and to determine those circumstances, if any, under which a student, researcher, or health care worker who is infected may perform such procedures.

To recommend to the Executive Vice President for Research infectious disease control policies and procedures to ensure the health and safety of all patients, staff and faculty of UTHSC-H.

To recommend to the Executive Vice President for Research policies and procedures to ensure UTHSC-H 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.

Environmental Health and Safety

The Biological Safety Manager serves under the Director of Environmental Health and Safety. He manages the Biological Safety Program with the assistance of the technical staff and administrative staff.

The responsibilities of EH&S are to:

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 BSC or 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 BSC and IBC and the UTHSC-H 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 UTHSC-H.

Serve as an ex-officio member of the BSC and 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 BSC or 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 Registration regulations as described in 42 CFR 73; and with other regulations as they are 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 BSC or IBC through EH&S prior to construction or modification.

Notify EH&S of any transfer of infectious agents to or from UTHSC-H.

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 clinical safety and refresher training is provided by EH&S. Several EH&S courses are offered during the calendar year and are available on-line. To supplement this training, videotapes and printed materials are also available. Specifics on any of these resources may be obtained by contacting EH&S at 713-500-8100 or visiting our website at www.uth.tmc.edu/safety.

1.4 Application for Approval to Use Hazardous Biological Agents

Various governmental agencies are involved in controlling the use of biological agents. Governmental controls exist in the form of both recommendations and regulations. To ensure compliance with the various administrative control measures, UTHSC-H has established formalized procedures for obtaining approval to use rDNA and potentially infectious agents. PIs are required to develop and ensure that laboratory safety procedures are followed in the workplace. A Memorandum of Understanding and Agreement (MUA) is necessary in order to use biological agents or rDNA:

Use of Infectious Microorganisms: A MUA and a completed Risk Assessment Summary Form (see Appendix 2) must be submitted to the BSC for any planned work with agents of Risk group 2 or that require Biosafety Level 2 containment or greater. Applications must be approved by the BSC prior to introducing the organism into the workplace.

NIH Use of Recombinant DNA 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 DNA Molecules* (see Appendix 3) require the submission of a completed MUA which is not reviewed by the IBC but remains on file for reference. In contrast, the **use of “non-exempt” molecules** requires the submission of a completed MUA to the IBC for review. Studies in category III-A through III-D require committee approval before work is initiated. Studies in category III-E require committee notification

simultaneously with work initiation. The Biological Safety Program is available to help classify your work with rDNA.

Use of Human Tissues and Body Fluids: Filing of an MUA with EH&S 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, 4th Edition* publication, 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 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 have been shown to carry agents infectious for humans and, therefore, laboratory safety plans should be developed with the assistance of the Executive Director, Center for Laboratory Animal Medicine and Care for all projects that use animals. The **MUA form** must be submitted to the BSC or 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, or use of retroviruses and other infectious organisms from any species** along with appropriate approval from the Animal Welfare Committee.

Use of CDC/USDA Select Agents: Any work to be conducted with a CDC/USDA Select Agent organism must be approved by the IBC or BSC and one of the Responsible Officials within Environmental Health & Safety prior to acquiring or working with the select agent. The PI and EH&S will have to meet *prior* to work commencement to set-up and equip the laboratory to meet the requirements of the select agent regulations. This preparation work must be performed before a MUA can be filled out. 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 4.5.

All MUA and Safety Review Forms are reviewed by the Biological Safety Manager or designated representative prior to being submitted to the BSC or 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 BSC. Expedited review of an application can be granted by the Committee Chair of the BSC. Expedited review is not an option for the IBC, 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 BSC or 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 precautions for certain types of operations and particular projects. To assist in observing safety precautions and to satisfy itself that the adequate measures of safety are being practiced, the BSC and IBC directs the EH&S to serve as a liaison between the Committee and the individual projects.

The MUA and registration are effective for a five year period or as long as the research is active with at least an annual review of its activity status. Changes to the existing safety plans, experimental protocols, or personnel must be made in writing to the committee through EH&S. An investigator may amend the MUA at any time provided it does not involve a change in classification or Biosafety Level.

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 DNA 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.

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 a designated infectious agent should be 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. 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 and freezers containing blood or other infectious materials. Labels must be affixed to other containers used to store, transport, or ship blood or other potentially

infectious materials. Acceptable color-coded (red or orange) bags or containers may be substituted for labeling requirement.

2.3 Biological 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 UTHSC-H does not have a facility to accommodate work with RG 4 agents.

The NIH *Guidelines for Research Involving Recombinant DNA Molecules* contain a broad list of agents classified by Risk Group. For additional information, also see *Biosafety in Microbiological and Biomedical Laboratories*. To locate copies of these references, please see Appendix 3. 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). 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.

