



BIOSAFETY MANUAL

**University of North Texas Health
Science Center
Fort Worth - Texas
July 2018 Version**

History & Revisions

- 4/20/2009** Biosafety policy and UNTHSC biosafety manual approved
- 12/2/2011** All the sessions were reviewed by IBC members. Modifications were incorporated based on the IBC self assessment review form from NIH/ OBA
Manual title page is changed.
- 11/19/2014** Confidentiality agreement form for IBC members
- 6/17/2015** rDNA risk assessment form (checklist) is approved
- 10/19/2016** IBC self assessment tool (adopted from NIH/ OBA)
- 4/20/2017** Standard Operating Procedures For human specimen collection, storage and transportation
- 4/20/2017** Safety Procedures For Human Anatomy lab operations for Educational programs at UNTHSC
- 4/28/2017** HUMAN BIOSPECIMENS RESEARCH
BioSafety Proposal Registration Form
- 2017- 2018** – All sections as need to update the 2016 changes of NIH guidelines and organizational changes.

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Abbreviations

BSC- Biological Safety Cabinets

CDC – Center for Disease Control and prevention

IBC – Institutional Biosafety Committee

rDNA – recombinant deoxyribo nucleic acid

UNTHSC – University of North Texas Health Science Center

BSO – Biosafety Officer

GMO - Genetically Modified Organisms

NIH – National Institute of Health

PI - Principal Investigator

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 and synthetic 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 Executive Vice President of Academic Affairs and 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, secretions, 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 – Genetically Modified Organism – 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 - PI– 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 – (r 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).

Synthetic DNA - Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, or molecules that result from the replication of rDNA or synthetic DNA.

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 the reports are to be made by or through the UNTHSC Safety Office. The incident report form (Supervisor's Investigation of Employee's Accident/ Incident) is available on safety office webpage-
<http://safety.hsc.unt.edu/office/forms/forms.html>

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 manager:
 - 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 and synthetic 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 -14-15 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.

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

- 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.**
- 6. Notify the Bio Safety Office extn: 5431.**
- 7. Wait for assistance.**

III. Roles and Responsibilities

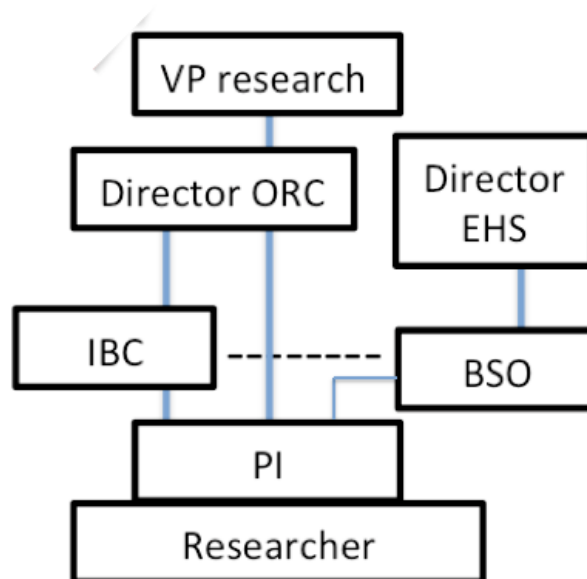
A. General

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 managers.

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 Science Policy, The Institutional Biosafety Committee Registration Management System (IBC-RMS) 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 and synthetic 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 and synthetic 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 and synthetic 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 and synthetic 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 at periodically and recommending revisions to the biosafety program and this Manual as needed to the IBC and Director, EH&S

E. Biosafety Officer (BSO)

1. The BSO shall be responsible for:

(a) periodically inspecting all laboratories where biohazardous agents, human materials, or recombinant and synthetic 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 Director, EH&S 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 Environmental Health and 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 and synthetic 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 and length of program
- (4) Instructor's name

Additional information may be kept as appropriate. The Biosafety office shall maintain the records (original) and a copy of the training record should be kept along with the biosafety procedures for each trainee in their laboratory. An online BSL-2 level training is developed and available to all the researchers working with Biohazard materials.

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 and synthetic DNA Research, the latest edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories and the NIH Guidelines for Recombinant and Synthetic 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 quarterly inspections by the University BSO. A report of the results of these inspections will be maintained in the Office of Research Services.

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 Biosafety 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 Services. Department Chairs are 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, the IBC and the Safety Department 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. As an alternative to specifying names and phone numbers on placards at laboratory entrances, the Safety Office hosts a database of laboratory emergency contacts which are maintained by department safety coordinators, and a printed list is on file at Campus Police for their use 24/7 which is updated quarterly. The BSO shall maintain biosafety information related to each laboratory using biological agents, and this information shall be integrated with other information in databases hosted by the Safety Office.

a. Visitors

Visitor entry controls shall preclude unauthorized access by any person under the age of 18 years (unless written parent/guardian consent is obtained) and preclude entry to areas having specific immunization requirements

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 managers. 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.

Experiments that are exempt from the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Section III-F of the NIH Guidelines details experiments that are exempt from the requirements of the NIH Guidelines. The following molecules are exempt: For synthetic nucleic acids, those that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the

criteria of Section III-C, it is not exempt under this Section. (See Section III-F-1)

Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. (See Section III-F-2)

Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. (See Section III-F-3)

Those that consist entirely of nucleic acids 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. (See Section III-F-4)

Those that consist entirely of nucleic acids 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). (See Section III-F-5)

Those 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. (See Section III-F-6)

Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. (See Section III-F-7)

Those that do not present a significant risk to health or the environment as determined by the NIH Director, with advice from the RAC and public comment. (See Section III-F-8)

Appendix C of the NIH Guidelines details the specific classes of experiments that may be exempt under Section III-F-8.

