UNT HEALTH SCIENCE CENTER

Institutional Biosafety Committee

BIOSAFETY MANUAL

University of North Texas
Health Science Center
Fort Worth - Texas

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Abbreviations

BSC- Biological Safety Cabinets
BSO – Biosafety Officer
CDC – Center for Disease Control and prevention
GMO - Genetically Modified Organisms
IBC – Institutional Biosafety Committee
NIH – National Institute of Health
rDNA – recombinant deoxyribo nucleic acid
PI - Principal Investigator
UNTHSC – University of North Texas Health Science Center

I. Introduction

UNTHSC Biosafety Manual (Scope)

The University of North Texas Health Science Center at Fort Worth (UNTHSC) has adopted this Biosafety Manual in order to establish a uniform safety program for all laboratory activities involving potentially biohazardous materials. The provisions specified in this Biosafety Manual are applicable to all persons working in laboratories including faculty, students, staff, contractors and visitors. This biosafety program applies to all activities involving recombinant deoxyribo nucleic acid (rDNA); genetically-modified organisms (animal or plant life) (GMOs), including their release into the environment; potential human, animal or plant pathogens; the use of living organisms (any size or type including GMOs) as control agents for growth, pest control or environmental change; human materials; and the disposal of potentially biohazardous materials

When reading this Manual, the words "must", "will" or "shall" indicate mandatory requirements; whereas the words "may", "should" or "recommend" indicate preferred or suggested for consideration as good practice.

Institutional Biosafety Committee (IBC)

The IBC adopts the procedures and controls specified herein with the advice and consent of the UNTHSC Vice President of Research. The IBC is responsible for the review, and approval or rejection, of all activities involving potentially biohazardous materials by persons working in laboratories associated with the University of North Texas Health Science Center. The IBC shall review supplemental procedures and requirements developed in support of this Manual by departments, principal investigators, project leaders, student laboratory coordinators and/or other responsible persons. Such supplements may be approved or modified for use by only the submitting person or agency (and their subordinates), or the IBC may adopt or modify and then adopt them for overall application and change this Manual accordingly.

Procedures Not Controlled Herein

When no specific procedures or requirements are specified herein or otherwise required by law, code, ordinance, standard, regulation, contract or grant agreement or other directive; compliance with a nationally or professionally recognized standard practice or prudent procedure acceptable to the IBC shall be deemed to satisfy the provisions of this Manual. The IBC or the Biosafety Officer (BSO) acting on behalf of the IBC may, however, impose additional requirements, restrictions or controls on specific projects as and when necessary for health, safety, environmental protection or the preservation of property. When imposed, such additional requirements are to be considered mandatory unless a specific waiver is granted by the IBC.

Applicability of External Controls

Applicable laws, regulations, ordinances, standards, contract guidelines or requirements applicable to UNTHSC activities are considered to be requirements of this Manual. However, where the requirements of this Manual provide for improved health, safety, environmental or property protection procedures, the stated Manual requirements must be met.

Definitions

Biohazardous activity – any activity involving the use of potentially biohazardous agents.

Biohazardous agent- any microorganism, virus, infectious substance, or toxin that is biological in nature and capable of producing deleterious effects upon humans, animals, or the environment.

Biological product - means a biological prepared and manufactured in accordance with regulations that govern the manufacture of vaccines, reagents, etc.

Diagnostic specimen - means any human, plant or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids, etc., which is reasonably believed might contain an etiologic agent, and is being shipped for purposes of diagnosis.

Etiologic agent - means a viable microorganism or its toxin that causes, or may cause, human disease.

Field study - any intentional release of a potentially biohazardous, genetically-modified or artificially-engineered living agent or their toxins to the environment, or the use of a chemical potentially capable of changing the environment for some biological control purpose (e.g., pesticide).

GMO – any organism which has had gene(s) and/or a recombinant DNA construct introduced into its genome in a heritable fashion.

Human Materials – human blood, blood components, blood products, body fluids, tissues, or organs.

Principal Investigator – any UNTHSC faculty member, staff employee, or student conducting research or other educational activities utilizing UNTHSC facilities or due to his/her status as a UNTHSC employee or student involving biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules.

Recombinant DNA – (1) molecules that are constructed by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) molecules that result from the replication of those described in (1).

Risk Group 1 Agents - agents that are not associated with disease in healthy adult humans

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

Risk Group 3 Agents - 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)

Risk Group 4 Agents - 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)

II Emergency Planning and Response

A. General Comments on Emergencies

Safety is an intrinsic part of each laboratory and/or other biohazardous operations; work is planned so that exposures to potentially hazardous agents will not occur. However, accidents creating exposure hazards do occur. These may involve spills or releases of potentially hazardous infectious or chemical agents. Also, failure of equipment and facility safeguards may place workers at a high risk of accidental exposure. Likelihood of severe injury or infection can be reduced if plans for emergencies are established and well known to all who need to know. For this reason, various regulations, standards and the National Institutes of Health (NIH) "Guidelines" require the preparation of emergency plans for laboratories and facilities involved in biohazardous activities. It is not possible to recommend a single plan of action that would be applicable in all situations. Laboratory personnel must be trained with regards to these emergency procedures. Each Principal Investigator and laboratory manager is responsible for developing appropriate emergency procedures for his/her work area and limiting access to authorized individuals only. The following basic principles should be used in developing specific procedures for dealing with accidental spills or releases of potentially hazardous materials in this type work.

1. **Render assistance to persons involved and remove them if necessary.**
2. **Warn personnel of the potential hazards to their safety and evacuate the area if necessary.**

B. Reporting of Incidents

All incidents must be reported immediately to the Principal Investigator or the laboratory manager. Such incidents include but are not limited to inadvertent fires, explosions, personnel exposures, injuries, release of biohazard materials and failure of biohazard containment. The Principal Investigator or lab manager will in turn make (using such help as necessary by the fire authority, medical personnel, BSO, etc.) such investigations and reports as required. All external reports involved with biohazard materials, other than those of an immediate nature such as summoning the fire department in case of a fire, are to be made by or through the UNTHSC Research Office.

All accidents shall be reported as follows:

1. Each person involved in or supporting biohazard work shall report to his/her Principal Investigator or laboratory supervisor:
    a. Each accident (both injury causing and those without injury).
    b. Each accident resulting in damage to University or other property.
    c. Each situation or condition observed on the job that has the potential for either injuring or endangering the health of people and/or causing damage to property.

2. In case of injury, illness, disease, or exposure to infectious material or disease, the

person involved or someone on his/her behalf, must report it to his/her department within 48 hours. Incidents involving injuries resulting in lost time, medical expenses or resulting in a laboratory-acquired illness are immediately reportable to Human Resource Services workers' compensation claims coordinator.

3. Each department is responsible for reporting all biosafety accidents to the BSO and the Safety Office within five (5) working days. To properly document the accident, additional reports may be required. The BSO and/or Safety Office may be contacted for clarification and assistance with this requirement.

4. Serious accidents shall be reported immediately by telephone to UNTHSC Police Department (817-735- 2600).

Serious accidents for this purpose are those, which result in:

a. Fatality;
b. Hospitalization or medical treatment (beyond first-aid) of any person; NOTE: This includes non-UNTHSC personnel;
c. First-aid treatment of five (5) or more persons;
d. Property damage exceeding $1000.00; or
e. Biohazard exposure resulting in lost time or accidental release of biohazards with a potential for involving the public or exposure of non-involved persons.

C. Infectious Material Incidents (Including recombinant Deoxyribo Nucleic Acid (rDNA) and Infected Animals)

All incidents involving infectious materials are to be immediately reported to the BSO and the Safety Office. Please see Appendix D of this manual for an incident report form. Such incidents may include spills or releases of materials or agents, escape of infected animals, rupture of plastic bags of infectious/medical waste, other loss of containment, or equipment failure. The BSO will direct or oversee cleanup, capture of animals, protection of personnel, packaging and disposal (after sterilization if possible) of residues and/or make arrangements for temporary storage and subsequent treatment of equipment, wastes and/or the area.

Any emergency incident requiring immediate assistance from UNTHSC PD or Safety Office, or from non-campus agencies such as the Fort Worth Fire Department, is to be reported immediately to UNTHSC PD (817-735-2600).

Reports should provide the dispatcher with the following information:

1. Where and what type incident has occurred.
2. Assistance needed, if not obvious, such as firefighters for a fire.
3. Whether the incident involves any injured or trapped persons.

4. What actions have been taken since the incident began: i.e., building evacuation has been initiated, etc.
5. Identity of caller, location from which he/she is calling and who and where someone will meet response personnel upon their arrival.

If an infectious organism or one containing recombinant DNA molecules were to acquire the capacity to infect and cause disease in humans, the first evidence of this potential may be demonstrated as a laboratory-acquired infection. For this reason, the Principal Investigator or laboratory manager must investigate any serious, unusual, or extended illness of a laboratory worker or any accident that involves inoculation of infectious organisms or those containing rDNA molecules through the skin, by ingestion, or probable inhalation. A finding that an infection is associated with such work or research will provide sufficient warning for evaluation of hazards and initiation of additional precautions to protect the general public, if necessary, in addition to other workers.

Prompt reporting of all accidents involving overt releases of or exposures to microorganisms is essential. The laboratory worker involved with such an occurrence should notify the Principal Investigator or laboratory manager (or another person in authority in their absence) immediately. The PI or manager should determine the immediate response to be taken. This response may include immediately requesting the support of medical personnel to help monitor individuals for possible infection or disease. The investigation of all accidents associated with research involving biohazardous agent (e.g toxins, microorganisms, human materials) or rDNA should also include a review of techniques, procedures and types and uses of equipment that may have been involved in the accident. The investigation should also establish the circumstances leading to the accident. In addition, the investigation report, by the BSO to the IBC, should provide recommendations for preventing future similar occurrences.

D. Recovery After Biohazard Incidents

Safety Office personnel, with assistance from fire department, Texas Department of Health, police and/or the BSO, will make the determination that an area/facility/room is safe for reentry after a biohazard incident. No other individuals are allowed to enter or reenter the affected area until that area is released. However, in the event of fire or explosion, Safety Office personnel may, if appropriate, allow limited entry of specialists who may investigate, remove, rebuild, reinforce, perform temporary fixes, or raze the facility as necessary before others are permitted to enter.

E. Decontamination

No equipment, facility, residue, or biological material that has been exposed to biohazardous agents is to be transferred from that site until it has been properly decontaminated.

F. Decontamination of Laboratory Spills

A major emphasis of this Manual is placed on preplanning for the immediate actions and

decontamination procedures necessary to address spills of biohazardous materials that may occur in the open laboratory and/or in safety cabinets. These procedures are described in other sections of this document according to the location and agent(s) involved. Each laboratory is to have a specific and appropriate response protocol for each agent or group of agents possessed by that laboratory.

G. Transportation of Materials

The need for transit of biohazardous materials is a primary factor in the occurrence of most potentially dangerous spills. The dropping and subsequent failure of primary agent containers is of particular concern. Therefore, protective secondary containers for transporting potentially biohazardous materials are strongly recommended as an effective approach to preventing such spills.

The use of secondary protective containers is strongly recommended and are mandatory for transit of infectious materials and or toxins within the corridors serving the laboratories. It should be recognized that air handling systems in the majority of modern laboratories maintain the air pressure positive in the corridors with respect to that of connected individual laboratories. Airborne microorganisms generated during a spill in a hallway are quickly dispersed into adjoining laboratories and office areas.

Spilled research materials may be inadvertently tracked over a wide area during ensuing confusion. Decontamination can then become a formidable task and invariably causes a major disruption of laboratory effort. This demonstrates the critical need for the use of secondary containers whenever possible. Adequate training will be provided the BSO. The employees who will be in charge of the transportation shall under go the training program.

H. Basic Concepts For Dealing With Spills Of Biological Agents

The possibility of an overt spill of potentially infectious material is always present in biological laboratories, but the time, circumstances and exact location of such an event cannot be predicted with any degree of certainty. Known aerosol-producing procedures are to be performed within biological safety cabinets where containment and decontamination of airborne microorganisms are possible. To avoid unrecognized aerosol release requires thoughtful planning, thorough evaluation of procedures and equipment, and constant adherence to aseptic techniques. Routine laboratory housekeeping procedures may provide some decontamination of unsuspected agent releases.

(1) Laboratory Area and Program Survey

Each Principal Investigator or Laboratory Manager is responsible for developing protocols to be used in the event of biohazardous spill. It is critical that Principal Investigators and Laboratory Managers survey the laboratory and adjacent areas in relation to the research program. This assessment should provide information that can be used to prevent exposure of personnel and the environment and to make preparations to

contain and decontaminate the spill. Kinds and levels of potential risks that may accompany the program must be known and assessed by principal Investigator.

Decontamination practices must be established for the biohazards involved. Salient facts should be determined about air handling systems, namely which unit serves which laboratories; arrangement of air particulate filters, of safety cabinet ventilation, and interconnected ducting; layouts of furniture and equipment; storage locations of biological materials; and routes for evacuation. Once these facts are known, appropriate actions can be taken in the event of a laboratory accident or spill to evacuate personnel appropriately from areas affected, to decontaminate without affecting adjacent areas or destroying valuable stock biological material, and to render assistance in the event of fire, flooding or other emergency.