Four levels have also been described for activities involving infectious disease activities with experimental animals. The four levels, designated as Animal Biosafety Levels 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 DNA Molecules*. The investigator's unique knowledge and judgement of the agent to be used is critical in assessing the associated risks of exposure. The Biological Safety Program is available to assist in selecting 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 DNA 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 DNA Molecules* 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 UTHSC-H 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 BSC or 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 with infectious or potentially infectious agents will 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, BSC, 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) examination 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.

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 effecicacy.

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 (i.e., 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 double walled, leakproof 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 handwashing 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 Biosafety Level 2 and 3 agents. 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 essentially three types 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 DNA 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.

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,
- 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 are not allowed for use inside cabinets.

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.

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 chemosterilizer and high level disinfectant
typically used for medical equipment such as endoscopes

Use only disinfectants approved for use with a particular organism.

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. 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. EH&S performs training sessions for those interested in receiving shipping training. Please contact the Biological Safety Program at 713-500-4193 for a training schedule and/or for assistance with shipping, or visit our website at www.uth.tmc.edu/safety.

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 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.
- **Pathological waste**
Body parts, tissues, recognizable human tissues, organs, bulk blood and body fluids.
- **Sharps**
Contaminated scalpel blades, razor blades, suture needles, disposal razors, disposable scissors, intravenous stylets and rigid intruders, glass Pasteur 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 UTHSC-H 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 spore *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	Na
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 and mail (via interoffice mail) the biological indicator to the EH&S Environmental Protection Program at OCB 1.330. Biological indicators for routine testing of Autoclave used treat biological wastes are provided by the EH&S Environmental Protection Program.

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 retainment 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 Dental Branch, 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:

DBB: 3.099
DAC: 938
IMM: 120
SPH: B01a

Waste generated at other locations at UTHSC-H; 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, leakproof 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 putrescence 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:

- a. Wear laboratory coat, eye protection and gloves during clean-up.
- b. Allow cabinet to continue to run during clean-up.
- c. Apply an approved disinfectant and allow a minimum of 15 minutes contact time.
- d. Wipe up spillage with disposable disinfectant-soaked cloth or tissue.
- e. Wipe the walls, work surface and any equipment in the cabinet with a disinfectant-soaked cloth.
- f. Discard contaminated disposable materials in appropriate hazardous biological waste container(s) and autoclave before discarding as waste.
- g. Place contaminated reusable items in biohazard bags or in autoclavable pans with lids before autoclaving and cleanup.
- h. Expose non-autoclavable materials to disinfectant and allow 15 minutes contact time before removing from the biological safety cabinet.
- i. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving if necessary.
- j. Run cabinet at least 15 minutes after cleanup before resuming work or turning cabinet off.

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

- a. Clear area of all personnel. Wait approximately 30 minutes for the aerosols to settle before entering spill area.
- b. Remove any contaminated clothing and place in biohazard bag to be autoclaved.
- c. Wear a disposable gown, shoe covers, eye protection and gloves. In a Biosafety Level 3 (BSL-3) facility, respiratory protection is usually required.
- d. Initiate cleanup with disinfectant as follows:
 - i. Soak paper towels in disinfectant and place over spill.
 - ii. 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.
 - iii. Decontaminate all items within the spill the area.
 - iv. Allow 15 minutes contact time to ensure germicidal action of disinfectant before passing items to clean area.
 - v. Place disposable contaminated spill materials in appropriate biological hazardous waste container(s) for treatment.

- vi. Place contaminated reusable items in autoclavable containers.

For hazardous biological spills inside the centrifuge:

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

For hazardous biological spills outside laboratory, during transport:

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

IF YOU ARE NOT SURE ABOUT THE PROPER PROCEDURES OR NEED ASSISTANCE, CALL EH&S at 713-500-8100. FOR AFTER HOURS SPILLS CALL 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, and parasites that can be transmitted to a person or animal, directly or indirectly, and are capable of causing disease in the new host.

EH&S maintains a list of all laboratories and personnel working with human pathogens, blood, tissue, body fluids, or cells lines. For purposes of this list, a pathogen is defined as any organism known to or suspected of causing infection in humans or animals. The Principal Investigator will complete a Safety Review Form for each Biosafety Level 2 or greater pathogen used and forward it to EH&S, for review and distribution to the IBC. A copy of the Safety Review Form may be sent by EH&S to the UT Employee Health Services if joint surveillance is deemed necessary.

A MUA and a Safety Review Form, which includes information on laboratory safety procedures, must be submitted for work with Biosafety Level 2, 3, or 4 agents and retroviruses from any species. The research protocols must be approved by the IBC prior to introducing the organism into the workplace.