Section III-F-8 of the NIH Guidelines refers to categories of experiments that the NIH Director has determined do not present a significant risk to health or the environment and are therefore exempt. This determination was made with the advice of the RAC, following

appropriate notice and opportunity for public comment. PIs and IBCs cannot make the determination that a class of experiments other than the ones listed below poses no significant risk.

The following classes of experiments are exempt under Section III-F-8:

Certain recombinant or synthetic nucleic acid molecules that contain less than one-half of any eukaryotic viral genome when propagated and maintained in cells in tissue culture [Appendix C-I – see question 8 below for more information on the limits of this exemption]

Escherichia coli K-12 host-vector systems [Appendix C-II]

Saccharomyces cerevisiae or *Saccharomyces uvarum* host-vector systems [Appendix C-III]

Kluyveromyces lactis host-vector Systems [Appendix C-IV]

Bacillus subtilis or *Bacillus licheniformis* host-vector systems [Appendix C-V]

Extrachromosomal elements of gram positive organisms [see specific list of organisms in Appendix C-VI]

The purchase or transfer of transgenic rodents [Appendix C-VII]

Generation of certain BL1 Transgenic Rodents via Breeding [Appendix C-VIII]

A full description of the exemptions with exceptions can be found in Appendix C of the NIH Guidelines.

Types of human gene transfer trials exempt from the requirements of the NIH Guidelines

If the investigational product meets the criteria described in Section III-C of the NIH Guidelines and involves the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants, then the research will be subject to the NIH Guidelines.

Synthetic nucleic acid molecules that contain less than 100 nucleotides, or do not possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or do not have the potential to replicate in a cell; or do not have the potential to be translated or transcribed are not covered under Section III-C.

In addition, Appendix M-III-A of the NIH Guidelines exempts certain types of vaccine trials from the requirements for submission of the protocol to the NIH Office of Science Policy(OSP) and subsequent reporting (Appendix M-I). Specifically, this exemption applies to“human studies in which induction or enhancement of an immune response to a vector encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected.”

Trials with these characteristics do not have to be registered with NIH OSP, but can be submitted on a voluntary basis, particularly if the investigator believes that a trial presents scientific, safety, or ethical concerns that would benefit from RAC review and public discussion. Investigators that submit trials voluntarily will be expected to comply with all aspects of the protocol submission and reporting requirements. NIH OSP encourages investigators and institutional review bodies to contact OSP

(HGTprotocols@mail.nih.gov)

for assistance in determining whether this exemption applies to a particular trial.

It is important to note that Appendix M-III-A does not exempt these vaccine trials from other requirements specified in the NIH Guidelines, including biosafety review. Thus, vaccine trials, like other human gene transfer trials subject to the NIH Guidelines, must be reviewed and approved by an IBC before research participants can be enrolled.

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/RAC 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) **Oversight of Human Gene Transfer Research:** In any area of biomedical research, many scientific and regulatory challenges stand between promising ideas generated from basic research and the approval of a therapeutic product. Among these emerging technologies, gene transfer research, in particular, stands out as a highly regulated area of scientific investigation. Because clinical gene transfer trials involve both recombinant DNA (rDNA) and human subjects, investigators must submit clinical gene transfer protocols to the Recombinant DNA Advisory Committee (RAC) and the U.S. Food and Drug Administration (FDA) at the federal level and institutional review boards (IRBs) and institutional biosafety committees (IBCs) at the local level before human subjects can be enrolled. This chapter summarizes the current regulatory, oversight, and policy context of this area of research in the United States with a focus on the National Institutes of Health (NIH) and the RAC, followed by a briefer consideration of the roles of FDA, IRBs, and IBCs, noting relationships among the oversight bodies.

V. Acquisition, Transportation and Shipping

A. Acquisition of Potentially Biohazardous Materials

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

The purchase of organisms that require biosafety level 3 (BSL3) work practices and engineering controls must have prior approval from BSO before the purchase order is sent to the vendor. All such purchases and approvals are handled through the ePro purchasing system. Use the ePro Goods Category 495-93.

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

<u>Categories</u>	<u>Description</u>
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
biological materials for work at BSL2

biological materials for work at BSL3

No special requirements
Notify UNTHSC BSO prior to the
transfer/receiving
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 Manager 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 units (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-sheath 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 BSL3 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. BSL3 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 of 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 posted 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 units (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-sheath the needle, needle-less systems, and other safe devices should be used when appropriate.
- c. Broken glassware must not be 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 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 protection 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 advice. 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).

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 draw 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

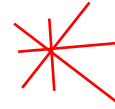
Appendix B: Autoclave and Steam Sterilizer

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.



New/Renew

University of North Texas Health Science Center Biosafety Committee

Recombinant DNA (r DNA) Safety Plan

Instructions:

All pertinent sections must be completed. Please retain the format as near as possible and answer questions appropriately placing answers in the space provided. When you have completed the form, print a copy, then sign and date the signature page. Return a signed Biosafety Officer:

If your research involves the use of rDNA, complete Parts 1, 2, 3 and 5. If your research involves the use of etiologic agents, complete Parts 1, 4 and 5.