(2) Devising Immediate Action Protocols

Immediate action protocols are the step-by-step procedures to be followed by laboratory workers immediately after the occurrence of a biohazard spill. The primary objectives are to protect personnel and prevent spread of the microorganism to the environment. The protocols should be brief, forceful and informative, leaving little room for ignoring or misinterpreting the required actions under the stress of the unanticipated event.
Additional directives may be required with respect to:

(a) location of spill alarm, if available;
(b) how room ventilation is handled;
(c) activation of U.V. lamps, if available; and
(d) manner of precluding inadvertent entry into the contaminated area. The supervisor should coordinate beforehand with medical personnel those actions that might require departure from protocol in the event that personal injury accompanies the mishap. Prominent display of the immediate action protocol at strategic locations within the laboratory may be particularly advantageous if transient personnel frequently use the laboratory.

(3) Biohazard Spills Outside Biological Safety Cabinets

Spills outside biological safety cabinets are complex events. They may involve amounts of material ranging from less than a milliliter up to several hundred milliliters or more. The amount spilled, the physical characteristics of the material, and how the spill occurs are important factors in determining the design of the action protocol. Laboratory personnel responsible for the decontamination of a spill should be provided with [at a minimum] a long-sleeve gown, and if appropriate, respiratory protection and medium- or heavy-duty rubber gloves. Knee-length rubber boots may also be useful and provide protection to the wearer against the chemical action of strong decontaminating solutions.

Decontamination personnel should enter the spill area, survey the extent of the spilled materials, and attention should be given to splashed materials to avoid tracking the agent about the laboratory. Starting from the outer perimeter of the area encompassed by the spilled material, liquid decontaminant should be gently poured around the spill area and allowed to flow into the spilled material. Paper towels soaked with the liquid

decontaminant may be used to cover the area. Avoid spraying or pouring decontaminating solutions directly onto the spilled materials or other abrupt actions that may create airborne particles containing the spilled agent.

The amount and concentration of decontaminant used should be sufficient to overcome any inactivating action of media or tissues that may be intimately associated with the biohazardous agent. The surrounding area should be scanned to identify additional areas that may harbor the spilled agent. If these are extensive and/or cannot be readily reached by liquid decontaminant, consideration should be given to additional decontamination procedures.

All spills do not present the same degree of risk. Minor spills may involve very small quantities of agent materials without involving container breakage or significant splashing. Potentially contaminated objects should be wiped down with decontaminant and set aside. All nearby surfaces should be similarly wiped down. The investigator should then wash hands and face with germicidal soap, change to fresh laboratory clothing, and bag the disposable contaminated materials for autoclaving.

Laboratories involved in an overt spill should subsequently receive particularly thorough treatment during application of routine housekeeping procedures.

(4) Biohazard Spills in Biological Safety Cabinets

The function of biological safety cabinets is not only to provide a work area free from background contaminants, but also to contain any microorganisms released as a result of various manipulations of biological materials. Operations such as centrifuging, blending, and homogenizing/sonicating samples, in particular, should be regarded as likely producers of "controlled spills." To these must be added the potential for an overturned or broken primary container of concentrated virus or an overturned stack of infected tissue culture plates.

Potential contamination resulting from routine procedures is normally dealt with following completion of an experimental procedure or at the conclusion of a work session. An overt biological spill occurring in the biological safety cabinet should be decontaminated immediately and the cabinet airflow maintained. The operator should have available at all times within the cabinet a supply of an appropriate decontaminant so that it is not necessary (barring operator injury) to withdraw the arms before proceeding with decontamination. If the operator's hands and arms have come into direct contact with the biological material, decontaminant should be liberally applied to them. The area of the spill should be gently flooded with decontaminant. The walls, any work surface, equipment, and recoverable supplies not previously treated should also be wiped down with a cloth or sponge saturated with decontaminant. Place all used cleaning materials in a suitable container and autoclave or treat with a strong hypochlorite solution.

(I) Establishing Criteria for Re-occupancy

The Principal Investigator or laboratory manager, upon completion of appropriate decontamination procedures, should have some assurance that the decontamination has

been effective to the degree required by the risk category of the biological material released. As the Principal Investigator or laboratory manager defines a level of assurance required, the conditions should be established under which the spill area can be reoccupied for continuation of the research or teaching activity. The greater the infectious potential of the spilled agent the more stringent should be the requirements to be met prior to allowing re-occupancy of the spill area.

Personal verification of the proper completion of a known effective chemical decontamination protocol may be the criterion selected by some PIs and managers for allowing normal activities to be resumed following the spill of an agent of low toxicity or having little potential as a human pathogen. Allowing for an appropriate time for the settling of airborne particulates prior to the decontamination is also advisable. The responsibility monitoring or carrying out the decontamination process may be delegated to a designated safety officer. Personal knowledge by the responsible supervisor or safety officer that an accepted decontamination procedure has been completed is considered essential prior to resumption of normal activities following spillage or release of potentially biohazardous materials.

(J) Periodic Review of Risk Assessment Information

Each PI or laboratory supervisor shall monitor the current literature for recommended changes in standard laboratory practices related to their specific biohazardous activities and update their practices accordingly.

(K) Emergency Response Protocols

As appropriate, signage with Emergency Response Protocols should be posted in the laboratory. A telephone must be located within the laboratory to allow reporting of the incident without spreading materials through corridors and into other labs and office areas.

<u>If you drop or otherwise spill a container of biohazardous microorganisms requiring BSL2 or above and are in the same room where this occurs</u>:

1. Hold your breath. Leave the room. Close the door behind you.
2. Remove and containerize contaminated protective garments (including shoes) immediately at the door after exiting.
3. Warn others of the spill, and isolate the area.
4. Assure that the Principal Investigator or laboratory manager is notified.
5. Wash hands and face or, if facilities are available, shower. Use germicidal soap.

<u>If you detect a spill which you don't know what to do?</u>

1. Secure the area to ensure no other personnel enter.

2. Call for assistance: UNTHSC Police at 817-735-2600 who will in turn notify the Bio Safety Office extn: 5431.

3. Wait for assistance.

III. Roles and Responsibilities

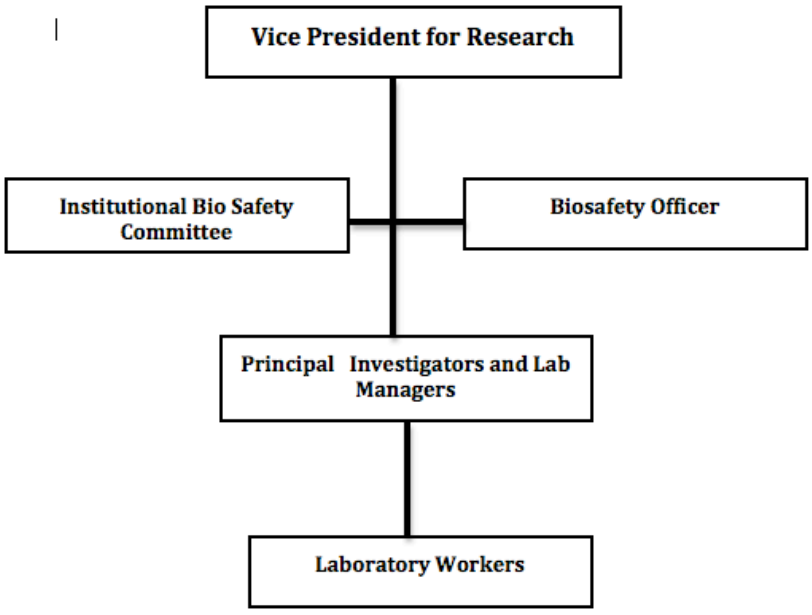
A. General

This Manual specifies the minimum criteria to be met with any covered potentially biohazardous materials or activities. Individual PIs and laboratory managers may set more stringent criteria if and when it is considered prudent. This Manual should not to be considered final or all-inclusive, however, since all possible situations can never be foreseen.

Modifications of this Manual will occur on a regular basis in order to meet continuously changing regulations and conditions. It is the responsibility of each individual associated with potentially biohazardous activities to adhere to both the intent of this Manual as well as to its specifics, and to make every reasonable effort to minimize risks to individuals, animals and the environment to the greatest degree possible.

The administrative framework under which potentially biohazardous activities within UNTHSC laboratories by UNTHSC faculty, staff, students, contractors and visitors will be carried out is described below. This section outlines the basic roles and responsibilities of persons involved at each level of the approval, the monitoring or the supervision of biosafety activities at the University. Further clarification and interpretation of these roles and responsibilities may be obtained by contacting the Chair of the IBC or the University's BSO.

B. Biosafety Program Organizational Structure



C. University Responsible Official

The University Responsible Official for all laboratory work involving biohazardous materials is the Vice President of Research. The University and the Responsible Official recognize their responsibility to monitor and control potentially biohazardous activities conducted within its facilities or by persons associated with the University, and thus has established and implemented rules and guidelines for conducting these activities as described in this Biosafety Manual. The Manual outlines the procedures for approval and safe conduct of potentially biohazardous activities and directs compliance with all directives and guidelines pertaining to such activities. The University has established an IBC to meet the requirements specified by the National Institutes of Health Guidelines and requirements of the U.S. Department of Agriculture (USDA).

The Vice President of Research has appointed a biosafety officer (BSO) and established the IBC. The Vice President of Research will ensure that the BSO and the IBC members receive the training necessary to perform their assigned duties and to keep familiar with new or pending changes in applicable federal/state/local guidelines related to biosafety. The BSO is responsible for training IBC members with regard to the IBC's standard operating procedures. The IBC, through the BSO, must ensure that necessary biosafety training of supervisory personnel as required by this Manual and/or externally imposed directives are provided. Responsibility for training others is delegated to PI's or laboratory mangers.

D. Institutional Biosafety Committee (IBC)

The IBC membership shall be qualified and appointed in accordance with guidelines established by the NIH and the USDA.

1. Membership of the IBC consists of a minimum of five (5) persons, two (2) of which cannot be affiliated with the University except as IBC members and will represent the interests of the surrounding community with respect to health and protection of the environment. The Vice President of Research appoint the members of the IBC. IBC members serve a term of 3 years. Membership appointments will be arranged in a staggered fashion, with approximately 1/3 of the positions expiring each year. Members are eligible for reappointment to multiple consecutive terms. The BSO is a mandatory member of the IBC and is eligible to be appointed as its chairperson. The IBC should have a representative from the Safety Office and a representative from the Office of Research.

2. Collectively the committee's members shall have the necessary experience and expertise in all areas necessary to carry out risk assessment of all activities involving potentially biohazardous agents within the University's facilities or by persons associated with the University. This shall include a working knowledge of recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health and the environment; potentially biohazardous

organisms; the risks of various activities involving the use of human-derived materials. The IBC shall include at least one scientist with expertise in animal pathogen containment principles. The IBC is encouraged to use consultants who are knowledgeable of institutional policies; applicable laws; occupational health and safety standards; environmental protection regulations; standards of professional conduct and practices; and of community attitudes.

3. The current IBC membership shall be submitted to the NIH Office of Biotechnology Activities (OBA) and, as appropriate, to other contract, grant or media authorities.

4. No member of the IBC may be involved (except to provide information) in the review or approval of any project in which he/she has been, or expects to become, engaged or in which he/she has a direct financial interest.

5. IBC meetings are to be open to the public whenever feasible and consistent with the protection of privacy and proprietary interests.

6. Minutes of the IBC meetings (including closed meetings) and documents submitted to or received from funding agencies are to be made available to the public in accordance with NIH Guidelines and the Texas Public Information Act. If comments are received from members of the public, the press or other governmental agencies on the IBC actions, the IBC will forward a copy of both comments and the IBC's response to the OBA.

7.The IBC, through its chair person and the BSO, shall keep the Vice President, Research informed of developments and practices regarding the use of potentially biohazardous materials and, upon request, provide an overall safety, health and environmental review of the University's activities involving potentially biohazardous materials. The IBC, or the BSO acting with the consent and on behalf of the IBC, shall be responsible for:

(a) assessing the containment levels required by the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) as well as other potentially biohazardous materials and organisms;

(b) the assessment of facilities, procedures, practices, and training and expertise of personnel involved in laboratory activities utilizing potentially biohazardous materials;

(c) notifying Principal Investigators, laboratory managers, the Office of Research and other UNTHSC committees of the results of the IBC's review of initial and renewal applications;

(d) adopting emergency plans covering accidental spills and personnel contamination resulting from laboratory activities. The BSO shall cooperate with state and local public health departments by reporting any significant research or education-related illnesses or accidents that may be hazardous to the public health;

(e) periodically reviewing laboratory work involving biohazardous agents, human materials, and recombinant DNA molecules and educational activities conducted at UNTHSC to ensure compliance with the latest edition of Biosafety in Microbiological and Biomedical Laboratories, the NIH Recombinant Guidelines, the OSHA Occupational Exposure to Blood borne Pathogens Standards, and any guidelines adopted by the IBC.

(f) reporting any significant problems with or violations of the NIH Guidelines and all laboratory accidents or illnesses involving recombinant DNA molecules to the UNTHSC Vice President, Research and to the NIH Office of Biotechnology Activities within 30 days as required, unless it is determined that a report has already been filed by the Principal Investigator;

(g) filing an annual report with the NIH Office of Biotechnology Activities;

(h) reviewing the manual every three years and recommending revisions to the biosafety program and this Manual as needed to the Vice President, Research.