Written laboratory safety procedures 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 Committee prior to introduction of the agents into the laboratory.

The individual laboratory safety plan should include information from this manual, National Research Council *Biosafety in the Laboratory*, CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, OSHA *Occupational Exposure to Bloodborne Pathogens (29 CFR Part 1910.1030)*, IATA *Dangerous Goods Regulations for Shipping Infectious Substances*, and the *CFR 49 Part 73; Select Agents*. These, and other documents, are available from EH&S by calling 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 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 UTHSC-H 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.

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”. UTHSC-H 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 DNA Molecules

It is the policy of UTHSC-H that research and teaching programs utilizing recombinant DNA technology will be conducted in full compliance with federal and state laws and regulations, irrespective of the source of funding for the research. Primary consideration will be given to (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 DNA Molecules* (the *NIH Guidelines*; see Appendix 3) UTHSC-H must:

Establish and implement policies that provide for the safe conduct of recombinant DNA 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 DNA research at the Biosafety Level 3 or 4 containment level. The Biosafety Officer is the Executive Director.

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 DNA projects will be reported immediately to the chairperson of the IBC. That official will then be responsible for investigating the incidents and reporting appropriate details to the NIH Office of Biotechnology Activities. 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 DNA research for compliance with *NIH Guidelines* as specified and approve projects found to be in conformity. The Committee will independently assess containment levels required by these Guidelines and will assess facilities, procedures, practices, personnel training, and personnel expertise, as appropriate.

Set containment levels for specified experiments including those involving whole animals or plants.

Review, periodically, recombinant DNA 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, report appropriate information to the NIH Office of Biotechnology Activities 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 Executive Director 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 for Research and Academic Affairs. If appropriate, the

details will be reported to the NIH Office of Biotechnology Activities. 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 DNA 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 Recombinant DNA Research*, U.S. Department of Health, Education, and Welfare (available from EH&S).

The Principal Investigator will:

Not initiate or modify recombinant DNA 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 DNA Molecules* (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 Biotechnology Activities 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 DNA research. EH&S will provide individual or group training upon request.

Comply with shipping requirements for infectious vectors used in recombinant DNA 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 Laboratory Incidents Involving rDNA

Lab incidents involving recombinant DNA or Noncompliance with NIH Guidelines

Any significant problems, significant research-related accidents or illnesses involving rDNA, or noncompliance with the *NIH Guidelines* may be brought forward by any person, and should be promptly reported to EHS (713-500-8100) for investigation and reporting of the incident to the National Institutes of Health Office of Biotechnology Activities (NIH/OBA) and the Institutional Biosafety Committee if required.

UTHSC-H 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/OBA within 30 days. Examples include needlesticks containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet.

Spills and accidents which result in overt exposures to risk group 2 (RG2) organisms or overt or potential exposures to risk group 3 (RG3) organisms containing recombinant DNA molecules must be immediately reported to EHS (713-500-8100) for investigation and reporting of the incident to the National Institutes of Health Office of Biotechnology Activities (NIH/OBA) 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 rDNA Human Gene Transfer

Human gene transfer experiments involve the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants. Researchers should contact EHS (713-500-8100) prior to beginning human gene transfer experiments and should consult Appendix M 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 EHS (713-500-8100) immediately if any of the above occur 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 UTHSC-H that may have involvement with human blood and body fluids.

For the areas under the direction of the BSC and/or 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 UTHSC-H 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 the Medical School, Dental Branch, School of Public Health, Mental Sciences Institute, Harris County Psychiatric Center, University Center Tower, and Graduate School of Biomedical Sciences, other clinical settings and the UT Employee/Student Health Services 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 UTHSC-H may be exposed. Tasks at UTHSC-H involving exposure include housekeepers with assignments to laboratory or clinical areas who may periodically encounter blood spills from accidents. All other housekeeping personnel at UTHSC-H 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. Areas recognized as housing such research and teaching labs include the Medical School, Dental Branch, School of Public Health, Mental Sciences Institute, Harris County Psychiatric Center, and Graduate School of Biomedical Sciences. 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
- Resident
- Laboratory Assistant

With such a diverse and dynamic population of workers at UTHSC-H, 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 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 BSC or IBC.

4.5 Experimental Animals

It is the policy of UTHSC-H 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 Clinic Safety training course is an integral part of the employee safety program at UTHSC-H.