Part 1. General Information:

a. Project Registration # (leave blank if new project)

b. Biosafety Level (circle all that apply) exempt BSL1 **BSL2** BSL3

c. Project Title:

d. Principal Investigator:

e. Department:

Campus Address:

f. Office phone:

Lab Phone:

Fax:

email:

g. Laboratory Safety Representative:

Phone:

email:

Part 2. Project Information:

- a. Is this project part of a course or teaching lab? YES NO
- b. List ALL Laboratories/Facilities where research is to be conducted and the corresponding biosafety level: include cold/warm rooms, tissue culture rooms and animal housing if appropriate. Please indicate room(s) where biosafety cabinets (BSC) are located.

Laboratory Room #

Biosafety Level

Part 3. Project Description:

- a. Outline the overall goal(s) of the project.**

Give enough information that the techniques used and purpose of the experiments are clear. Be as concise as possible using reasonably non-technical terms.

List of Hosts:

Inserts:

Description of study:

b. Specific questions, answer as appropriate.

Source of Gene, Insert or Clone:

1. Specify DNA/RNA source (or probe), nature of insert, is a protein expressed, and percent of any viral genome in construct:

2. Do any sequences code for toxins? If so, what LD50?

3. Is the DNA source from a USDA-regulated plant or animal? If the regulated organism is grown or stored at UNTHSC, please include a copy of the USDA permit.

Vectors and Host Cells:

1. Identify cloning/expression / transfection vectors used, recipient bacterial strains, and recipient host cell lines (human, mouse, plant, etc.). Provide a restriction map of vector, describe the location and type of promoters and other control sequences and percent of any viral genome in construct.

2. If using viral vectors, indicate packaging cell lines and assay system used to measure frequency of replication competent virus (background) generated. Include host range of packaged viral vector.

Use of Recombinant DNA in Animals:

1. Will transgenic or “knockout/in” animals be generated or used in the project? If so, indicate injected gene and vector as well as the recipient animal/mouse strain.

IACRAC Protocol #_____

2. What is the expected phenotype of the animal, (e.g., immunodeficient, early disease onset/resistance, etc.)?

Large Scale Research:

1. Do experiments involve growth of more than 10 liters of culture at a time? If YES, identify culture room and type of equipment used for culture growth and handling.

c. Are pre-project serum samples, immunization or medical monitoring or surveillance advisable?

(Contact BioSafety Officer for assistance) Is an FDA approved vaccine available if individuals working with micro-organisms involved in this research project want it?

d. Will radioactive materials be used? Radiation Protocol #_____

Part 4. Infectious Agent Use:

- a. Infectious agent (i.e., H. pylori, SV40, EBV, E.coli 0157) and recommended Biosafety Level (CDC):
- b. Source of infectious agent (i.e., new isolate from human tissue, blood, animal, tissue culture, another laboratory, ATCC, etc.):
- c. Host range:
- d. Length of time agent has been maintained in laboratory culture. Is this agent periodically passaged in animals?
- e. Describe disease pathology and mode of transmission. Is this a zoonotic agent?
- f. Is a vaccine or therapeutic treatment available?
- g. Are pre-project serum samples, medical monitoring or surveillance needed? (Biological and Chemical Safety Officer at 8-2494 for assistance if unsure) If so, please describe:
- h. List all laboratory facilities where viable agent will be handled and stored, include cold/warm rooms and tissue culture rooms, indicate rooms where Biosafety Cabinets (BSC) are located:

Laboratory Room #

Biosafety Level

Experimental Procedures:

1. Describe procedures involving use of infectious agent (indicate culture volume, maximum concentration). How and at what stage of the experiment is the infectious agent inactivated or lysed?
2. Will experiments result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance or change in host range? If so, explain:

Safety Procedures:

1. Outline protective equipment required to minimize exposure of laboratory personnel during all procedures requiring handling or manipulation of infectious agent:
 2. Outline procedures for decontamination of work surfaces, instruments, equipment, liquid containing infectious materials and glassware:
 3. Outline disposal/decontamination procedures for contaminated sharps, contaminated solid waste, tissues, pipette tips, etc.
 4. Will radioactive infectious wastes be generated? YES NO
Will hazardous chemical infectious wastes be generated? YES NO
IF YES, outline what steps are taken to kill agent before disposal of materials to radioactive waste containers. The Radiation Protection Office must approve all work with radioactive compounds.
-

Part 5. Certification and Signatures

The information contained in this application is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines, the NIH Guide for Grants and Contracts, other specific NIH instructions pertaining to the proposed project, UNTHSC Policies and Procedures, local state and federal regulations.

In addition, I agree to abide by the following requirements:

- a. I will initiate no recombinant DNA research subject to the NIH Guidelines until that research has been reviewed and approved/registers with the Institutional Bio Safety Committee (IBC).
- b. I will follow appropriate biosafety level laboratory techniques in the research.
- c. I will comply with all shipping requirements for recombinant DNA materials.
- d. I will make available to the laboratory staff copies of the approved protocols that describe the potential biohazards and the precautions to be taken.
- e. I will train staff in: good microbiological practices and techniques required to ensure safety for this project, in the procedures for dealing with accidents, and in waste management procedures.
- f. I will ensure that all laboratory workers are registered with the IBC.
- g. I will supervise staff, and correct work errors and conditions that could result in breeches of the NIH Guidelines and UNTHSC policy.