E. Biosafety Officer (BSO)

1. The BSO shall be responsible for:
(a) periodically inspecting all laboratories where biohazardous agents, human materials, or recombinant DNA research or other educational activities are being conducted to ensure that laboratory standards are being followed;
(b) reporting to the IBC and to the Vice President of Research any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biosafety Officer becomes aware, unless the Biosafety Officer determines that a report has already been filed by the Principal Investigator;
(c) developing emergency plans for handling and investigating laboratory accidents involving biohazardous agents, human materials, toxins or recombinant DNA molecules;
(d) working with the Safety Office to provide technical advice on research safety and laboratory security procedures to Principal Investigators, laboratory personnel, and the IBC;
(e) serving as a liaison between UNTHSC and external regulatory agencies concerned with the use of biohazardous agents, human materials, toxins and recombinant DNA molecules;
(f) serving as a voting member of the IBC, including eligibility for appointment as Chair;
(g) maintaining and updating the Biosafety Manual.
(h) reviewing all funded grants for compliance with applicable sections of this Manual
(i) maintaining a list of organisms present in the agency facilities and where these agents are used and stored.
(j) Ensure project specific biosafety plans are in place for each PI

F. Principal Investigator (PI) and/or Laboratory Manager

The PI or laboratory manager is directly and primarily responsible for the safety of operations under their control. His/her knowledge and judgment are critical for assessing and controlling risks associated with the handling of potentially biohazardous materials, training laboratory personnel and responding to emergency situations. He/she is also ultimately responsible for full compliance with this Manual and other applicable directives (state and federal law and NIH and USDA "Guidelines", etc.) during the conduct of activities involving potentially biohazardous materials. **Specifically the PI or laboratory supervisor shall:**

1. Be adequately trained in the appropriate laboratory techniques.
2. If the research activities submitted require approval by EPA, NIH and/or USDA, the PI must obtain such approval prior to the submission of the protocol to IBC. PIs shall not initiate or modify research involving potentially biohazardous materials that requires IBC approval until that research or the proposed modification has been approved by the IBC.
3. Determine whether experiments are covered by "Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation," Section III-D of the NIH Guidelines, and that the appropriate procedures are followed.
4. Determine appropriate guidelines and other directives applicable to the research or educational activity and comply with them during all such activities.
5. Prior to and during all potentially biohazardous laboratory work, select appropriate procedures to be used and make available to their staff/students copies of work protocols that describe potential hazards, actions required to diminish hazards and any other necessary precautions.
6. Prior to start of activities, conduct or oversee instruction and training of those working in laboratories under the control of the PI in the practices and techniques required to ensure safety, and for dealing with accidents.
7. Advise those working in laboratories under the control of the PI of reasons and provisions for any advised or requested precautionary medical practices such as vaccinations or serum collection.
8. Supervise those working in laboratories under the control of the PI to ensure that safe practices and techniques are followed in operations.
9. Maintain an inventory of all vectors, microbial strains, viruses and other potentially biohazardous materials used or stored in their laboratory and make it available for inspection.
10. Immediately report and, in coordination with the BSO, forward, in writing to the IBC any violations of or significant problems pertaining to operation and implementation of containment practices and procedures.
11. Identify and immediately report to the BSO any accidental releases, illnesses or diseases to workers, plants or animals involved in or potentially exposed to the activity and of any possible adverse personnel exposures. The BSO will take appropriate action(s) and then file a written report with the IBC.

12. Identify and correct work protocols and conditions that unnecessarily increase the chance of a spill or the release of potentially biohazardous material or in an injury or illness.
13.Ensure the integrity of physical containment facilities/equipment (storage facilities, fume hoods, biosafety cabinets, etc.) used for manipulation or storage of biohazardous materials or substances. Biosafety cabinets shall be certified after installation and prior to use, and certified annually thereafter. Prior to moving a biosafety cabinet, the cabinet shall be decontaminated. Prior to using the cabinet at a new location, it shall be re-certified.
14. Coordinate and monitor custodial activities and/or facility or equipment maintenance carried out during activities involving potentially biohazardous materials (or in restricted access areas where potentially biohazardous materials are utilized), ensuring appropriate training, security and/or decontamination as necessary to protect both persons involved and the potentially biohazardous activity.
15.Keep those working in laboratories under the control of the PI informed of new or changing criteria, guidelines, directives or procedures that may become applicable to activities under the direction of the PI or laboratory supervisor.
16.Remain in communication with the IBC throughout the time during which the approved project is in effect. The PI/Laboratory Supervisor is also responsible to arrange for and monitor any final decontamination of the facility and disposal of any potentially biohazardous residues that may remain after the completion of the project/activity.
17.Ensure proper decontamination of the laboratory or animal facility and the equipment as necessary to ensure safety during any required inspection, calibration, and recertification activity.
18. Ensure proper disposal of all potentially biohazardous materials.
19. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
20.Comply, or assure compliance, with applicable U.S. Department of Transportation, EPA, and USDA criteria in the transportation (on campus) or shipping (off campus) of regulated potentially biohazardous materials or wastes.

G. Laboratory Workers

Each laboratory worker conducting potentially biohazardous activities must share responsibility. Workers shall report all accidents and exposures to potentially biohazardous materials, work-related (or possibly work-related) illnesses and hazardous circumstances and incidents to the PI or laboratory supervisor in a timely fashion. Laboratory workers must be familiar with and carefully follow all work protocols and operating procedures applicable to their activities. This includes familiarity with this Biosafety Manual. Workers must also keep their PI or laboratory supervisor informed of any personal conditions such as an illness, use of medication, pregnancy, or reduced immunity that could make work with potentially biohazardous materials more hazardous to themselves or others.

IV. Requirements

A. Biosafety Program Fundamentals

UNTHSC's biosafety program includes (1) education and training; (2) maintenance; (3) surveillance and enforcement, (4) and emergency planning.

The education and training requirement for biosafety stipulates that only those with an appropriate formal education be directly involved with the use of potentially biohazardous materials and that they be formally trained for their specific tasks. Specific individual formal education requirements may be developed, if necessary, by the IBC for persons involved in certain biohazardous activities. Additional specialized training in biohazard techniques and controls may be required if deemed necessary. All persons working with potentially biohazardous materials and those working around or in support activities must also be instructed in (1) the specific hazards of their work area(s) or activities, (2) methods they can utilize to minimize hazards, and (3) actions required should an emergency situation arise.

The maintenance and surveillance concepts cover all materials, equipment and facilities required to make biohazardous work as safe as feasible. It considers both people and their work conditions and includes among other things: (1) the selection and monitoring of personnel, areas, facilities and equipment; (2) the design, construction, renovation or modification, inspection, certification and maintenance of facilities and equipment; (3) the destruction or safe disposal of potentially biohazardous waste; and (4) the decontamination of facilities and equipment no longer to be used for biohazardous activities.

Enforcement requires self-discipline by all persons directly or indirectly involved in potentially biohazardous activities. They must avoid creating any undue danger to themselves or others. It also involves reviews of all biohazardous activities by knowledgeable peers and inspections or surveys of both work and work places by qualified officials. Finally, as implied by this term, there are procedures to order correction or termination of unsafe biohazardous practices or conditions.

An appropriate, equipped and in-place response capability for emergencies completes the four parts of our program. This utilizes the services of not only the University itself but those of the community as well.

1. Education and Training

While no overall educational or training level can be specified for all persons who are, or will become, engaged in biohazardous activities, all should at least meet minimum requirements stated below for the area or activity involved. Whenever gaps in educational

background are noted, or whenever remedial or update training is needed, it is to be given. Educational evaluations and additional education or training requirements are to be imposed on an individual and specific project basis when needed. **All persons working with or around biohazards must:**

(a) be instructed in entry control procedures; the meanings of the various signs, signals or other controls used; applicable emergency procedures applying to their work activities and area, recognition and prevention of dangerous situations and/or exposures, and the symptoms (acute and chronic) of possible exposures.

(b) receive documented training in basic level biosafety; applicable directives (including use of this Manual); and specific methods and requirements of their work and work area. Awareness training shall be provided to maintenance personnel. The BSO, in accordance with the potential risk associated with exposure, will determine the extent of the required training. In an effort to provide timely and convenient access to basic level biosafety training materials, BSO developed a web-based self paced Biological safety training program. This also include a quiz to evaluate the basic understanding of the principles of biological safety. The basic biosafety level training will be available on the biosafety web page.

c) All persons working in laboratories where biohazardous materials are used or stored shall participate in and complete biosafety training appropriate to their work environment and position duties. Such training shall be repeated on a basis deemed necessary by the IBC, and based on requirements to improve safety at UNTHSC, increase safety awareness in work areas and meet requirements set forth by CDC, NIH, OSHA, and other applicable regulations and standards. Required training includes, but is not limited to:

Employee Training: Training will be provided to laboratory personnel working with potentially biohazardous materials, and may include refresher training as may be required by the IBC or by state or federal law.

Student Training: Students shall participate in a general biosafety program provided through student orientation or on a case-by-case basis, additional training based on laboratory activities.

High Risk Situation Training: BSL-2 and higher work may require the establishment and maintenance of site specific, in-depth safety training programs for employees and students working in BSL-2 facilities.

(d) Documentation of training shall be kept for each employee, faculty, student, and contract worker. Such documents shall be updated on a regular basis and additional trainings required. Documentation of safety training must contain:

(1) Name of trainee
(2) Date of training
(3) Title of program
(4) Instructor's name

Additional information may be kept as appropriate. The department or school shall maintain records appropriate for each trainee.

2. Maintenance (and Design and Construction)

Design and construction of new facilities and modifications of existing facilities for biohazardous activities shall conform to the NIH Laboratory Safety Monograph, the supplement to the NIH Guidelines for Recombinant DNA Research, the latest edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories and the NIH Guidelines for Recombinant DNA Research. Maintenance and repairs to existing biohazard facilities or equipment shall not violate containment requirements specified for the area considering the type activity involved. Containment integrity shall be certified by a qualified inspector before new construction, remodeling or renovation is considered complete.

NOTE: it is not expected that all biohazardous activities shall necessarily cease, or that areas be completely decontaminated before emergency repairs can be made. All other maintenance and repair activities in biohazard areas shall however, be jointly scheduled between Facilities Management and the person or persons in charge of the biohazard area/activity so that dangers to personnel, projects and/or the environment can be controlled.

Redundant containment controls for potentially biohazardous materials shall be used in activities to the extent required for the specific work. The IBC has authority to impose additional controls to contain biohazards whenever deemed necessary.

3. Surveillance and Enforcement

The preferred and most effective method biosafety enforcement is that self-imposed by the individual(s) involved in potentially biohazardous activities. No system of rules or guidance concerning so extensive a subject can be expected to completely cover all aspects of the biosafety needs for the research and teaching activities of a major university. All persons involved in these activities, including persons not directly associated with UNTHSC (such as visiting scientists) are expected to always act carefully and prudently and to conform to both the specifics and spirit of this Manual and to refrain from any potentially biohazardous laboratory activity. Each person is expected to be familiar with the known hazards of the materials or substances utilized; the rules or regulations pertaining to their activities; and to carefully observe appropriate/approved protocols for specific projects. Each individual engaging in potentially biohazardous activities is further expected to correct any observed unsafe conditions or practices if this is within his/her ability or authority, or to report them to the responsible PI, laboratory manager, or to the BSO for correction.

Redundancy in enforcement is necessary because individuals may unconsciously develop unsafe practices or fail to recognize unsafe conditions. For this reason, all PIs and others

supervising or overseeing potentially biohazardous activities are expected to closely and thoroughly inspect the work, work practices and work conditions of subordinates and expeditiously correct any unsafe conditions and/or practices observed. All laboratories utilizing potentially biohazardous agents will be subject to annual inspections by the University BSO/BSO Designee/IBC members. Inspections of these laboratories will be performed for compliance with NIH Guideliles and CDC regulations (BMBL) as applicable. A report of the results of these inspections will be maintained in the Biosafety Office.

4. Emergency Planning

Please see section II of this Manual

Compliance with this policy shall be monitored by the IBC. Information regarding the training guidelines established by the committee may be obtained by contacting Biosafety officer. Questions regarding required training or concerning new training for specific areas might be directed to Biosafety officer.

B. Standard Operating Procedures (SOPs)

PIs and others proposing work with potentially biohazardous materials must develop detailed protocols for those activities. These protocols must be submitted to the IBC when required by directives or this Manual. The IBC, or the BSO acting on behalf of the IBC, shall evaluate the protocols and potential hazards involved and, as appropriate, approve or direct/suggest changes.

It is the responsibility of the PI or laboratory manager to see that protocols are carefully followed once approved by the IBC. The IBC, with the assistance of any subcommittees or specialists as may be required, will oversee and, and if necessary, enforce the provisions of individual project protocols, legal requirements, the UNTHSC Biosfety manual.

The BSO will perform all surveys and inspections as required by contract, grant guidelines, this Manual or as directed by the IBC. Reports shall be provided to the PI or supervisor involved, the responsible department(s) and the IBC. Corrective actions, to the satisfaction of the IBC, are to be taken for each deficiency noted. Copies of all reports will be maintained in the Office of Research. PI is accountable for the biosafety of students and/or subordinates and their activities. As such they shall ensure security and controls necessary for safely conducting biohazard activities within their jurisdiction. They are encouraged to use the assistance of the BSO, and IBC when necessary.

1.Applicable Standards

This Manual adopts by reference the standard operating procedures of the latest edition of the NIH/CDC publication Biosafety in Microbiological and Biomedical Laboratories.