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 newly implemented law:

HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- _ Crimean-Congo haemorrhagic fever virus
- _ *Coccidioides posadasii*
- _ Ebola viruses
- _ Cercopithecine herpesvirus 1 (Herpes B virus)
- _ Lassa fever virus
- _ Marburg virus
- _ Monkeypox virus
- _ *Rickettsia prowazekii*
- _ *Rickettsia rickettsii*

South American haemorrhagic fever viruses

- _ Junin
- _ Machupo
- _ Sabia
- _ Flexal
- _ Guanarito

Tick-borne encephalitis complex (flavi) viruses

- _ Central European tick-borne encephalitis
- _ Far Eastern tick-borne encephalitis
 - _ Russian spring and summer encephalitis
 - _ Kyasanur forest disease
 - _ Omsk hemorrhagic fever

- _ Variola major virus (Smallpox virus)
- _ Variola minor virus (Alastrim)
- _ *Yersinia pestis*
- _ Abrin
- _ Conotoxins
- _ Diacetoxyscirpenol
- _ Ricin
- _ Saxitoxin
- _ Shiga-like ribosome inactivating proteins
- _ Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- _ *Bacillus anthracis* variegated chlorosis strain
- _ *Brucella abortus*
- _ *Brucella melitensis*

- _ *Brucella suis*
- _ *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- _ *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- _ Botulinum neurotoxin producing species of *Clostridium*
- _ *Coccidioides immitis*
- _ *Coxiella burnetii*
- _ Eastern equine encephalitis virus
- _ Hendra virus
- _ *Francisella tularensis*
- _ Nipah Virus
- _ Rift Valley fever virus
- _ Venezuelan equine encephalitis virus
- _ Botulinum neurotoxin
- _ *Clostridium perfringens* epsilon toxin
- _ Shigatoxin
- _ Staphylococcal enterotoxin
- _ T-2 toxin

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)

- _ Akabane virus
- _ African swine fever virus
- _ African horse sickness virus
- _ Avian influenza virus (highly pathogenic)
- _ Blue tongue virus (Exotic)
- _ Bovine spongiform encephalopathy agent
- _ Camel pox virus
- _ Classical swine fever virus
- _ *Cowdria ruminantium* (Heartwater)
- _ Foot and mouth disease virus
- _ Goat pox virus
- _ Lumpy skin disease virus
- _ Japanese encephalitis virus
- _ Malignant catarrhal fever virus (Exotic)
- _ Menangle virus
- _ *Mycoplasma capricolum*/ M.F38/*M. mycoides capri*
- _ *Mycoplasma mycoides mycoides*
- _ Newcastle disease virus (VVND)
- _ Peste Des Petits Ruminants virus
- _ Rinderpest virus

- _ Sheep pox virus
- _ Swine vesicular disease virus
- _ Vesicular stomatitis virus (Exotic)

- _ *Phakopsora pachyrhizi*
- _ Plum Pox Potyvirus
- _ *Ralstonia solanacearum* race 3, biovar 2
- _ *Schlerophthora rayssiae* var *zeae*
- _ *Synchytrium endobioticum*
- _ *Xanthomonas oryzae*
- _ *Xylella fastidiosa* (citrus variegated chlorosis strain)

LISTED PLANT PATHOGENS

- _ *Liberobacter africanus*
- _ *Liberobacter asiaticus*
- _ *Peronosclerospora philippinensis*

Anyone at UTHSC-H 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. UTHSC-H 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.cdc.gov/od/sap/> or contact the Biological Safety Program.

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 Executive Director 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 Executive Director 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 510, 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 and serum banking for designated personnel, 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 Operations and Remodeling Services.

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:

- a. Laboratory tests including complete hematology, urinalysis, serum chemistry.
- b. Pulmonary function (FEV₁, FVC, FEV₁/FVC)
- c. Hearing (500, 1000, 2000, 3000, 4000, 6000, 8000 Hz)
- d. Visual Acuity (Near & Far)
- e. Serum samples collected and stored. In some situations, serum samples may be collected and banked as soon as possible after arrival at the University, at set intervals during employment, in the event of disease outbreak and at termination. The serum will be maintained in the bank for the duration of the individual's stay, and for a period of 10 years thereafter.
- f. 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.

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 maybe 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 life saving. 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 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. A Supervisor's First Report of Injury Form must also be completed for reporting to Worker's Compensation and Insurance. All students/residents who sustain an exposure should page the 24 hour Exposure Hotline at 713-951-8013.

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:

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 work related risks and can consider work assignment modification to avoid exposure to specific hazards.

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 UTHSC-H: infectious microorganisms and/ or vectors used in recombinant DNA 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 Biosafety Level 1 and 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: Fill out a "Supervisor's First Report of Injury" form. Report to UT Employee Health Services at UCT 1620 (713-500-3267). Students/residents should report to UT Professional Building 510 (713-500-5171, or after hours at 713-951-8013).

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 is performed when recommended by a UT Employee Health Services physician.