Principal Investigator

Date

Biosafety Officer

Date



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

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



**The University of North Texas Health Science Center
Fort Worth, Texas
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

BSO, UNTHSC

Date

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



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



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



The University of North Texas Health Science Center Fort Worth, Texas
Incident Reporting Form

Type of incident:

Recombinant DNA	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Infectious Agents	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Select Agents	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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*.



University of North Texas Health Science Center 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)

Biosafety Officer
(Training given by)

Date

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)

Biosafety Officer
(Training given by)

Date

CONFIDENTIALITY AGREEMENT

University of North Texas Health Science Center (UNTHSC)

Institutional Biosafety Committee

I, _____, will for professional or educational purposes be participating in the review of or have access to documents associated with the review of Biological material research conducted by the Institutional Biosafety Committee (IBC) of the University of North Texas Health Science Center (UNTHSC). Regardless of my role, I understand and agree that the information and documentation that I will be exposed to during and related to my participation with the IBC is confidential. I further acknowledge and agree that I will not, without appropriate authorization, access information that the IBC considers privileged or confidential, release such privileged or confidential information to anyone neither outside of the review process nor within or outside of UNTHSC, or use such information for unauthorized purposes.

Printed Name: _____

Signature: _____

Affiliation: _____

Date: _____

IBC Checklist for Risk Assessment and *NIH Guidelines* rDNA -

PI Name _____

Biosafety level _____

Agent or Vector: risk factors

- ☐ Agent name(s) and risk group(s):
- ☐ Infectious material, pathogen, opportunistic pathogen, biological toxin, human/NHP body fluid, cells, or tissue
- ☐ Host range: human, broad/multi-host, environmentally or agriculturally important
- ☐ Infectious agent/viral vector pose a risk of infecting other animals: horizontal versus vertical transmission
- ☐ Unusual characteristics, spore former, exotic agent
- ☐ Hard to kill or easy to acquire, low infectious dose
- ☐ Mode of transmission: aerosol
- ☐ Large quantity and/or high concentration of agent made or used in work
- ☐ Prophylaxis or treatment available or recommended
- ☐ Viral vector
 - ☐ Parent virus _____
 - ☐ host range: xenotropic, amphotropic (envelope/pseudotype)
 - ☐ vector : commercial, lab made, colleague, core facility
 - ☐ vector production: propagated in lab, purification methods used by lab or supplier, helper virus
 - ☐ safety features; split genome in multiple plasmids, deleted structures, self-inactivating, gutless
 - ☐ replication competent virus: modifications, has it been tested

Host: risk factors

- ☐ Animal used in any part of the research
 - ☐ Species: rodent, fish, fly, nematode, etc
 - ☐ Existing transgenic or creating new strains
 - ☐ Viral vector or infectious agent challenge/exposure
 - ☐ Permissive species: humanized, immune deficient, carry endogenous adventitious agents, viruses, or sequences such as retroviral LTR
 - ☐ Used for xenograft or tumor studies
- ☐ Cell culture used in any part of the research
 - ☐ Human cells, non-human primate cells, stem cells, or primary cell culture
 - ☐ Transformed, transfected, or cancer (tumor) cell line
 - ☐ Cells contain endogenous adventitious agents/viruses/viral sequences
 - ☐ Host for expression system, virus packaging cell line, or virus propagation
 - ☐ *In vitro* use only or *in vivo* for transplant/allograft/xenograft studies
- ☐ Insect cell lines used?
 - ☐ Baculovirus
- ☐ Plant hosts used in any part of research?
 - ☐ Agrobacterium and/or plant viral vectors or significant agricultural microorganism
 - ☐ Noxious plant
- ☐ Bacteria, fungi, virus, or parasitic agent used as host?
 - ☐ Risk Group 1: *E. coli* K-12 strain, *Saccharomyces*, *B. subtilis*, etc. cloning/expression systems only
 - ☐ Risk group: opportunistic pathogen or RG-2, RG-3, or RG-4
 - ☐ Cloning/expression between natural exchangers or within same species or closely related strain
 - ☐ Will the virulence or pathogenicity of host be modified
 - ☐ Can a surrogate organism, attenuated strain, or killed organism be used?

Genes Manipulated: risk factors

- ☐ Is the gene or *sequence (*including synthetic) from RG-2, RG-3, or RG-4 agent, or biological toxin
- ☐ Are the genes or *sequences to oncogenes, virulence factors, toxins, or cause immune suppression
- ☐ Does the gene/*sequence change sensitivity to antibiotics, pesticides, or insecticides that would be used to control the host

Risk Assessment and Comments:

NIH Guidelines Sections:

Please Check all that apply in the boxes below: *Recombinant or synthetic nucleic acid molecules (rsNA) apply to all <i>Guideline</i> sections. Synthetic sequences are considered the same as RNA, DNA, recombinant RNA/DNA and use RG of host/gene in sequence.			NIH Guidelines reference:
a.	<input type="checkbox"/>	Transfer of Drug Resistance trait to microorganisms i.e., a drug used to treat disease caused by the biological agent under study if compromises ability to control disease agent -Requires NIH/OBA, RAC approval	III-A-1-a
b.	<input type="checkbox"/>	Cloning of toxin molecules with an LD₅₀ < 100 ng/kg body weight -Requires NIH/OBA approval	III-B
c.	<input type="checkbox"/>	Deliberate transfer of rsNA or DNA or RNA derived from rsNA into humans -Requires NIH/OBA, RAC approval	III-C
d.	<input type="checkbox"/>	Use of Risk Group 2, 3, 4 or restricted agent as Host-Vector Systems	III-D-1
e.	<input type="checkbox"/>	Administration of rsNA material into animals (transformed/transduced cells, vectors, siRNA, microorganisms)	III-D-1, III-D-4
f.	<input type="checkbox"/>	Experiments involving transgenic/knockout animals requiring ABSL-2 containment or higher	III-D-1, III-D-4-b
g.	<input type="checkbox"/>	Cloning genes from a Risk Group 2, 3, 4 or restricted agent into a nonpathogenic prokaryotic or lower eukaryotic Host-Vector System except toxins with an LD ₅₀ < 100 ng/kg BW -Requires NIH/OBA approval	III-D-2
h.	<input type="checkbox"/>	Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in a tissue culture system	III-D-3, or III-E-1
i.	<input type="checkbox"/>	De novo generation of transgenic/knockout animals requiring ABSL-1 containment	III-D-4-a
j.	<input type="checkbox"/>	De novo generation of transgenic/knockout animals requiring ABSL-2 containment or higher	III-D-4-b
k.	<input type="checkbox"/>	Experiments involving whole plants including algae, creating transgenic plants	III-D-5 or III-E-2
l.	<input type="checkbox"/>	Propagating modified organisms with culture volumes exceeding 10 liters	III-D-6
m.	<input type="checkbox"/>	Experiments involving influenza virus (H2N2, HPAI H5N1, 1918 H1N1)	III-D-7
n.	<input type="checkbox"/>	Use of cells/cell lines containing <2/3 eukaryotic viral genome (cells must lack helper virus if using defective virus if propagated and maintained in culture)	III-E-1
o.	<input type="checkbox"/>	Use of RG-1 Host-Vector systems & genes not covered elsewhere, may be conducted using BSL-1 containment	III-E
p.	<input type="checkbox"/>	De novo generation of transgenic/knockout Rodents requiring ABSL-1 containment	III-E-3
q.	<input type="checkbox"/>	Synthetic nucleic acid molecules that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA and (3) do not produce a toxin that is lethal for vertebrates at an LD ₅₀ of < 100 ng/ kg body weight.	III-F-1
r.	<input type="checkbox"/>	Use of rsNA that is not in organisms or viruses and not modified to penetrate cell membranes, or consists of DNA segments from a single nonchromosomal or viral DNA source	III-F-2 or III-F-3
s.	<input type="checkbox"/>	Consist entirely of nucleic acids from a prokaryotic host including indigenous plasmids or viruses when propagated in that host	III-F-4
t.	<input type="checkbox"/>	Consist entirely of nucleic acids from a eukaryotic host propagated in that host	III-F-5
u.	<input type="checkbox"/>	Consist entirely of DNA molecules segments from different species exchange DNA by a known physiological process (see Appendix A for qualified natural exchangers exempt species sublist)	III-F-6 Appendix A
v.	<input type="checkbox"/>	Genomic DNA that has acquired a transposable element if it does not contain any rsNA	III-F-7
x.	<input type="checkbox"/>	Use of cells/cell lines containing <1/2 eukaryotic viral genome of RG-1 or RG-2 viruses (propagated and maintained in culture)	III-F-8 Appendix C-I
x.	<input type="checkbox"/>	E. coli K-12 Host-Vector Systems for cloning/expression except if <i>E. coli</i> host contains: (i) conjugation proficient plasmids or generalized transducing phages, (ii) lambda/lambdoid/Ff bacteriophages or non-conjugative plasmids used as vectors (iii) >10L cultures, (iv) cloning of DNA from RG-3, RG-4, restricted organisms, biotoxins	III-F-8 Appendix C-II
y.	<input type="checkbox"/>	S. cerevisiae, S. uvarum, or Kluyveromyces Host-Vector Systems for cloning/expression (except (i) >10L cultures, (ii) cloning of DNA from RG-3, RG-4 or restricted organisms or biotoxins)	III-F-8 Appendix C-III III-F-8 Appendix C-IV
z.	<input type="checkbox"/>	B. subtilis or B. licheniformis Host-Vector Systems (asporogenic strains) for cloning/expression (except (i) >10L cultures, (ii) cloning of DNA from RG-3, RG-4 or restricted organisms or biotoxins)	III-F-8 Appendix C-V
aa.	<input type="checkbox"/>	The purchase or transfer of transgenic rodents requiring ABSL-1 containment	III-F-8 Appendix C-VII
ab.	<input type="checkbox"/>	Transgenic rodent colony maintenance, breeding, crossing strains to create a new strain requiring ABSL-1 containment except if either parent strain or progeny requires ABSL-2 and neither parent strain contains genetic modifications of (i) incorporation of >1/2 exogenous eukaryotic virus genome; or (ii) incorporation of transgene under control of gammaretroviral LTR, and progeny is not expected to contain >1/2 exogenous eukaryotic virus genome	III-F-8 Appendix C-VIII

Considerations for Assessing Risk in the Biological Research Laboratory

Review of rDNA and Biosafety protocols submitted to the IBC should include a risk assessment of the biohazardous materials used including pathogens, toxins, human cells and tissue, animal use, host, vector, and gene, the facilities and methods that will be used in the project. Synthetic sequences are considered the same as RNA, DNA, recombinant RNA/DNA and use RG of host/gene in sequence. *NIH Guidelines* Section II provides guidance for performing a comprehensive risk assessment and determining the appropriate containment conditions. Additional resources referenced are: the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th ed. and the Occupational Safety and Health Administration (OSHA) regulation, 29CFR 1910.1030 and OSHA publication 3127.