1.Biosafety Level 1 – work with risk group one agents; see section V. of this Manual
2.Biosafety Level 2 – work with risk group two agents; see section V. of this Manual

3.Biosafety Level 3 – work with risk group three agents; see section V. of this Manual
4.Biosafety Level 4 – (no work at this containment level will be approved)

2. Entry Restrictions

Minimum entry requirements are specified by biosafety level in this Manual. Restricted access areas shall be fully identified by meaningful signs that provide necessary information to any persons, including emergency response personnel. At a minimum, such signs shall provide the biosafety level of the lab. The BSO will maintain biosafety information related to each laboratory using biological agents, and a print out of this information should be provided to the campus police to use in the case of emergency.

a. Visitors

Visitor entry controls shall preclude unauthorized access by any person under the age of 18 years and preclude entry to areas having specific immunization requirements. All visitors under the age of 18 should be under constant supervision and the Pi will be responsible for the supervision.

b. Non-qualified laboratory workers

Laboratory worker access is limited to such equipment and supplies as needed for activities within the area which have been protected for contamination related to work conducted by biohazard qualified laboratory personnel.

3. Emergency Action Plans

Emergency action plans for individual laboratories should be made available to emergency crews so that they can better control the emergency, decontaminate themselves and/or their equipment as necessary, and/or receive any needed prophylactic treatments. It is expected that one or more knowledgeable persons from the facility involved will be available to assist in, or advise on response actions, and shall along with emergency response personnel check the safety of any incident area before the area/facility is returned to normal usage or turned over to repair/demolition personnel.

Information regarding biohazardous materials or substances involved or possibly encountered is to be made available to response crews at the time of their response. Copies of this information, if needed, shall also be provided to medical care personnel. Contractor personnel, unless they themselves are qualified in the biohazards to which they could potentially be exposed, shall not work on or in biohazard areas unless prior decontamination of the area has been satisfactorily accomplished. If any potentially biohazardous activities are to continue while contractor personnel are in the area, adequate isolation provisions shall be established to protect both personnel and work.

C. Laboratories with Activities Involving Potentially Biohazardous Agents, Human Materials, and Recombinant DNA Molecules

All work in laboratories with activities involving biohazardous agents, human materials, and recombinant DNA molecules must conform to requirements of this Manual, applicable NIH / EPA / USDA Guidelines and any other directives or guidelines determined applicable by the IBC for the specific activity. Any renovations of facilities necessary for biohazard activities shall conform to requirements of this Manual (including "Guidelines" and other directives adopted by reference) and the UNTHSC Policy Manual.

D. Approval of Projects Using Biological Agents

The initial assessment of the risk level and approval requirements for all funded research activities involving potentially biohazardous materials will be made by the Principal Investigators and/or laboratory supervisors. In all cases, the BSO shall also review the project for proper risk categorization. In the event the PI and BSO disagree on the risk level of proposed experiments, the protocol shall be submitted to the IBC for their review and determination of risk level.

For details about registration and forms see section X of this Manual and visit biosafety web page.

Approval requirements for the various risk levels of experiments involving recombinant DNA constructs are described below.

1. Exempt Recombinant Experiments

Recombinant DNA experiments exempt from the NIH recombinant DNA Guidelines include:

(a) Those that are not in organisms or viruses (e.g. PCR, Northern or Southern blotting),

(b) Those that involve DNA segments consisting entirely of single non-chromosomal source or manipulations of a viral DNA source though one or more of the segments may be a synthetic equivalent,

(c) Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses propagated in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means,

(d) Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (excluding viruses) propagated in that host (or a closely related strain of the same species),

(e) Those that consist entirely of DNA from different species that exchange DNA by well known physiological processes, through one or more of the segments may be a synthetic equivalent. A list of such exchangers is prepared and periodically revised by NIH

(f) Those that do not present a significant risk to health or the environment, as determined by the NIH Director with the advice of the RAC. Experiments or activities involving the use of BSL1 organisms that do not contain rDNA constructs or into which rDNA constructs are not introduced.

(g) **Specific Recombinant DNA Exemptions Defined:**

1. Recombinant DNA molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical), that are propagated and maintained in cells in tissue culture are exempt from the NIH Guidelines with the exceptions listed in Appendix C-1-A of the NIH Guidelines.

2. Experiments that use Escherichia coli K-12 host-vector systems with the exception of those experiments listed in Appendix C-11-A of the NIH Guidelines.

3. Experiments involving Saccharomyces cerevisiae and Saccharomyces uvarum host-vector systems, with the exception of experiments listed in appendix C-III-A of the NIH Guidelines.

4. Any asporogenic Bacillus subtilis or asporogenic Bacillus licheniformis strain which does not revert to a sporeformer with a frequency greater than 10-7 may be used for cloning DNA with the exception of those experiments listed in Appendix C-IV-A of the NIH Guidelines.

5. Recombinant DNA derived entirely from extra chromosomal elements of the organisms listed below (including shuttle vectors constructed from vectors described in Appendix C of the NIH Guidelines), propagated and maintained in organisms listed below are exempt from the NIH Guidelines:

Bacillus amyloliquefaciens	Bacillus amylosacchariticus	Bacillus anthracis
Bacillus aterrimus	Bacillus brevis	Bacillus cereus
Bacillus globigii	Bacillus licheniformis	Bacillus megaterium
Bacillus natto	Bacillus niger	Bacillus pumilus
Bacillus sphaericus	Bacillus stearothermophilis	Bacillus subtilis
Bacillus thuringiensis	Clostridium acetobutylicum	Latobacillus casei
Listeria grayi	Listeria monocytogenes	Listeria murrayi
Pediococcus acidilactici	Pediococcus damnosus	Pediococcus pentosaceus
Staphylococcus aureus	Staphylococcus carnosus	Staphylococcus epidermidis
Streptococcus agalactiae	Streptococcus anginosus	Streptococcus avium
Streptococcus cremoris	Streptococcus dorans	Streptococcus equisimilis

Streptococcus facecalis	Streptococcus ferus	Streptococcus lactis
Streptococcus ferns	Streptococcus mitior	Streptococcus mutans
Streptococcus pyogenes	Streptococcus salivarious	Streptococcus sanguis
Streptococcus sobrinus	Streptococcus thermophylus	

2. Experiments that Require IBC Approval Prior to Initiation

(a) Experiments that use human, plant or animal pathogens (RG2 - RG4 and Restricted Agents).

(b) Experiments involving DNA from human, plant or animal pathogens cloned into a nonpathogenic prokaryotic or lower eukaryotic host-vector system.

(c) Experiments involving the use of infectious animal or plant DNA or RNA viruses of defective animal or plant DNA or RNA viruses in the presence of helper virus in tissue culture systems.

(d) Recombinant DNA experiments involving whole animals (IACUC approval also required).

(e) Experiments involving whole plants to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes, to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA.

3. Experiments that Require IBC and NIH/ORDA Approval Before Initiation

(a) Recombinant DNA experiments that clone toxin molecules with an LD50 less than 100 ng/kg body weight.

4. Experiments that Require Institutional Biosafety Committee Approval, RAC Review and NIH Director Approval Before Initiation Recombinant DNA experiments that involve:

(a) The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
(b) Human gene transfer experiments.

V. Acquisition, Transportation and Shipping

A. Acquisition of Potentially Biohazardous Materials

The institution does not have facilities for work at biosafety level 4 or 3 (BSL-4 or 3). Organisms and molecules that require biosafety level 4 or 3 work practices and engineering controls may NOT be possessed or used in health science center owned and leased facilities.

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The purchase of organisms, recombinant materials and exempt quantities of toxins for work BELOW biosafety level 3, do not require prior approval of the BSO. Departments should use ePro Goods Categories 495-91 and 495-92 as appropriate.

1. Purchase of biological materials and organisms

EIS Goods Categories	Description
495 -91	biological materials requiring BSL1
495-92	biological materials for work at BSL2
495-93	biological materials for work at BSL3

Lab staff are responsible for providing the BSL level to the person entering orders into the EIS system. The person entering the order into EIS is responsible for using the correct goods category. For guidelines for BSL levels can be found in the latest edition of the Centers for Disease Control and Prevention/National Institute of Health(CDC/NIH) Biosafety in Microbiology and Biomedical Laboratory (BMBL). Online version is available on http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.html.

B. Transfer of Potentially Biohazardous Materials

No individual associated with the University of North Texas Health Science Center may transfer potentially biohazardous materials to another individual or facility (at UNTHSC or another location) without first obtaining written approval from the BSO at the receiving agency that the individual to whom the potentially biohazardous materials are being provided is authorized to possess those materials. Individual with UNTHSC will receive potentially biohazard materials from other researchers should follow the following procedures

Description	
biological materials requiring BSL1	No specialreqirements
biological materials for work at BSL2	Notify UNTHSC BSO prior to the transfer/receiving
biological materials for work at BSL3	need to get approval from UNTHSC BSO prior to the transfer/receiving

C. Packaging Requirements and Methods for Shipment of Biohazardous

Before Biohazardous Agents, Human Materials, or Recombinant DNA Molecules can be shipped to any location, the Biosafety Officer must receive written approval from an authorized official at the recipient institution confirming that the institution is authorized to possess the materials to be shipped. Further, when any such materials are to be shipped to any location, the sender must obtain a receipt confirming that the materials were received. If no receipt is obtained within 5 days after the materials were shipped, the sender must then notify the Biosafety Officer of that situation. The Biosafety Officer shall determine if notification to the Centers for Disease Control is warranted. All materials shipped must be packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling and transportation (passage through cancellation machines, sorters, conveyors, etc.). CDC Regulations for the transportation of etiologic agents and related materials can be found in the Department of Transportation Final rule "Hazardous Materials – Revision to Standards from Hazardous Infectious Substances (67 FR 53118, August 2002) as revised from Hazardous Materials Regulations eCfr 49 available at http://ecfr.gpoaccess.gov

D. Shipping by Overnight Delivery Carriers:

Etiologic agents transported by these carriers do not require receipt of shipment as they may be traced by contacting the specific carrier.

VI. Biohazardous Agents Classification by Risk Group

A. Risk Assessment and Risk Groups

The Principal Investigator is required to make an initial risk assessment for each project based on the Risk Group of an agent. There are four Risk Groups (RGs) in the NIH Recombinant DNA Guidelines:

- **Risk Group 1:** Agents not associated with disease in health adult humans.
- **Risk Group 2:** Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
- **Risk Group 3:** Agents associate with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).
- **Risk Group 4:** Agents 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).

B. Examples of Agents in Risk Groups 1-4

Examples of organisms that have been classified into particular risk groups are provided below. It is the responsibility of the PI or laboratory supervisor to assign risk categories to risks not listed below.

Risk Group 1 Agents:

- *Escherichia coli-K12*
- *Bacillus subtilis or Bacillus licheniformis*
- *Adeno-associated virus types 1 through 4*

Risk Group 2 Agents:

- *Borrelia burgdorferi*
- *Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen*
- *Mycobacterium (except those listed in Risk Group 3) including M. avium complex*
- *Staphylococcus aureus*
- *Leishmania including L. major and L. mexicana*
- *Toxoplasma including T. gondii*
- *Adenoviruses, human - all types*
- *Eastern and western equine encephalomyelitis virus*
- *Yellow fever virus vaccine strain 17D*
- *Rabies virus - all strains*

Risk Group 3 Agents:

- *Brucella including B. abortus, B. canis, B. suis*

- *Mycobacterium bovis (except BCG strain)*
- *Mycobacterium tuberculosis*
- *Rickettsia species*
- *Yersinia pestis*
- *Histoplasma capsulatum*
- *Venezuelan equine encephalomyelitis virus (except vaccine strain TC-83 - RG2)*
- *Japanese encephalitis virus*
- *Human immunodeficiency virus (HIV) types 1 and 2*

Risk Group 4 Agents:

- *Lassa virus*
- *Crimean-Congo hemorrhagic fever virus*
- *Ebola virus*
- *Herpes virus simiae (Herpes B or Monkey B virus)*
- *Hemorrhagic fever agents and viruses as yet undefined*

C. Animal Viral Etiologic Agents in Common Use

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans and they are commonly used in laboratory experimental work. For those agents that do not infect human cells, a containment level appropriate for Risk Group 1 human agents is recommended. A containment level appropriate for Risk Group 2 human agents is recommended for those that do infect human cells.

- Baculoviruses
- Herpesviruses (H. ateles, H. saimiri, Marek's disease virus, murine cytomegalovirus)
- Papovaviruses (bovine papilloma virus, polyoma virus, simian virus 40)
- Retroviruses (avian leukosis virus, bovine leukemia virus, feline leukemia virus, feline sarcoma virus, gibbon ape leukemia virus, Mason-Pfizer monkey virus, murine leukemia virus, murine sarcoma virus)

D. Virus Vectors

Murine retroviral vectors to be used for gene transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered under BSL1 containment.

VII. Microbiological and Biomedical Laboratories

Biosafety Guidelines and Biosafety Levels
University of North Texas Health Science Center adheres to the procedures outlined in the most current edition of *Biosafety in Microbiological and Biomedical Laboratories* by the U.S. Department of Health and Human Services, National Institutes of Health and the NIH Guidelines for Research Involving Recombinant DNA Molecules.
http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.html

A biosafety level defines a combination of laboratory practices and techniques, safety equipment, and laboratory facilities that allow for the safe handling of a particular organism. The Principal Investigator or Laboratory Manager is specifically and primarily responsible for assessing risks and for appropriately applying the recommended biosafety levels.