For Biosafety Level 3 or 4 Agents, and Human Hepatitis (all agents), and Retroviruses from Humans, Nonhuman Primates, Rodents, and Other Vertebrate Species:

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: Fill out a "Supervisor's First Report of Injury" form. Report to UT Employee Health Services at UCT 1620 (713-500-3267) or UT Professional Building 510 (713-500-5171, or after hours at 713-951-8013) for students/residents. 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: Comprehensive Health History Form should also be updated to reflect significant changes in health status. Serum banking is performed when recommended by a UT Employee Health Services physician.

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. Page 713-951-8013 if you are a student/resident or call 713-500-3267 if you are an employee/faculty member to receive an initial evaluation, counseling, treatment and follow-up according to "Management of Accidental Exposures to Blood/Body Fluids" (available from EH&S). Physical examination will be conducted in the event of suspected work-related illness. 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. Serum banking is performed when recommended by a UT Employee/Student Health Services physician.

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 when recommended by a UT Employee/Student Health Services physician.

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 nor 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 for employees/faculty members or page 713-951-8013 for students/residents to speak with the UTHSC-H 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. UTHSC-H Administration - Auxiliary Enterprises is responsible for the cost of all exposure-based lab studies on UTHSC-H students. Residents, medical school staff and all other UTHSC-H employees file under worker's compensation.

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 Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings". These 2005 Guidelines replace the 1994 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

- I Use of administrative measures to reduce the risk of exposure to persons with suspected or confirmed infectious TB.
- II Use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei.
- III 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 UTHSC-H.

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 BSC and EHS. 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 2005 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 BSC 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 BSC, 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 in a retrievable aggregate database.

PPD conversion rate will be calculated as follows:

A = # health care workers 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 BSC. 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 2 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:

- a. 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.
- b. 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.
- c. 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:

- a. Refer to Administrative Controls initial assessment section.
- b. 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.
- c. Schedule patient to minimize exposure to other patients.
- d. 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.
- e. If patients are known to be non-compliant with TB medications, institute Airborne Infection Precautions until they are documented to be non-infectious.
- f. Patients with previously diagnosed TB infections should be considered to be infectious until the physician determines otherwise.

6. Tuberculin Skin Testing:

- a. Administration of tuberculin test (Mantoux):

- 1) 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.
 - 2) Tuberculin is injected just beneath the surface of the skin.
 - 3) Discrete, pale elevation of the skin 6-10 mm should be produced.
- b. Reading of the skin test
- 1) 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.
 - 2) 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 713-599-3600.

8. Cough - Inducing Procedures:

- a. 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.
- b. 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).
- c. 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.

- d. 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.
- e. 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.
- f. 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.
- g. 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.
- h. 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.
- i. For patients with suspected or confirmed active TB, it is preferable to use oral instead of aerosolized, prophylaxis for pneumocystic pneumonia if clinically practical.
- j. Harris County TB Control Center should be notified (713-599-3600) for contact investigation prior to discharge; especially when children are in the household.

9. Other Infection Control Measures:

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

1. 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 2005 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.
2. Individuals with a previous history of a positive TB skin test should not continue to undergo skin testing. However, a baseline chest x-ray should be on file in the employee's health record.
3. All health care workers with a history of a positive skin test should either have a chest x-ray on employment or when they initially convert to a positive skin test.
4. Tuberculin PPD is not contraindicated for pregnant employees.
5. Health care workers who previously received BCG vaccine as a child should receive a baseline TB skin test. If positive, the employee should have a chest x-ray.
6. Health care workers with immunosuppression should follow guidelines employed by the UT Employee/Student Health Services. Because these individuals may be at higher risk for acquisition of TB and rapid progression to active disease, voluntary reassignment to lower risk areas may be advisable.

9.9 Health Care Workers with TB Infection or Active Disease

1. 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.

2. 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.
3. 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).
4. All information provided by health care workers regarding their health status will be treated confidentially.

9.10 Education and Training

All health care workers should receive initial employment and annual education about TB that is appropriate to their job category.

The following is an outline of the materials to be covered:

1. The basic concepts of TB transmission, pathogenesis, and diagnosis, including the difference between latent TB infection and active TB disease, the signs and symptoms of TB, and the possibility of secondary inoculation in the person with a positive PPD test. Collection of specimens for AFB cultures should be included.
2. The potential for occupational exposure to patients with infectious TB, including the prevalence of TB in the community and nationwide, situations with increased risk of exposure to TB (bronchoscopy, autopsy, etc.) and working with people reported to have high risk for TB.
3. Appropriate isolation measures (negative pressure rooms etc.)
4. The principles and practices of infection control that reduce the risk of transmission of TB, including the hierarchy of TB infection control measures, and exposure control plan. Include Respiratory/Airborne Precautions, Transportation of TB patients, and required Personal Protective Equipment.