Risk Assessment References: *NIH Guidelines*: Section II-A and Appendix A, B, C, and E. *BMBL*: Sections I, II, and VIII, and Appendix D, F, and H

Physical and Biocontainment Conditions References: *NIH Guidelines*: Sections III-D, III-E, and III-F have work specific minimum containment conditions and described in Appendix C, F, G, I, K, P and Q. *BMBL*: Sections III, IV, and V and Appendix A, E, and I

Recommended Biosafety level based on IBC review and approval _____

IBC office use only

Institutional Biosafety Committee Self-Assessment Tool



July 2017

Self-Assessment Tool for Institutional Biosafety Committees and Programs of Oversight of Recombinant or Synthetic Nucleic Acid Research

The National Institutes of Health (NIH) Office of Science Policy (OSP) is pleased to introduce its revised Institutional Biosafety Committee (IBC) self-assessment tool, which was originally published in 2009. The revised tool is a resource that institutions may use to evaluate their IBCs and programs of oversight for research involving recombinant or synthetic nucleic acid molecules for compliance with the requirements articulated in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*.

Users of this resource should carefully consider the answers to each question in the checklist, which relate to specific standards and expectations or, in some cases, recommended best practices regarding implementation of the *NIH Guidelines*. As an evaluation exercise, institutions may wish to involve key personnel involved with the IBC (for example, IBC members and administrators, biological safety officers, veterinarians, and animal care staff, as well as investigators and laboratory staff) with responsibility for implementing the *NIH Guidelines* to obtain and share information. The answers given may be compared to the comments from NIH OSP provided on each question, and users may use the blank spaces provided to make notes about whether and how specific requirements are being fulfilled.

There is no “score” that results from the self-assessment process; it is qualitative in nature. Nonetheless, after completing the self-assessment, institutional officials should have a good sense of whether their programs are in line with the expectations, standards, and requirements of the *NIH Guidelines*, and where their programs may benefit from modification or augmentation.

We hope you find this resource helpful. Comments are always welcomed and may be sent to NIH OSP at: NIHGuidelines@od.nih.gov

Question Number	NIH Guidelines Citation	Question	NIH Comments	Institution Comments/Notes
IBC MEMBERSHIP				
1	IV-B-2-a-(1)	How many members are currently on the institution's IBC?	The institution's IBC must be composed of no fewer than five members who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology, the capability to assess the safety of research with recombinant or synthetic nucleic acid molecules, and the ability to identify any potential risk to public health or the environment. At least two of these individuals must not be affiliated with the institution except for their membership on the IBC.	
2	IV-B-2-a-(3)	Has the institution designated an IBC Chair?	The institution must file an annual report with NIH OSP which includes a roster of all members of the IBC and clearly indicates who is serving as the IBC Chair.	
3	IV-B-2-a-(1)	Has the institution designated a BSO on the IBC (if necessary)?	A BSO must be appointed to the IBC if the institution conducts research at BL3, BL4, or conducts Large Scale research (defined as research in which a single containment vessel has greater than 10 liters of volume). When required, the individual serving as the BSO should be indicated on the roster registered with NIH OSP.	

4	IV-B-2-a-(1)	Has the institution designated a plant, plant pathogen, or plant pest containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments subject to Appendix P, <i>Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants</i> , are conducted at the institution. When required, the individual serving as the plant expert should be indicated on the roster registered with NIH OSP.	
5	IV-B-2-a-(1)	Has the institution designated an animal containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in animal containment principles when experiments subject to Appendix Q, <i>Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals</i> are conducted at the institution. When required, the individual serving as the animal expert should be indicated on the roster registered with NIH OSP.	
6	IV-B-2-a-(1)	How many IBC members are not affiliated with the institution but represent the interests of the surrounding community with respect to health and protection of the environment?	The IBC shall have at least two members who are not affiliated with the institution (apart from their membership on the IBC) and who represent the interests of the surrounding community with respect to health and protection of the environment. These two individuals must be indicated on the roster registered with NIH OSP.	

7	IV-B-2-a-(3)	Has the institution designated an IBC contact person on the IBC?	NIH OSP requires institutions to designate a contact person on the IBC roster whom NIH OSP can contact with questions and important information regarding the institution's IBC.	
8	IV-B-2-a-(3)	Does the institution file a committee membership report annually with NIH OSP?	<p>The institution must submit to NIH OSP at least annually:</p> <ul style="list-style-type: none"> I. a roster of all IBC members clearly indicating the Chair, contact person, biological safety officer (BSO - if applicable), plant, animal or human gene transfer experts (if applicable) and non-affiliated members; and II. biographical sketches for all IBC members. <p>IBC registrations and annual updates can be submitted using the IBC Registration Management System (IBC-RMS).</p>	
9	IV-B-6	Has the institution designated a human gene transfer expert on the IBC (if necessary)?	When conducting or sponsoring research with recombinant or synthetic nucleic acid molecules involving human subjects, the institution must ensure that there is an IBC member who has adequate experience and training in the field of human gene transfer. This individual must be indicated on the roster registered with NIH OSP.	