1. Biosafety Level 1 (BSL1)

A BSL1 lab is suitable for work involving agents or possible exposure to agents of minimal potential hazard to laboratory personnel and the environment. It is appropriate for undergraduate and secondary education training and teaching laboratories, as well as facilities in which work is carried out using well defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Biosafety Level 1 represents a basic level of containment that relies on standard "good" microbiological practices. Laboratory personnel should have specific training in the procedures conducted in the laboratory and are supervised by a scientist or Laboratory Manager with general training in microbiology or a related science.

(a) BSL1 Standard Microbiological Practices

- A warning sign incorporating the universal biosafety symbol is posted on/at the access door to the laboratory/work area. The hazard warning sign identifies the biosafety level for the laboratory and well as contact information for the Principal Investigator and/or laboratory manager.
- Access to the laboratory is limited or restricted at the discretion of the laboratory manager when experiments or activities utilizing cultures and specimens are in progress.
- Persons wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in any laboratory or work area where potentially biohazardous agents, human materials, or recombinant DNA molecules are used. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the laboratory or work area in cabinets or refrigerators designated and used for this purpose only.
- Mouth pipetting is prohibited; mechanical pipetting devices are used.

- All procedures are performed carefully to minimize the creation of splashes or aerosols.
- Work surfaces are decontaminated at least once per day (following use) and immediately after any spill of viable material.
- All cultures, stocks and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leak proof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the laboratory are packaged in accordance with applicable local, state and federal regulations, before removal from the facility.
    - An insect and rodent control program is in effect.
    - A current inventory of microbial strains and vectors being used or stored in the laboratory is to be maintained and provided to the BSO annually.

1. BSL1 Special Practices (none)

2. **BSL1 Safety Equipment (Primary Barriers)**

- Special containment devices or equipment such as a biological safety cabinet are generally not required for manipulations of agents assigned to Biosafety Level 1.
- It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.
- Gloves should be worn if the skin on the hands is broken or if a rash exists.
- Protective eyewear should be worn for anticipated splashes of microorganisms or other hazardous materials to the face.

3. Laboratory Facilities (Secondary Barriers)

- Each laboratory shall contain a sink for hand washing.
- The laboratory is designed to be easily cleaned. Rugs in laboratories are not appropriate, and should not be used because proper decontamination following a spill is extremely difficult to achieve.
- Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are readily accessible for proper cleaning.
- If the laboratory has windows that open, they are fitted with fly screens.

a. Vacuum Systems Must be Protected from Potentially Hazardous Biological Agents

The aspiration of tissue culture media from monolayer cultures and of supernatants from centrifuged samples into primary collection flasks is a common laboratory procedure. To prevent the accidental

contamination of house vacuum system or vacuum pumps, protection should be provided against the transfer of biohazardous aerosols or overflow fluid into the vacuum system. This protection should be provided by the use of an air filter in the line immediately leading into the house vacuum line and an overflow flask for liquids between the collection flask and the air filter.

2. Biosafety Level 2 (BSL2)

A BSL 2 lab is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by scientists competent to work with these agents, (2) access to the laboratory is limited when work is being conducted, (3) extreme precautions are taken with contaminated sharp items, and (4) procedures which may create aerosols or splashes of infectious agents are conducted in biological safety cabinets or other physical containment equipment.

(a) BSL 2 Standard Microbiological Practices

- The Principal Investigator or Laboratory Manger limits access to the laboratory when experiments are in progress.
- The Principal Investigator or Laboratory Manager establishes policies and procedures to ensure that only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g. immunization) may enter work areas.
- Laboratory coats, gowns, smocks or uniforms are worn while in the laboratory. Protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory prior to exiting the laboratory. Appropriate protective gloves should be worn.
- Persons wash their hands after they handle viable materials/animals, after removing gloves and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas where there is reasonable likelihood of exposure to potentially infectious materials. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the laboratory in cabinets or refrigerators designated and used for this purpose only.
- Mouth pipetting prohibited; mechanical pipetting devices are used.
- All procedures are performed carefully to minimize the creation of splashes or aerosols.
- Work surfaces are decontaminated at least once a day and after any spill of viable material.
- All cultures, stocks and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leak proof container and

close for transport from the laboratory. Materials to be decontaminated at off-site from the laboratory are packaged in accordance with applicable local, state and federal regulations, before removal from the facility.

- An insect and rodent control program is in effect.
- A current inventory of microbial strains and vectors being used or stored in the laboratory is to be maintained and provided to the BSO annually.

b. BSL2 Special Practices

- Access to the laboratory is limited or restricted by the laboratory manager when work with potentially infectious agents is in progress. In general, persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous (e.g. immunosuppressed or immunocompromised individuals) are not allowed in the BSL 2 laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory manager has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
  The laboratory manager establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet specific entry requirements (e.g., immunization) enter the laboratory or animal rooms
- The organisms in use in the laboratory require special provisions for entry (e.g. vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator, Laboratory Manager, or other responsible party and indicates the special requirement(s) for entering the laboratory.
- Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g. hepatitis B vaccine or TB skin testing).
- When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.
- A biosafety manual is to be prepared or adopted. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.
- Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes.
- A high degree of precaution must always be taken with any contaminated

sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles.
Disposable/breakage resistant plastic ware should be substituted for glassware whenever possible.

- Only needle-locking syringes or disposable syringe-needle unites (i.e., needle is integral to the syringe) are used for injection or aspiration or infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate and possible.
- Broken glassware is not handled directly by hand, but must be removed by mechanical means such as a brush/dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated according to any local, state, or federal regulations prior to final disposal.

- Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
- Laboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after over spills, splashes, or other contamination by infectious materials. Contaminated equipment is decontaminated according to local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.
- Spills and accidents that result in overt exposures to potentially infectious materials are immediately reported to the laboratory manager and the IBC. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.
- Plants/animals not involved in the work being performed are not permitted in the laboratory.

c. BSL2 Safety Equipment (Primary Barriers)

- Properly maintained biological safety cabinets, preferably Class II, or
  Other appropriate personal protective equipment or physical containment devices are used whenever:

1.procedures with a potential for creating infectious aerosols or splashes are

conducted.
These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.
2.high concentrations or large volumes of infectious agents are used. Such materials 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.

- Face protection (goggles, mask, face shield or other splatter guards) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face, when the microorganisms must be manipulated outside the biosafety cabinet.
- Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution. Personnel should never take protective clothing home for any reason.
- Gloves are worn when handling infected animals and when hands may contact infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate; if a spill or splatter occurs, the outer glove can be removed and the hand will still be protected after the contaminated glove is removed.
- Gloves are disposed of when contaminated, removed when work with infectious materials is completed, and are not worn outside the laboratory. Disposable gloves are not washed or reused.

d. BSL 2 Laboratory Facilities

- Each laboratory contains a sink for hand washing.
- The laboratory is designed so that it can be easily cleaned. Rugs in laboratories are not appropriate, and should not be used because proper decontamination following a spill is extremely difficult.
- Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are readily accessible for cleaning.
- If the laboratory has windows that open, they are fitted with insect screens.
- A method for decontamination of infectious or regulated laboratory wastes is available (e.g., autoclave, chemical disinfection, incinerator, or other approved decontamination system).
- An eyewash facility is readily available.

3. Biosafety Level 3 (BSL3)

A BL3 is applicable to facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling

pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents. At this time UNTHSC has no approved BSL3 activities, and proposals to carry out BSL3 activities should not be initiated without prior consultation with the BSO and IBC. BSL3 practices and facility requirements are described below.

a. BL3 Standard Microbiological Practices

- Access to the laboratory is limited or restricted at the discretion of the laboratory manager when experiments or work with cultures and specimens are in progress.
- Persons wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas where there is reasonable likelihood of exposure to potentially infectious materials. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated and used for this purpose only.
- Mouth pipetting prohibited; mechanical pipetting devices are used.
- All procedures are performed carefully to minimize the creation of splashes or aerosols.
- Work surfaces are decontaminated at least once a day and after any spill of viable material.
- All cultures, stocks and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leak proof container and close for transport from the laboratory. Materials to be decontaminated at off-site from the laboratory are packaged in accordance with applicable local, state and federal regulations, before removal from the facility.
- An insect and rodent control program is in effect.
- A current inventory of microbial strains and vectors being used or stored in the laboratory is to be maintained and provided to the BSO annually.

b. BSL3 Special Practices

- Laboratory doors are kept closed when experiments are in progress.
- The laboratory manager controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. For example, persons who are immunocompromised or immunosuppressed may be at risk or acquiring infections. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The manager has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
- The laboratory manager establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any

specific entry requirements (e.g. immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms.

- When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posed on all laboratory and animal room access doors.
- Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).
- Baseline serum samples are collected and stored for all laboratory and other at-risk personnel.
- Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.
- A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.
- Laboratory personnel receive appropriate training on potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.
- The laboratory manager is responsible for insuring that before working with organisms at BSL3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory manager or other competent scientist proficient in safe microbiological practices and techniques.
- A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral infection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
  - **a.** Only needle-locking syringes or disposable syringe-needle unites (i.e., needle integral to the syringe) are used for injection or aspiration or infectious materials.
    1. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container
    2. for transport to a processing area for decontamination, preferably by autoclaving.

b. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

c. Broken glassware must not be handled directly be hand, but must be removed by mechanical means such as a brush, dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.

- All manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.
- Laboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials.
- Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.
- Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
- All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories or animal rooms are decontaminated before disposal or reuse.
- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material.
- Spills and accidents which result in overt or potential exposures to infectious materials are immediately reported to the laboratory manager. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.
- Animals and plants not related to the work being conducted are not permitted in the laboratory.

c. Safety Equipment

- Properly maintained biological safety cabinets are used for all manipulation of infectious materials.
- Outside of a biological safety cabinet, appropriate combinations of personal protective equipment are used (e.g., special protective clothing, masks, gloves, face protection, or respirators), in combination with physical containment devices (e.g., centrifuge safety cups, sealed centrifuge rotors, or containment caging for animals). Any use of respirators will require persons using these devices to have a fit test and a lung function test performed prior to use of this equipment. Contact the **Executive health and Wellness Center Services at x 5051** to get these tests performed.

- This equipment must be used for manipulations of cultures and of those clinical or environmental materials which may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected animals.
- Face protection (goggles and mask, or face shield) is worn for manipulations of infectious materials outside of a biological safety cabinet.
- Respiratory projection is worn when aerosols cannot be safely contained (i.e., outside of a biological safety cabinet), and in rooms containing infected animals. Any use of respirators will require persons using these devices to have a fit test and a lung function test performed prior to use of this equipment. Contact the **Executive health and Wellness Center Services at x 5051** to get these tests performed.
- Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls must be worn in, and not worn outside, the laboratory. Reusable laboratory clothing is to be decontaminated before being laundered.
- Gloves must be worn when handling infected animals and when hands may contact infectious materials and contaminated surfaces or equipment. Disposable gloves should be discarded when contaminated, and never for reuse.

d. Laboratory Facilities

- The laboratory is separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. A clothes change room (shower optional) may be included in the passageway.
- Each laboratory contains a sink for hand washing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.
- The interior surface of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontamination.
- Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are accessible for cleaning.
- Windows in the laboratory are closed and sealed.
- A method for decontaminating all laboratory wastes is available, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method).
- A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air from "clean" areas into the laboratory toward "contaminated" areas. The exhaust air is not re circulated to any other area of the building, and is discharged to the outside with filtration and other treatment optional. The outside exhaust must be dispersed away from occupied areas with air intakes. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper.

- The High Efficiency Particulate Air (HEPA)-filtered exhaust air from Class II or Class III biological safety cabinets is discharged directly to the outside or through the building exhaust system. If the HEPA-filtered exhaust air from Class II or III biological safety is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system. Exhaust air from Class II biological safety cabinets may be re circulated within the laboratory if the cabinet is tested and certified at least every twelve months.
- Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.
- Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent, which are routinely maintained and replaced as needed.
- An eyewash facility is readily available.

4. Biosafety Level 4 (BSL4)

A BL4 laboratory is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. At this time, UNTHSC does not have a facility that meets BL4 containment requirements and therefore does not allow the initiation of projects using organisms that require this degree of containment. Please refer to the NIH Guidelines for a listing of BSL4 agents, BSL4 regulations/procedures and a full description of a BSL4 maximum containment facility.

VIII. Bioengineering

General Comments

The University of North Texas Health Science Center adopts the guidelines published by the U.S. Office of Science and Technology Policy, as its requirements for biotechnology activities.

Regulations

The following brief notes on biotechnology are provided to aid in understanding the detailed requirements of the Federal control system. The National Environmental Policy Act (NEPA) requires all Federal agencies to prepare detailed analysis before finalizing any action that may significantly affect the environment. A coordinated framework for the regulation of biotechnology policies over research and products has been developed from already existing regulations and experience. The framework attempts to assure reasonable safeguards while achieving a balance between regulation, health and environmental safety concerns and the growth of industry. It allows Federal agencies to integrate and coordinate their programs to cover the full range of microorganisms, animals and plants derived through bioengineering. Bioengineering includes traditional genetic modification techniques and emerging genetic manipulation technologies. Traditional genetic modification techniques affect us every day through enhancement of the characteristics of food (e.g., selective breeding, hybridizing of plants, fermentation), waste disposal (e.g., bacterial sewer treatment), medicine (e.g., vaccines and hormones), pesticides (e.g., *Bacillus thuringiensis*) and other uses. Emerging genetic manipulation technologies include cloning, embryo transfers, recombinant DNA (rDNA) and recombinant RNA (rRNA) activities and cell fusion.