5. The purpose of PPD testing, the significance of a positive result and the importance of participation in the skin test program.
6. The principles of preventive therapy of latent TB infection, indications, use and effectiveness, including the potential adverse effects of the drugs.
7. The responsibility of the employee to seek medical evaluation promptly if symptoms develop that may be due to TB or if PPD test conversion occurs in order to receive appropriate evaluation and therapy and to prevent transmission of TB to patients and other employees.
8. The principles of drug therapy for active TB. This should include the practice of direct observed therapy in the hospital and community.
9. The importance of notifying the appropriate group (Student and Employee Health, etc.) if diagnosed with active TB so appropriate contact investigation can be instituted.
10. The responsibilities of the institution to maintain the confidentiality of the employee while assuring that the employee with TB receives appropriate therapy and is non-infectious before returning to duty.
11. The higher risk posed by TB to individuals with HIV infection or other causes of severely impaired cell-mediated immunity including:
 - a. the more frequent and rapid development of clinical TB after infection with *Mycobacterium tuberculosis* (MTB).
 - b. the differences in the clinical presentation of disease.
 - c. the high mortality rate associated with MDR-TB (M. tuberculosis organisms that are resistant to more than one anti-TB drug) disease in such individuals.
12. The potential development of cutaneous anergy as immune function declines (measured by CD4 and T-lymphocyte counts).
13. The institution's policy on voluntary work reassignment options for immunocompromised employees.
14. Respiratory Training to include:
 - a. define HEPA respirator and why OSHA requires it's use.
 - b. when to use a respirator (in room care of TB patient, bronchoscopy etc).
 - c. recognize the respirators used for TB.
 - d. describe how to clean and inspect the respirator.

- e. describe how long to use respirator.
- f. describe how to fit a respirator.
- g. demonstrate a respirator fit-check.
- h. medical surveillance requirement of respirator program.
- i. describe the OSHA requirements for the program.

10.0 NONHUMAN PRIMATE EXPOSURE PROCEDURES

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

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.

Procedure for Macaque Exposures (Herpes B Precautions in Event of Macaque Bite or Scratch or Injury From Cage):

1. If the wound is open and you feel comfortable with taking a culture yourself, quickly culture the wound using the Collection-Eze culture system. If you do not feel comfortable trying to take a culture and there is no one to help you, start scrubbing the wound immediately and call for help when you are finished.
2. Locate the Macaque Exposure Kit. 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.)
3. Immobilize the macaque responsible for the exposure with ketamine.
4. Collect from the macaque:

At least 3 mls. blood in a red top tube
3 separate cultures using Collection-Eze system of:

- a Right conjunctiva
- b Left conjunctiva
- c Buccal cavity
- d Note and record any unusual lesions of these areas.

5. Properly label culture tubes with human name or macaque number, collection site and date. Place in freezer until shipment. To prevent bacterial contamination of the sample, add 50 ug/ml. gentamicin sulfate to the culture tubes (Take a stock solution of 50 mg/ml. and dilute 1:100 for a final concentration of 0.5 mg/ml. Use 0.1 ml. of this solution per ml. culture media.)
6. Collect from human: 5 mls. blood in a red top tube.
7. Centrifuge both blood samples and place separated serum into plastic screw top vials.
8. Properly label serum tubes with name or macaque number, type of sample, and date. Place both samples in freezer until shipment.
9. Fill out a submission form available in Exposure Kit, Main office, or Experimental Surgery. Give the original form to the secretary so that she can enter a P.O. number into the computer for shipping and payment. Make sure a copy of the completed form is submitted for inclusion in the exposure log.
10. Prepare a Styrofoam box for shipment of the samples with ice packs or dry ice. The Styrofoam box and ice packs should be in a pre-designated location (in the case of Animal Care, the diagnostic lab).
11. Make sure a completed submission form is placed in the waterproof envelope and included in the shipment. Double check the submission form against the samples to make sure all the samples are in the shipping container.
12. The package and submission form need to be in Receiving by 3:45 p.m. Please note: some overnight carriers do not deliver until 10:30 on Saturday morning so plan Friday shipments accordingly.
13. In the event an exposure happens so late in the day that the institutional deadlines cannot be met, use a Federal Express drop-off office. The most convenient office to the Medical School is located on Travis immediately south of the Southwest Freeway (800-463-3339). Packages can be dropped off there until 8:00 pm.
14. Telephone Dr. Hilliard's lab at 404-651-0808 to let them know to expect a shipment the next day.
15. In the event of a weekend exposure, collect all samples as described and freeze for shipment on Monday.
16. Repeat serology samples on exposed human and macaque in 10-14 days.