10	Recommended Practice	Does the institution formally appoint IBC members?	A written policy should be in place that addresses the appointment of IBC members. Appointments of IBC members should be made by a senior institutional official.	
11	Recommended Practice	Are IBC members appointed for a fixed term?	NIH OSP recommends that members of the IBC be appointed for a fixed term of appointment, thus allowing for fresh perspectives to rotate periodically onto the IBC.	
12	Recommended Practice	How many staff members support the IBC and what are the lines of reporting for those staff?	Institutions should periodically conduct a thorough assessment of the resources necessary for the IBC to fulfill all of its responsibilities as articulated in Section IV- B of the <i>NIH Guidelines</i> , taking into account not only the protocol submission and review process, but also training and surveillance responsibilities as required under Sections IV-B-1-h and IV-B-2-b-(5) of the <i>NIH Guidelines</i> respectively.	
13	Recommended Practice	What does the institution do to recognize or promote service on the IBC?	The ability to retain and recruit qualified IBC members is critically important for an IBC program to succeed. Recognition of service on the IBC is valuable not only for encouraging faculty to join the committee when invited to serve, but also for acknowledging institution-wide the value that the institution places on the IBC's role. At many institutions, IBC service counts toward service requirements that are a consideration for promotion and tenure.	

MEETINGS AND MINUTES

14	IV-B-2-a-(4)	<p>How does the IBC identify and handle potential conflicts of interest between IBC members and the review or approval of a research project in which they have a personal or financial interest?</p> <p>Is there a written policy for conflicts of interest?</p>	<p>Section IV-B-2-a-(4) of the <i>NIH Guidelines</i> states that no member of an IBC may be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest.</p> <p>NIH encourages institutions to develop formal conflict of interest policies since this promotes attention to this matter and consistent approaches to dealing with it.</p>	
15	IV-B-2-a-(6)	<p>Are members of the public (other than non-institutional IBC members) permitted to attend IBC meetings?</p>	<p>When possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public.</p>	
16	IV-B-2-a-(6)	<p>How would an interested member of the general public learn about future IBC meetings dates, times and location?</p>	<p>When possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to make information regarding meeting times and locations available. Such Information could be posted on the institution's website or be otherwise publically accessible.</p>	

17	IV-B-2-a-(6) and IV-B-2-a-(7)	Is the conduct of official IBC business (e.g., protocol review and approval) done at a convened meeting (e.g., interactive/real-time/in-person)?	The <i>NIH Guidelines</i> do not prescribe how IBCs should be convened, but they do speak to the preparation of meeting minutes, and they encourage institutions to accommodate public attendance at meetings. Thus, IBCs should be convened in a manner that allows for fulfillment of these two expectations. Email exchanges cannot fulfill these expectations and thus are not an acceptable manner for the IBC to conduct official business.	
18	IV-B-2-a-(7)	Has the IBC ever received comments or questions from the general public about its activities? Are there policies or procedures for how such comments or questions would be handled? Has the institution forwarded any such comments to NIH OSP?	When public comments are made on the IBC's actions, the institution must forward both the public comments and the IBC's response to NIH OSP.	
19	IV-B-2-a-(7)	Does the IBC record minutes for every meeting?	Minutes must be kept for every IBC meeting.	

20	IV-B-2-a-(7)	<p>Are IBC meeting minutes available to the public upon request?</p> <p>If so, how are they provided?</p>	<p>Upon request, the institution shall make IBC meeting minutes available to the public. NIH OSP recommends the institution develop a formal written policy for how requested minutes will be provided.</p>	
21	IV-B-2-b	<p>Is any information pertaining to the IBC meeting routinely not captured in the meeting minutes (e.g., Select Agent information, PI names, research agent descriptors, location of agents)? If so, please describe.</p>	<p>IBCs adequately document fulfillment of their review and oversight responsibilities as articulated in Section IV-B-2-b of the <i>NIH Guidelines</i></p>	
22	Recommended Practice	<p>With what frequency is the IBC convened?</p>	<p>While the <i>NIH Guidelines</i> do not speak to the frequency that the IBC should meet, NIH OSP encourages institutions assess the volume of their research and determine an appropriate frequency for the IBC to convene in order to ensure timely review of research.</p>	
23	Recommended Practice	<p>Are PIs encouraged to attend IBC meetings where their research is discussed?</p>	<p>PI participation in the IBC meeting can not only enrich the discussion of the research at hand, but also raises the profile of the IBC within the investigator community. PI attendance can be particularly useful if the project is novel or especially complex and the IBC would benefit from a full description of the activities.</p>	

24	Recommended Practice	Does the institution have written policies for the redaction of IBC meeting minutes before they are released to the public?	In keeping with Section IV-B-2-a-(6) of the <i>NIH Guidelines</i> , institutions may redact certain information from IBC minutes if there are privacy or proprietary concerns.	
PROTOCOL REVIEW AND RISK ASSESSMENT				
25	III-D	Does the institution have a form for registering protocols involving research with recombinant or synthetic nucleic acid molecules with the IBC?	The <i>NIH Guidelines</i> require that PIs submit a registration document to the IBC with pertinent information regarding their protocols. This information includes, but is not limited to, the source of the nucleic acid, the nature of the inserted nucleic acid sequence, the host and vector to be used, and containment conditions.	
26	IV-B-2-b-(1)	Does the IBC use delegated or expedited reviews whereby any individual or subcommittee approves research on behalf of the IBC?	The IBC is responsible for reviewing all research with recombinant or synthetic nucleic acid molecules conducted at or sponsored by the institution that is subject to the <i>NIH Guidelines</i> . Expedited reviews or approvals by a subgroup of the IBC on behalf of the entire IBC for research subject to the <i>NIH Guidelines</i> is not in keeping with the requirements of the <i>NIH Guidelines</i> . Such formal business should only be conducted when a quorum of the IBC is present at a convened meeting.	