The framework for the regulation of research in biotechnology by regulatory agencies seeks to cover plants, animals and microorganisms modified, produced or derived by bioengineering technologies. The National Institutes of Health Guidelines for rDNA form the basis for the rules in this Manual. In addition to adherence to UNTHSC and federal requirements, an investigator must also comply with any biosafety procedures imposed by an external sponsor of research. Copies of the pertinent regulations may be obtained from the UNTHSC Office of Research Services

1X. Health Risk

Risk Disclosure

Principal Investigators and laboratory supervisors will disclose to the workers, researchers and students the risks involved in any procedure involving potentially biohazardous agents, human materials, or recombinant DNA molecules. Individual workers, researchers or students should consult a qualified physician for any questions regarding how such risks may impact his/her individual health risks.

Immunizations

Immunization requirements for biohazardous work are to be developed on a case-by-case basis by the PI or supervisor in consultation with the IBC and after consideration of medical advise. Generally those working with the following disease agents should be immunized against them unless contraindicated by medical authority. Depending upon the level of risk presented by the infectious agent in use, the Principal Investigator may be required to initiate a regular monitoring program for all persons who may be exposed to the agent.

Representative Diseases For Which Immunizations are Suggested

- Cholera
- Diphtheria
- Eastern Equine Encephalitis
- Influenza
- Measles
- Mumps
- Plague
- Poliomyelitis
- Q-Fever
- Rabies
- Rubella
- Russian Spring Summer Encephalitis
- Tetanus
- Typhoid
- Vaccinia
- *Varicella zoster*
- *Vibrio comma*
- Viral Hepatitis

X. Registration of Activities Involving Recombinant DNA, Human Materials, and/or Potentially Biohazardous Agents

All activities involving potentially biohazardous materials must be registered with and approved by the IBC/BSO. The registration/approval process is as follows:

(1) The Principal Investigator or Laboratory Manager will obtain and complete a Recombinant DNA Safety plan and Pathogen safety plan form. A copy of these forms is available in appendix D of this manual.

(2). The completed and signed registration form will be submitted to the BSO.

(3) The submitted form will be assigned a unique IBC file number by the Office of Biosafety.

(4) Depending upon the level of risk presented by the proposal activity and the requirements of any granting agency supporting the activity, the proposed activity may be initiated immediately following review by the BSO or may not be initiated until formal approval by the IBC and any other required agency (e.g. NIH, USDA, etc).

(5) The submitting Principal Investigator or Laboratory Manager will be informed typically within 7 working days after the date of submission of the proposal. Under any circumstances if the proposal need to be reviewed by the IBC. The Principal Investigator or Laboratory Manager will be informed the actions of both the BSO and IBC in a timely manner (Typically 4 weeks).

(6)The protocol approval will be granted for 3 years. Upon the completion of 3 years, a new registration form should be submitted to IBC for approval.

(7) PI is also required to submit an amendment form /new registration for registering any changes to the protocol. A copy of the amendment form is available in appendix D of this manual.

XI. APPENDICES

Appendix A: Biological Safety Cabinets, Clean Benches and HEPA-Filtered Exhaust Systems

Biological Safety Cabinets (BSCs)

BSCs are classified as Class I, Class II or Class III cabinets. Biosafety cabinets should not be confused with clean benches that only provide product protection. Clean benches must never be used with infectious agents.

Class I BSCs provide personnel and environmental protection, but not product protection.

Class II BSCs are the most commonly used BSC on the campus. These cabinets provide personnel, environmental and product protection. Only those that are hard ducted to the outside should be used when working with volatile chemicals. Additionally, personnel using ducted systems must be aware that the cabinets are not designed to prevent ignition of volatile chemicals. Class II BSCs come in four types (Type A, B1, B2 and B3):

Types A and B3 exhaust 30% of the air and re circulates 70% through the supply HEPA filter and back into the work zone. Type B3 is hard ducted to the outside, while Type A discharges air back into the laboratory after it is HEPA filtered. Type B1 exhausts 70% of the air and re circulates 30% through the supply HEPA filter, back to the work zone. Type B2 is a total exhaust cabinet; no air is re-circulated. This type of cabinet is hard ducted to the outside.

Proper use of Class II BSCs

Turn on the unit for at a minimum of 10 - 15 minutes prior to use. Turn off the germicidal U.V. light. Prepare a written checklist of materials necessary for a particular activity and place the materials in the BSC. Items should be placed in the cabinet such that a general flow of materials from a clean side/area to a dirty side/area is possible. Appropriate personal protective equipment must be worn. At a minimum this will include a buttoned laboratory coat and gloves.

The working height of the stool should be adjusted so that the worker's face is above the front opening. Manipulation of materials should be delayed for approximately one minute after placing the hands/arms in the cabinet working area. Activities should be organized/designed to minimize the frequency of moving your hands in and out of the cabinet. Do not cover any of the grillwork with materials. This disturbs the airflow. Movement within the cabinet should be conducted at a pace that minimizes airflow disruptions that can occur as a result of rapid movements.

Following completion of work, wipe the bottom and side of the hood surfaces with disinfectant.

NOTE: Be very careful when using small pieces of lightweight materials such as Kim wipes in the hood. These can drawn into the hood and disrupt the motor operations.

Biological Safety Cabinet Inspection
Biological Safety Cabinets should be inspected. Proper function should be verified upon receipt and before they are placed into use. Hoods must be inspected annually and following relocation. Failure to do so may lead to the use of a cabinet that is not functioning properly. Proper function of new biological safety cabinets also ensures that any necessary repairs are completed under manufacturers' warranties.

Installation of new biosafety cabinet
When installing a new (or used) biological safety cabinet, the Biosafety Officer should be provided with the
following information:
1) the name of the principal investigator
2) department in which the cabinet has been installed
3) manufacturer's name, model number, serial number
4) location of the cabinet (building and room number)
UNTHSC Biological Safety Cabinet Movement/Installation Form should be filled out and submitted to the Biosafety officer when ever you install/ move a Bio safety Cabinet. The form will be available from BSO

Appendix B: Autoclave and Steam Sterilizer

Inspection and Maintenance Autoclaves and steam sterilizers are pressure vessels requiring periodic testing and maintenance to assure their operability and safety. Operatives within user departments are required to perform periodic testing and maintenance of their units.
Autoclaves and steam sterilizers are important barrier systems used in research with potentially hazardous microorganisms. They are used as the principal devices for sterilizing contaminated wastes to insure safe disposal. Good safety management requires that the efficacy of these sterilization devices be verified before they are used for the sterilization of materials contaminated with potentially hazardous microorganisms. Efficiency of these systems will be evaluated periodically by certified agencies.

Appendix C: Protection of Vacuum Systems from Potentially Hazardous Biological Agents

The aspiration of tissue culture media from monolayer cultures and of supernatants from centrifuged samples into primary collection flasks is a common laboratory procedure. To prevent the accidental contamination of house vacuum system or vacuum pumps, protection should be provided against the transfer of biohazardous aerosols or overflow fluid into the vacuum system. This protection should be provided by the use of an air filter in the line immediately leading into the house vacuum line and an overflow flask for liquids between the collection flask and the air filter.

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee (IBC) Protocol Application

This Protocol Application must be completed for all activities which, in whole or in part, involve (i) recombinant deoxyribonucleic acid (rDNA) molecules, or (ii) organisms and viruses containing recombinant DNA molecules. Recombinant DNA molecules (rDNA) are defined by the NIH Guidelines for Research Involving Recombinant DNA Molecules as (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Consult (1) NIH Guidelines for Research Involving Recombinant DNA Molecules, (2) UNTHSC's Policy and Procedures for Research Involving Recombinant DNA Molecules, (3) CDC's Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, and (4) UNTHSC's Biohazard Recognition and Control: Guidelines for Handling Pathogenic Microorganisms & Disposing Biohazardous Waste for more information during completion of this application.

Submit the completed Protocol Application to the Office of Research Administration:
E-mail to ibc@unthsc.edu Drop off at CBH 160 E
Questions? Please contact Biosafety Office at 817-735 - 5431, ibc@unthsc.edu, or visit the website:
http://www.hsc.unt.edu/Sites/Biosaf

PART I. (All Recombinant DNA Experiments)

SECTION A: General Information

1A. Investigator name: 1B 3. Department :

2. Contact Information: Office Lab Email

3. Protocol Title:

4. Funding Agency/ Grant / Contract Number (Please attach copy of grant abstract):

5. Proposed start date: Proposed end date:

6. Location of work: Building Room

7. Additional Collaborators (include all faculty, students, and staff who will work on this protocol. (*All text boxes will expand)*

8. Conflict of interest

SECTION B: Protocol Information

9. Please include a brief overview of the project in layman's terms and its goals into the box below. Please avoid technical terms and jargon, or provide definitions when necessary.

SECTION C: The Use of Recombinant DNA

10. Please provide a brief description of the recombinant DNA (rDNA) work to be conducted for this project, including a description of any significant risks if appropriate.

11. **Exempt Recombinant DNA Experiments**: The *NIH Guidelines* provide a description of rDNA molecules that are considered exempt. UNTHSC's *Policy and Procedures for Research Involving Recombinant DNA Molecules* requires registration of exempt rDNA, via submission of **Part I** of this Application, to properly document the exemption. If any category below applies to your research, please check the appropriate box and proceed to the **"Principal Investigator Certification & Signature"** section. If the categories in Table 1 do not apply to your research, proceed to **Part II** of the Protocol Application.

Table 1. Exempt rDNA Experiments under *NIH Guidelines*, Section III-F.

☐	Exemption 1: Recombinant DNA molecules that are not in organisms or viruses.
☐	Exemption 2: Recombinant DNA molecules that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
☐	Exemption 3: Recombinant DNA molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
☐	Exemption 4: Recombinant DNA molecules that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
☐	Exemption 5: Recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director. See NIH Guidelines Appendices A-I through A-VI, *Exemptions Under Section III-F-5--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt.
☐	Exemption 6: Recombinant DNA molecules that do not present a significant risk to health or the environment. See NIH Guidelines Appendix C, *Exemptions under Section III-F-6* for other classes of experiments which are exempt.

SECTION D: Principal Investigator Certification & Signature

I am familiar with and agree to abide by the *NIH Guidelines*, UNTHSC's Policy and Procedures for Research Involving Recombinant DNA Molecules, and CDC's *Biosafety in Microbiological and Biomedical Laboratories*, *5th Edition.*
In accordance with the *NIH Guidelines*, I accept responsibility for training all personnel involved in the proposed project in matters of potential biohazards, relevant biosafety practices, techniques, laboratory emergency procedures, and the biology of the organisms used in the experiment(s). **I understand that I must document this site-specific training (dates, attendees, topics) and have it available to the IBC or Environmental Health & Safety as requested.**

I will submit reports to the Institutional Biosafety Committee concerning (i) any accident that results in potentially toxic exposures to recombinant DNA materials, or any incident releasing recombinant DNA materials into the environment; (ii) any problems with physical or biological containment; and (iii) any novel information bearing on the safety of this work such as new technical data relating to biological hazards of specific recombinant DNA molecules.

I will not carry out the work described in this Protocol Application until it has been acknowledged (exempt experiments) or approved (non-exempt experiments) by the IBC.

I understand that I am responsible for the accuracy of the statements made in this protocol and for the conduct of research.

_____ _____

Principal Investigator **Date**

PART II. (Non-Exempt Recombinant DNA Experiments)

If your project involves experiments with rDNA that are not clearly *exempt* as described in Table 1, Part I of the Protocol Application, please proceed with this section – **Part II**.

SECTION E: The Use of Recombinant DNA

12. **Non-Exempt Recombinant DNA Experiments**: Please complete Table 2. Attach additional copies of Table 2 as necessary.