Macaque Exposure Kit Contents

Concise Instructions: Step by step numerical instructions individualized for each institution

Container for "Tide with Bleach" prominently marked "Step 1" with shortened directions for 5 minute scrub

Betadine Scrub Sponge prominently marked "Step 2" with shortened directions for additional 10 minute scrub

Ketamine: 1 bottle or single dose drawn up in syringe for adequate macaque restraint

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)

Syringes and Needles:

- 1 Syringe and needle for Ketamine injection of primate
- 2 Syringe and needle for primate blood collection
- 3 Syringe and needle for human blood collection
- 4 Extra syringes and needles in case needed

Alcohol Wipes: Individually packaged wipes for venipuncture site preparation

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

Permanent Marker for tube labels and pen for submission form

Shipping Labels and waterproof plastic envelope for enclosure of submission form with shipment

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)**

TO: National B Virus Resource Center
Viral Immunology Center
Georgia State University
50 Decatur Street
Atlanta, Georgia 30303

FROM: University of Texas Health Science Center at Houston
Center for Laboratory Animal Medicine and Care
6431 Fannin
Houston, Texas 77030

Case Information Date of submission: _____

Date of Injury: _____ Bite _____
Scratch _____

_____ Cage scratch _____ Other

Date of follow-up: _____ Needle
stick (palpebra) _____

_____ Needle stick

(venipuncture)
Describe
incident:

Species: macaque mulatta fascicularis (circle one)

Human: _____

Macaque: _____

Serology
____ Initial
____ Follow-up
____ Routine

Serology
____ Initial
____ Follow-up
____ Routine
____ Herpesvirus antibody
demonstrated in past?

Culture
____ Wound, pre-scrub
____ Wound, post-scrub
____ Wound biopsy, Initial
____ Wound biopsy, follow-up
____ Vesicle

Culture
____ L. conjunctiva
____ R. conjunctiva
____ Buccal
____ Vesicle
____ Other

All samples must be labeled with name or I.D. number, swab site and date specimen was taken. Make sure all samples as checked above are in shipping container along with this submission form.

Contact Dr. Hilliard's laboratory at 404-651-0808 prior to shipping to let them know to expect the samples.

Requested by: Dr. Terry Blasdel 713-792-5804 (W)
713-522-5393 (H)
Dr. Chris Smith 713-792-5127 (W)
713-565-0495 (H)

Purchase order number:
Purchase order date:

APPENDIX 1 EH&S DIRECTIVES

Copies of the following directives are available by contacting Environmental Health & Safety at 713-500-8100.

THE HANDBOOK OF OPERATING PROCEDURES

Chapter 18

Safety and Health

- 18.01 Emergency Situation Response Plan
- 18.02 Suspension of Operations: Adverse Conditions
- 18.03 Medical Emergencies
- 18.04 Campus Security
- 18.05 Substance Abuse in the Workplace
- 18.06 Substance Abuse-Students
- 18.07 AIDS, HIV, and HBV Infection
- 18.08 Controlled Substances and Dangerous Drugs in Non-clinical Setting
- 18.09 Radiation Safety
- 18.10 Hazardous Chemical, Infectious, and Radioactive Waste
- 18.11 Safe Use of Biological and Chemical Agents

RADIATION SAFETY MANUAL

- 1.0 Radiation Safety Committee
- 2.0 Safety Officer
- 3.0 The Authorized User
- 4.0 Individual Responsibility
- 5.0 Authorization to Obtain and Use Radiation Sources
- 6.0 Procurement, Accountability and Transfers of Radioactive Materials
- 7.0 Disposal of Radioactive Waste
- 8.0 Radiation Protection Program
- 9.0 Emergency Procedures
- Appendix
- Permissible Concentration Limits in Air and Water

EH&S HEALTH AND SAFETY GUIDES

Management of Accidental Exposures to Blood/Body Fluids
Chemical Storage Guide
Hazardous Waste Disposal Procedures

CHEMICAL HYGIENE PLAN

- 1.0 Introduction
- 2.0 Responsibilities
- 3.0 Standard Operating Procedures

- 4.0 Controlling Chemical Exposures
- 5.0 Fume Hoods and Other Engineering Controls
- 6.0 Prior Approval
- 7.0 Medical Consultation
- 8.0 Chemical Hygiene Officer
- 9.0 Special Provisions for Select Carcinogens, Reproductive Toxins, and Acutely Toxic Chemicals

Appendices

- A. Chemical Waste Disposal Procedures
- B. EH&S Policy
- C. Reference Materials
- D. Chemical Resistance Chart
- E. Chemical Hygiene Plan General Training Certificate
- F. Compatible Chemical Storage

VIDEOS

List of videos available upon request.

APPENDIX 2

FORMS

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
INSTITUTIONAL BIOSAFETY COMMITTEE
MEMORANDUM OF UNDERSTANDING AND AGREEMENT FOR THE USE OF BIOLOGICAL AGENTS AND
DNA TECHNOLOGY**

P.I. Name: _____ *Phone No:* _____ *Fax:* _____
Title: _____ *Dept:* _____ *Lab Room No(s):* _____

Please provide a descriptive title of the protocol:

Provide a brief lay description of the research. Attach page, if necessary.

Biological agents involved (list Infectious agent / rDNA):

Human subjects or Lab animal use: _____ *Yes; ___ No CPHS or AWC approval number (if applicable):*

For protocols involving infectious agents, identify the appropriate biosafety level.

The containment and facilities for the biological agent(s) to be used in the protocol must meet Biosafety Level X requirements, as cited in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories Guidelines (4th Edition-1999).

For protocols involving recombinant DNA technology, mark the appropriate description:

This research protocol is described in the most recent NIH Guidelines For Research Involving Recombinant DNA Molecules, (April 2002) as amended in Section:

III-A____ III-B____ III-C____ III-D____ III-E ____ III-F____

Principal Investigator Acknowledgment

I agree to comply with all applicable safety guidelines and standards established for this work and understand that I am primarily responsible for the health and safety related activities under my direction. I also understand that this Memorandum of Understanding and Agreement is not effective until the appropriate signature(s) is/are obtained from the official(s) designated below.

P.I. signature: _____ *Date:* _____

Environmental Health & Safety Review

Environmental Health & Safety has reviewed this proposal, verified the classification and/or containment level indicated above, and confirmed that the identified facilities and practices meet the Biosafety Level specifications. The protocol review requirements are:

1. [] III-E.....protocol requires IBC notification simultaneous with initiation of work
2. [] III-Fprotocol is exempted from IBC review
3. [] BSL-1protocol is exempted from IBC review
4. [] BSL-2protocol must be submitted for full review and approval by IBC
5. [] BSL-3protocol must be submitted for full review and approval by IBC
6. [] Other/s....._____

*Biological Safety Officer/EH&S Representative:*_____ *Date:*_____

Institutional Biosafety Committee Review (For BSL-2 and Greater):

The Institutional Biosafety Committee has reviewed the proposal and has found it to be in compliance with the appropriate Guidelines. The Committee will review this research annually.

IBC Committee Chair: _____ *Date:*_____

Dr.: "Title"

Protocol summary:

Biological agents involved:

Applicable Regulations/Guidelines/References: NIH Guidelines for Research Involving Recombinant DNA Molecules (April 2002) as amended, CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (4th edition-1999), and UTHSC-H Biosafety Manual.

Biosafety Level (BSL):

AWC/CPHS approval:

Personnel:

Protective equipment:

Location of work:

Biological waste disposal:

Lab Status:

Shipping Infectious Substances (if any):

Conditions (if any):

Date received (for review):

Projected start date:

INSTITUTIONAL BIOSAFETY COMMITTEE APPLICATION FORM INSTRUCTIONS

Any use of microbiological/infectious agents and/or recombinant DNA 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, 4th edition" contains safe practices and laboratory requirements for research using microbiological agents. The NIH "Guidelines for Research Involving Recombinant DNA Molecules" contains requirements for protocol review and safe practices.

The UTHSC-H 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 department at 713-500-8100.

USING THESE FORMS:

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 had by contacting EH&S. All levels of Recombinant DNA work requires notification and/or approval to the Institutional Biosafety Committee.

REQUIRED MATERIALS:

1. Completed Institutional Biosafety Committee Summary Form and Memorandum of Understanding and Agreement
2. A copy of the research protocol which should include practices to ensure safety and health in the laboratory.
3. Copies of any relevant articles

IBC MEETING DATE: First Thursday of every month.

SUBMISSION DEADLINE: 14 days prior to facilitate review and preparation. This is a flexible deadline as we will work with investigators to meet any and all grant deadlines whenever feasible.

OBTAIN FORMS & SUBMIT TO: Environmental Health & Safety, OCB 1.330, 500-8100 or DBB B51, 500-4193.

ONCE APPROVED: Protocols will be reviewed on an annual basis.

CHANGES IN METHODS, MICROBIOLOGICAL AGENT/RDNA, OR PERSONNEL: Apply by memo 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 is the individual who submits the application to employ biological agents or recombinant DNA in his or her work. This individual is responsible for adherence to all guidelines and regulations. The Principal Investigator 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 Principal Investigator are described in the UTHSC-H Biological Safety Manual and HOOP policies.

APPENDIX 3

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 DNA Molecules, April 2002.

Website address: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

Biosafety in Microbiology and Biomedical Laboratories, 4th Edition, May 1999.

Website address: <http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>

Code of Federal Regulations

Website address: www.osha.gov/comp-links.html