Table 2. Non-Exempt rDNA Experiments

RECOMBINANT INSERT (TRANSGENE) AND VECTORS	
Original source(s) of DNA/RNA sequences (include genus, species, gene name and abbreviation)	
Agent's NIH Risk Group (*NIH Guidelines*, Section II) **Note: Human pathogenic materials must be registered with IBC	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
Nature of inserted sequences (include gene names, biological markers, sequences, etc. and describe the function/activity of the DNA or its product)	
Will the experiment involve use or production of more than 10L of culture of viable organisms containing rDNA?	☐ Yes If yes, specify how you will meet the criteria of *NIH Guidelines*, Appendix K for Large Scale Use: ☐ No
Will the genetically modified organism (GMO) be released into the environment?	☐ Yes If yes, describe: ☐ No
Is the inserted sequence or GMO harmful to humans or animals?	☐ Yes Describe diseases or symptoms caused by agent and possible routes of exposure: ☐ No ☐ N/A
Is the inserted sequence or GMO harmful to plants? (See USDA's 7 CFR 340)	☐ Yes (please describe appropriate safeguards and address 7 CFR 340) ☐ No ☐ N/A
Physical containment as specified in *NIH Guidelines* Section II and Appendix G. Please note: the CDC classifies work with human and non-primate blood, body fluids, or tissue (e.g. human cell culture) as a minimum of BL-2.	☐ BL1 ☐ BL2 ☐ BL3 or BL4 (Requires approval of UNTHSC Administration) and/or Experiments Involving Plants: ☐ BL1-P ☐ BL2-P ☐ BL3-P ☐ BL4-P and/or Experiments Involving Animals: ☐ BL1-N ☐ BL2-N ☐ BL3-N ☐ BL4-N
Vector(s) to be used, and source	
Host strain(s) for propagation (genus, species and parent strain)	
Is a helper virus required?	☐ Yes If yes, specify: ☐ No
For experiments involving a deliberate attempt to obtain expression of *a foreign gene*, identify what proteins will be produced and their biological activity (enter "none" if not applicable)	

TARGET RECIPIENT	
☐ Cultured Cells?	Describe:
☐ Animals?	Describe:
☐ Plants?	Describe:
☐ Humans?	Describe:
☐ Other?	Describe:

DUAL USE RESEARCH (research intended to enhance scientific understanding and public health but could generate results that could be misused to advance biological weapon effectiveness)

Check any categories below that pertain to your project:
- ☐ Renders a useful vaccine ineffective
- ☐ Adds antibiotic resistance affecting response to a clinically useful drug
- ☐ Enhances pathogen virulence
- ☐ Widens a pathogen's host range
- ☐ Lets a pathogen evade diagnostic or detection modalities
- ☐ Weaponization (e.g., environmental stabilization of pathogens)

SECTION F: Hazardous Materials and Training

13. If your project will utilize human blood, body fluids, or tissue, please describe the source of these materials and any information relevant to determining its infectious potential. Attach a copy of your Pathogen safety plan approved by IBC, If this does not apply to your project, please enter "N/A."

14. Hazardous Materials – List all labs where work will take place, and check the appropriate box(es) if the lab contains any of the materials listed on the left.

Table 3. Hazardous Materials

Lab Room #							
Recombinant DNA	☐	☐	☐	☐	☐	☐	☐
Infectious Agents	☐	☐	☐	☐	☐	☐	☐
X-ray Equipment	☐	☐	☐	☐	☐	☐	☐
Lasers	☐	☐	☐	☐	☐	☐	☐
Radioactive Materials	☐	☐	☐	☐	☐	☐	☐
Animals	☐	☐	☐	☐	☐	☐	☐
Hazardous Chemicals	☐	☐	☐	☐	☐	☐	☐
Human Blood, Fluids, Tissue	☐	☐	☐	☐	☐	☐	☐

Reminder: If your project involves the use of **animals**, you must obtain Institutional Animal Care and Use Committee (IACUC) approval prior to commencement of the research. If your project involves the use of **human subjects**, you may require approval from the Institutional Review Board for the Protection of Human Subjects (IRB) prior to commencement of the research. If your project involves **human pathogenic material(s)**, you must register with the Institutional Biosafety committee If your project involves **radioactive material**, you must obtain approval from the Radiation Safety Officer prior to commencement.

15. In accordance with the *NIH Guidelines*, the Principal Investigator is responsible for training all personnel involved in the proposed project in matters of potential biohazards, relevant biosafety practices, techniques, laboratory emergency procedures, and the biology of the organisms used in the experiment(s). Training documentation must be made available to the IBC as requested. Please describe how you will perform and document (dates, attendees, topics) this training for all lab personnel.

ADDITIONAL TRAINING: The following training is required for each of the hazardous materials listed. **All protocol personnel must complete the online "Research Involving Recombinant DNA" module.**

Hazardous Material	Training Requirement	How to Obtain Training
Recombinant DNA	Research Involving Recombinant DNA	http://www.hsc.unt.edu/Sites/Biosafety/index.cfm?pageName=Biosafety%20Training ibc@unthsc.edu
Chemical Hazards	Hazard Communication (HazCom) Training	Safety Office 817-735-2697
Radioactive Material & X-Rays	Radiation Safety Training	Radiation Safety Office 817—735-
Lasers	Laser Safety Training	
Animals	Animal Care & Use Training	Department of Lab Animal Medicine/ IACUC
Human Blood, Body Fluids, or Tissue	Bloodborne Pathogen Training	Biosafety office ibc@unthsc.edu
Shipping & Receiving Hazardous Materials	Shipping & Receiving Hazardous Materials Training	Biosafety office ibc@unthsc.edu

16. Laboratory Personnel – list all lab workers that use hazardous materials under your jurisdiction (please note training requirements listed above for each of these items).

Table 4. Laboratory Personnel

Name & Status (Faculty, Staff, or Student?)	rDNA	Chemical Hazards	Radioactive Material & X-Rays	Lasers	Animals	Human Blood, Body Fluids, or Tissue	Shipping or Receiving Hazardous Material
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐

SECTION G: Laboratory Safety

17. Reference Materials: Please note the location of laboratory safety information below. The location of this information should be communicated to all laboratory personnel.

Table 5. Reference Materials

LOCATION	INFORMATION
	Biohazard risk, containment, and disposal procedures (UNTHSC Biosafety Manual)
	Location of Lab Emergency Plan (Specific to PI's protocol/experiments)
	Location and availability of known reference material, including MSDS, on the hazards, safe handling, storage, and disposal of hazardous materials
	Location and availability of the UNTHSC Lab Safety Manual
	Posted contact information for research-related accidents, injuries, or emergencies

18. Personal Protective Equipment (PPE): Describe the eye, face, and hand personal protective equipment to be used in the laboratory while performing experiments.

19. Containment: Identify additional safety equipment or procedures such as fume hoods, biological safety cabinets, autoclaves, etc.

20. Emergency Procedures: Please describe procedures to be followed in the event of a chemical spill, contamination of biological material, or personnel exposure (*__PI__ is responsible for informing all laboratory personnel of the content and location of the Emergency Plan*).

21. Lab Security: Describe the procedures for site security (How will lab access be limited? How will lab entries be kept secure? Will anyone have access besides personnel listed in this protocol?).

22. Immunizations: Immunization is generally recommended for laboratory workers who will be engaged in research with infectious organisms for which an effective vaccine is available. If your research involves infectious agents, please describe the available vaccines (if any) and the method of obtaining the vaccine for laboratory personnel.

23. Waste Disposal: Describe procedures for inactivation of recombinant DNA materials or biohazards (autoclave, chemical treatment, incineration, etc.).

24. Transfer of Recombinant DNA and Transgenic Materials: If rDNA or transgenic materials will be transferred between laboratories or work locations, please describe the transport procedures, containment, and appropriate safety precautions.

SECTION H: Biosafety Certification & Signature

The biosafety office must certify all Biosafety Level 2 (and higher) laboratories before research commences. Please contact the Biosafety office at 817-735 5431 or ibc@unthsc.edu to make an appointment to certify your lab and/or biosafety cabinets used in this research protocol. (This process may occur simultaneously with submission and IBC review of your protocol, but biosafety office must provide final sign-off below before research can commence.)

I hereby certify that the facilities are in accordance with UNTHSC's *Policy and Procedures for Research Involving Recombinant DNA Molecules*, UNTHSC's *Biohazard Recognition and Control: Guidelines for Handling Pathogenic Microorganisms & Disposing Biohazardous Waste,* the *NIH Guidelines*, and CDC's *BMBL* (5th Edition) recommendations.

_____ _____

Bio Safety Officer **Date**

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee

Pathogen _____

Project Title _____

Principal Investigator _____ Date _____
(Signature)

Department _____

Phone _____

Date of activity From _____ To _____

Project Summary _

Name of Organism (note specific strain)
_____--

Principal Risk _____ Sharps _____

Infectious Dose _____

Ordinary Route of Entry _____

Does the organism exhibit antibiotic resistance ? Yes _____ No _____

Does the organism produce a toxin? _____ No _____

If yes, will work be done with the toxin? Yes _____ No _____

Will the organism be inactivated prior to the other laboratory manipulations?
Yes _____ No _____ Specify methods(s)
Heat _____
Chemical _____
Radiation _____
Other _____

Amount, number of organisms used per week, and total volume _

The University of North Texas Health Science Center
Fort Worth, Texas
PATHOGEN SAFETY PLAN

Location of Organisms

Laboratory(s) where organism is used _____
Is the laboratory (s) posted with BIOHAZARD warning sign?
Yes _____ No _____

Indicate where the organism is stored (check all that apply and enter room number)
Cold room _____ Room Number _____
Refrigerator _____ Room Number _____
Bench Top _____ Room Number _____
Incubator _____ Room Number _____
Freezer _-80C_____ Room Number _____
Other _Biosafety Cabinet__ Room Number _____
Centrifuges Room Number _____

Are these sites where the agents are incubated or stored posted with BIOHAZARD warning signs? Yes _____ No _____

Control Procedures
Indicate containment equipment to be used
_____

Indicate personal protective equipment to be used
_____

Is medical surveillance required? _____

Describe briefly decontamination procedures and frequency
_____
_____

What disinfectants will be used? _____

Is an autoclave available? Yes _____ No _____

Describe disposal procedures for wastes and unused stocks
_

The University of North Texas Health Science Center
Fort Worth, Texas
PATHOGEN SAFETY PLAN

List personnel working on the project Prior Experience

What monitoring procedures are necessary for personnel?

_____

What monitoring procedures are necessary for area contamination?

_____

Emergency Procedures

Emergency contact person _____
Office Phone _____ Cell Phone _____

Indicate emergency procedures in the event of personnel exposure (inhalation, ingestion, inoculation, etc.) _

Indicate emergency procedures in the event of a spill or release not involving personnel exposure _Contain spill.

Additional Special Handling Procedures: Including any transport between labs or buildings (i.e., secondary containment):

The University of North Texas Health Science Center
Fort Worth, Texas
PATHOGEN SAFETY PLAN

Unattended Operations: Portions of the experiment that may run unattended and steps taken to prevent accidental exposures:

Animal Use

Are laboratory animals in this research project? Yes _____ No _____

If yes, please provide the following information

- Animal Project Number _____
- Are the animals infected with the agent? Yes _____ No _____
- What is the route of inoculation for this experimental ?
  Iv _____ ip _____ aerosol _____ _____
  Other (specify) _____

Will infected animals show signs of clinical disease? Yes _____ No _____
Will the agent(s) be shed by the infected animals? Yes _____ No _____
Indicate route(s) _____

Are special precautions required for housing the infected animals?
Yes _____ No _____
If yes, please explain
_____
_____
_____

Are special precautions required for handling animal cages? Yes ___ No ___
If yes, please explain
_____
_____
_____

How are animal carcasses to be disposed?
_____
_____
_____

_____ _____ _____
PI (Name) PI (Signature) Date

Maya P. Nair, Ph.D., BSO

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee

LABORATORY EQUIPMENT DECONTAMINATION FORM

Principal Investigator

Department :

Bldg./Rm.#

Equipment Description

Manufacturer Model #, Serial #

UNTHSC ID#

This equipment is going: _____ _____

To Surplus For Repair

This equipment:

Has never been used with biological agents

NOTE: must still be cleaned with detergent/70% alcohol solution.

Date cleaned: _____

Biological Agents (list biological agents used) mark the appropriate biohazard level_____

_____

Describe process and agent for deactivating/removing/disinfecting the hazardous materials.

_____ _____

Printed Name and Title of Person Doing the Cleaning Signature

_____ _____

Date Phone Number

_____ _____

Signature (PI/ Lab Manager) Date

_____ _____

Date

BSO, UNTHSC

Please fill out and signed the form and send it to Biosafety office

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee

Biological Safety Cabinet Movement/Installation Form

Check one box:

☐ - Existing cabinet for movement

I, _____, have followed the relevant policy and advice concerning the sterilization and decontamination of this Biological Safety Cabinet. The working surface of this Biological Safety Cabinet has been decontaminated with _____ (disinfectant) on _____ (date).

The biosafety of this cabinet no longer poses a biohazardous threat and is now considered safe to transport, from _____ to new location of _____.

☐ - New cabinet for installation

A new cabinet was installed in _____ (room number) on _____ (date) certified by _____.

BSC information:
Model Number: _____
Serial Number: _____
Type: _____

_____
Principal Investigator/ Alternate for Principal Investigator

_____
Date

Note: Please send the original to Biosafety officer

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee

Incident/Accident Report Form

Type of incident:

Recombinant DNA	Yes ☐	No ☐
Infectious Agents	Yes ☐	No ☐
Select Agents	Yes ☐	No ☐

Person Involved:

Room Number:

Phone Number:

Department:

Summary of Incident:

Name	Signature	Date
BSO	Signature	Date

Recombinant DNA

In order to ensure compliance with the National Institute of Health (NIH) Guidelines and to avoid the potential loss of Federal Research Grant Funds, UNTHSC researchers have the responsibility to *report*.

* All potential or Actual accidental incidents involving material containing Recombinant DNA (rDNA).

All incidents involving rDNA must be reported to UNTHSC Biosafety office. Biosafety office will subsequently forward *reportable incidents* to the appropriate NIH-OBA Department.

Infectious Agents: Regulations on Reporting

Title 2 Chapter 84 of the Texas Health and Safety Codes set forth by the Texas Department of Health and Human Services requires all occupational infections involving infectious agents that are confirmed by laboratory diagnosis to be reported to the Dallas County Health Department.

Definition of an infectious agent:

An agent of biological origin that has the capacity to produce deleterious effects on humans and/or animals, i.e. microorganisms, toxins and allergens derived from those organisms, allergens and toxins derived from higher plants and animals; and proteinaceous molecules that lack nucleic acids

What does the Texas Department of Health define as a reportable infectious agent:

Infectious Disease Reporting

This process will involve The University of North Texas health Science Center Bio Safety Committee. These institutional Biosafety committee will respond to, and review all incidents involving infectious agents and will report as necessary to meet all regulatory requirements

Select Agents: Regulation on Reporting

All theft, loss, release and/or exposures involving *select agents* must be immediately reported to the *Responsible Official* as required by the Department of Health and Human Services Code of Federal regulations *42 CFR Part 73.19.*

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee

Laboratory Biosafety Training Certification/Exemption

Please print or type:
(Last Name) (First Name) (MI)

(Employee ID #) (Department)

INSTRUCTIONS: If your supervisor has determined that you will not be exposed or you will not have the potential for exposure to biological hazardous materials in your work area, sign the exemption on this form, have your supervisor sign and return the form to Your Biological Safety Officer within 30 days of hire or transfer. If it has been determined that you are exposed or have the potential for exposure to biological hazardous materials in the course of your job performance at the University of North Texas Health Science Center, state law requires that you be informed of the hazards of such exposures or potential exposures, and that you be given specific biohazard training. This training. After completing the training, sign on the appropriate line below and return this form to your Biological Safety Officer. You are entitled to a copy of this form.

Basic Biohazard Training Certification: On this date, I have received the basic Biohazard training. The topics covered during the training will be Introduction to Biosafety Containment Levels, Personal Protective Equipment (PPE),Biological Safety Cabinet and Chemical Fume Hood, Biological Exposure, Transportation of Biological and Non-biological Material Emergency Procedures, Disinfection, Waste Handling and Disposal Procedures, Autoclave, General Laboratory Procedures and Personnel Practice, Record Keeping and Reporting accidents,

_____

(Employee Signature) (Date) **B**iosafety Officer/Date
(Training given by)

Organism specific Biohazard Training Certification: On this date, I have received the basic Biohazard training appropriate for the specific organisms. The topics covered during the training will be Biosafety Containment Levels, Personal Protective Equipment (PPE),Biological Safety Cabinet and Chemical Fume Hood, Biological Exposure, Transportation of Biological and Non-biological Material Emergency Procedures, Disinfection, Waste Handling and Disposal Procedures, Autoclave, General Laboratory Procedures and Personnel Practice, Record Keeping and Reporting accidents,

_____

(Employee Signature) (Date) **B**iosafety Officer Date
(Training given by)

UNT HEALTH SCIENCE CENTER

Office of Research

Institutional Biosafety Committee

Protocol Amendment form

Principal Investigator:	
Department:	
Email:	
IBC Study #:	
Approved Biosafety Level:	
Project Title:	
Funding Agency(s)	
Date	

Perform a risk assessment per Section II-A-3 of the NIH Guidelines in order to determine the appropriate level of review by the IBC. Factors to consider include: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain more hazardous than the parent (wild-type) strain should be considered for handling at a higher Biosafety level. Also consult OSHA requirements for guidance. If the proposed change **is considered a major amendment a new research application must be completed along with this form.** If this amendment involves BSL2 or above studies, or the addition of new laboratory locations a laboratory inspection by the Biosafety Officer will be necessary. Submit all materials to ibc@unthsc.edu.

MINOR AMENDMENT*:

☐ Adding/removing personnel (new personnel should email ibc@unthsc.edu that they "have read, understood and agreed to participate in the protocol"). New personnel should also complete the biosafety training before submitting the application.

☐ Adding/changing/removing cell lines

☐ Adding/changing/removing transgenic animals

IACUC study #:

IACUC amendment #:

☐ Adding/changing/removing laboratory room numbers:

Current room number(s): _____

Proposed room number(s): _____

☐ Other

*Submit amendment form and any supporting documents. The amendment will be considered by an IBC member for expedited review.

MAJOR AMENDMENT**:

☐ Adding/changing organism

☐ Adding/changing transgene

☐ Adding/changing infectious agents

☐ Upgrade in containment level:

Current Biosafety Level: _____

Proposed Biosafety Level: _____

☐ Other

**Submit signed amendment form, AND a signed revised IBC Protocol Submission Form, and any supporting documents. The amendment will be considered in a convened meeting of the Biosafety Committee.

Describe the proposed change(s) and rationale for the change(s):

NOTE TO INVESTIGATORS: Study amendments may not be instituted until approval from the UNTHSC Institutional Biosafety Committee is given. Retain this form for your records.

Investigator: _____ Date: _____

The amendment of this project has been reviewed and approved by the UNTHSC Institutional Biosafety Committee.

Authorized IBC Member: _____Date: _____

UNT HEALTH SCIENCE CENTER Office of Research

Institutional Biosafety Committee
Laboratory Biosafety Compliance Inspection Checklist -Biosafety Levels 1 and 2

Date _____ Laboratory Location(s) _____
Responsible Individual _____
IBC# _____ Lab Manager _____

Title: _____
_____

Queries are based on Appendix G of the *NIH Guidelines* (April 2002) and the Biosafety Level 1 & 2 sections of the *Biosafety in Microbiological and Biomedical Laboratories,* 5th Edition, 2007

Abbreviations: NA, not applicable; BSL-1, biosafety level 1 practices; BSL-2, biosafety level 2 practices; PPE, personnel protective equipment; PI, primary investigator
(Note: All BSL-1 practices are also followed in BSL-2 containment laboratories.)

Circle the response that best describes the laboratory in which work will be performed.

A. Standard Microbiological Practices	
1. Access to the laboratory is limited or restricted at the discretion of the PI or laboratory manager when work with biohazardous agents are in progress. [BSL-1]	Yes, No
2. Work surfaces are decontaminated at least once a day and after any spill or splash of potentially infectious material with the appropriate disinfectant. [BSL-1]	Yes, No
3. Personnel are instructed to wash their hands after handling infectious materials, after removing gloves, and before leaving the laboratory to a non-laboratory area. [BSL-1]	Yes, No
4. Eating, drinking, handling contact lenses, and applying cosmetics are not permitted in the laboratory area. [BSL-1]	Yes, No
5. Food is stored and consumed ONLY outside of all laboratories [BSL-1]	Yes, No
6. Mechanical pipetting devices are used; mouth pipetting is prohibited. [BSL-1]	Yes, No
7. Precautions are taken to minimize the creation of splashes and/or aerosols while working with a biohazard agent [BSL-1]	Yes, No

8. Policies for the safe handling of sharps such as needles, scalpels, pipettes, and broken glass are instituted. [BSL-1]	Yes, No
9. An effective integrated pest management program is in effect [BSL-1]	Yes, No
10. Biohazardous waste is decontaminated on-site before disposal. [BSL-1] If yes: List the method of decontamination. List the method used to monitor the decontamination process. List room number where the decontamination process occurs.	Yes, No _____ _____ _____
11. Work surfaces are decontaminated routinely with disinfectants effective against the biohazardous agent(s) utilized. [BSL-1] List disinfectant(s). If Bleach is used, a mechanism is in place to discard all diluted bleach within 2 weeks after diluting.	Yes, No _____ Yes, No, NA
12. Broken glass used in biohazardous work is properly handled to prevent cuts and placed into a hard-walled container for disposal. [BSL-1]	Yes, No
13. Disposable laboratory supplies (pipettes pipette tips, glass slides, etc.) whether contaminated with a biohazardous agent OR NOT contaminated are placed into a sturdy puncture proof container and subsequently disposed as biohazardous waste. [BSL-1]	Yes, No
14. A biohazard sign is posted on the entrance to the laboratory where biohazardous materials are used and includes the following information: the biosafety level symbol, the contact's name, and the contacts telephone number. [BSL-1]	Yes, No
15. The PI or laboratory manager recognizes that he/she is ultimately responsible for activities in the laboratory and that all personnel receive appropriate training and they understand the necessary precautions to prevent exposure. [BSL-1]	Yes, No
16. The laboratory director/manager provides annual updates and additional training when procedural or policy changes occur. [BSL-1]	Yes, No
17. The PI or laboratory manager provides information to employees regarding immune competence and conditions that may predispose them to infection such as immune status of individuals and risks to women of child-bearing age and encourages all employees to self-identify to the institutions healthcare provider for appropriate counseling and guidance, if needed. [BSL-1]	Yes, No

B. Special Practices	
1. All persons entering the laboratory must be advised of the potential hazards and meet any specific entry and/or exit requirements. [BSL-2]	Yes, No
2. Laboratory personnel are provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the lab. [BSL-2]	Yes, No
3. A biohazard symbol is posted on all equipment such as refrigerator, centrifuge, incubator, etc. that store and/or are used in the manipulation of biohazardous agents. [BSL-2]	Yes, No
4. Biosafety practices and lab standard operating procedures are incorporated into a laboratory specific Biosafety Manual which is available and accessible for all personnel in the laboratory and which is upgraded on an annual basis. [BSL-2]	Yes, No
5. The laboratory director/manager ensures that laboratory personnel demonstrate proficiency in standard and special microbiological practices BEFORE working with risk group-2 agents. [BSL-2]	Yes, No
6. Needles and syringes are restricted in the laboratory and used only when there is no alternative. [BSL-2] If used, special containers are available for disposal.	Yes, No, NA Yes, No
7. Laboratory equipment is routinely decontaminated after spills, splashes, or other potential contamination and before being sent for repair, maintenance, or for removal from the site. [BSL-2]	Yes, No
8. A biological spill emergency plan is posted in the laboratory and all exposures to infectious materials are reported immediately to the laboratory director/manager. [BSL-2]	Yes, No
9. Potentially infectious materials are placed in a durable, leak-proof container during collection, storage, and transport within a facility. [BSL-2]	Yes, No
10. The PI and laboratory manager are familiar with the University policies pertaining to a “Biological Spill” and the “Reporting of Research Related Adverse Events” and instructs laboratory personnel to report to them any incidents that may result in exposure to infectious materials. [BSL-2]	Yes, No
11. All procedures involving the manipulation of infectious materials that may generate an aerosol are conducted within a biological safety cabinet or other physical containment device. [BSL-2]	Yes, No

13. Biohazardous agents are used in animals. [BSL-2] If yes: Record the location where these procedures are done. List the procedure(s) that are used. Indicate whether the procedures are terminal or survival. Indicate whether the animals are kept in or returned to the animal facility. If no: Other animals not permitted in the laboratory where biohazards are used.	Yes, No _____ _____ _____ _____ Yes, No
C. Safety Equipment (Primary Barriers and PPE)	
1. Personal protective equipment such as non-powdered latex gloves, protective clothing, and eye protection are available when needed to perform experiments. [BSL-1]	Yes, No
2. Personal protective equipment is removed and retained in the laboratory before leaving for non-laboratory areas. [BSL-1]	Yes, No
3. Gloves are worn to protect hands from exposure to biohazardous materials and personnel are instructed to remove gloves and wash hands when work with the hazardous material has been completed. [BSL-1]	Yes, No
4. An alternative to latex gloves is available in the laboratory. [BSL-1]	Yes, No
5. Disposable gloves are not washed or reused and gloves that have been used to handle biohazardous materials are disposed with other contaminated laboratory waste. [BSL -1]	Yes, No
6 A. No open flames are used in the laboratory. [BSL -1] If no: Explain why another alternative to an open flame is not available. Indicate the procedure(s) that utilize an open flame	Yes, No _____ _____
6 B. Is there a Fire extinguisher is available If the lab personal understands it's operation Is there a fire blanket available Is the lab personal trained to use the open flame	Yes, No Yes, No Yes, No Yes, No
7. Biological safety cabinet(s) is (are) available for the containment of biohazardous agents (only necessary when performing procedures with a potential for creating infectious aerosols or splashes). [BL-2] If yes: List the Class type. Indicate the date(s) of last certification.	Yes, No _____ _____
8. Centrifugation of highly concentrated or large volumes of an infectious agent is	Yes, No, NA

done in the open laboratory ONLY IF the rotor head can be sealed or centrifuge safety cups are used and the rotors or safety cups are opened in a biosafety cabinet. [BL-2]	
D. Laboratory Facilities (Secondary barriers)	
1. Each laboratory contains a sink for hand washing located near the exit door. [BSL -1]	Yes, No
2. Bench tops are impervious to water and resistant to chemicals used to decontaminate the work surfaces and equipment. [BSL -1]	Yes, No
3. Windows that open to the exterior are fitted with fly screens. [BSL -1]	Yes, No, NA
4. The laboratory is designed to be easily cleaned and no carpets or rugs are used in the laboratory.[BSL -1]	Yes, No
5. Laboratory furniture is sturdy and appropriate for the tasks performed. [BSL -1]	Yes, No
6. Spaces between benches, cabinets, and equipment are accessible for cleaning. [BSL -1]	Yes, No
7. All chairs used in the laboratory work are covered with non-fabric material that can be easily cleaned and decontaminated with the appropriate disinfectant. [BSL -1]	Yes, No
8. An eyewash station is readily available. [BSL -1]	Yes, No
9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision. [BSL -1]	Yes, No
10. Laboratory doors are self-closing and have locks in accordance with institutional policies. [BSL-2]	Yes, No
11. Vacuum lines are in use. [BSL-2] If yes: An in-line HEPA filter and/or disinfectant trap is (are) available.	Yes, No Yes, No
12. A method for decontamination of laboratory waste is available in the facility such as an autoclave, chemical disinfection set-up, incineration, or other validated method. [BSL-2]	Yes, No