27	IV-B-2-b-(1) and IV-B-7-c-(3)	<p>Do PIs determine whether their research is exempt from the <i>NIH Guidelines</i>?</p> <p>Is the determination verified by the BSO or IBC?</p> <p>Are PIs required to register exempt work with the IBC?</p>	<p>Recombinant or synthetic nucleic acid molecule research that is exempt from the <i>NIH Guidelines</i> under section III-F need not be registered with the IBC, however the institution is responsible for ensuring PIs are correctly determining under which section of the <i>NIH Guidelines</i> their research falls. Many institutions register all recombinant DNA research and have the BSO or IBC Chair verify that the PIs initial determination is correct.</p>	
28	IV-B-7-c-(3)	<p>Do PIs register all research subject to Section III-A through III-E of the <i>NIH Guidelines</i>?</p>	<p>PIs must submit the initial research protocol and any subsequent changes if covered under Section III-A, III-B, III-C, III-D, or III-E to the IBC for review and approval or disapproval.</p>	
29	IV-B-7-c-(3) and IV-B-7-a-(2)	<p>Does the registration document require PIs to identify what section of the <i>NIH Guidelines</i> their research is subject to?</p>	<p>PIs must submit the initial research protocol and any subsequent changes if covered under Section III-A, III-B, III-C, III-D, or III-E to the IBC for review. Thus it is incumbent upon PIs to be able to identify the appropriate section of the <i>NIH Guidelines</i> their research falls under.</p>	
30	Recommend Practice	<p>How does the institution assess the IBC's performance and compliance with the <i>NIH Guidelines</i>?</p>	<p>NIH OSP recommends that institutions have mechanisms in place that allow senior administration to assess the performance of the IBC. For example, annual reports to the Institution's Responsible Official.</p>	

31	Recommend Practice	<p>How do PIs submit registrations detailing their research with recombinant or synthetic nucleic acid molecules to the IBC for review?</p> <p>How are PIs informed of the procedures for submitting new research to the IBC?</p>	NIH OSP recommends institutions have a formalized written policy that communicates how PIs should submit their registrations to the IBC for review and approval. Furthermore, the institution should develop training for PIs in order to communicate these requirements.	
32	Recommend Practice	What systems does the institution have in place to ensure that all research with recombinant or synthetic nucleic acid molecules that is subject to the <i>NIH Guidelines</i> and requires IBC review is being captured?	Various approaches can be used to ensure that all research requiring IBC review and approval is being captured. These include coordination and sharing of information between the IBC, IACUC, and the IRB, coordination with the grants and contracts office, and surveying relevant academic departments.	
33	Recommend Practice	Is the IBC empowered with the authority to enforce the <i>NIH Guidelines</i> and ensure that IBC approved conditions are adhered to?	The IBC should be granted the appropriate authority to fully investigate potential violations or compliance problems. The IBC's authority should be articulated in an IBC charter or similar document.	
34	Recommend Practice	Does the IBC ever grant approvals dependent upon certain conditions being met?	If the IBC grants approvals based on specific conditions being met then there should be a formal mechanism for verifying the conditions are indeed fulfilled.	

35	IV-B-2-b-(2)	How are PIs informed of the outcome of the IBC's review of their submitted research protocols involving recombinant or synthetic nucleic acid molecules?	Section IV-B-2-b-(2) requires the IBC to notify PIs of the results of the IBC's review and approval. For example, sending a formal letter stating the approval conditions, protocol expiration date and other pertinent information.	
36	Recommend Practice	<p>Do registrations have an expiration date?</p> <p>How long is approval granted for?</p> <p>Does the IBC require periodic (annual) updates?</p> <p>How are PIs made aware of these requirements?</p>	Because research is typically dynamic, NIH OSP recommends that protocol registrations have an expiration date, after which time a new registration document must be submitted. Many institutions also have a periodic (annual) update form or an amendment form for registering any changes to the protocol.	
37	Recommend Practice	Does the institution encourage communication and coordination between the IBC and other institutional oversight committees (such as the IRB and IACUC)?	Communication between the IBC, the IRB, and the IACUC can be one of an array of mechanisms for institutions to ensure that they are capturing all research with recombinant or synthetic nucleic acids subject to the <i>NIH Guidelines</i> .	
POLICIES AND PROCEDURES				
38	IV-B-1-A	What policies are in place to ensure that the institution is in compliance with the <i>NIH Guidelines</i> ?	The <i>NIH Guidelines</i> require that institutions establish and implement policies that provide for the safe conduct of research with recombinant or synthetic nucleic acid molecules and ensure compliance with the <i>NIH Guidelines</i> .	

39	Recommend Practice	Has the institution developed a charter or other document defining IBC member roles and responsibilities, and policies and procedures for the general implementation of the <i>NIH Guidelines</i> ?	NIH OSP recommends that institutions develop an IBC charter or similar document that clearly articulates the responsibilities the IBC. The IBC charter is also an ideal mechanism for documenting IBC policies and procedures, such as managing conflict of interest, minute taking, etc.	
40	Recommend Practice	What review activities, if any, beyond those described in the <i>NIH Guidelines</i> have been delegated to the IBC by the institution?	Although not required by the <i>NIH Guidelines</i> , many IBCs review research that is not subject to the <i>NIH Guidelines</i> but nonetheless may pose a biohazard.	
TRAINING AND EDUCATION				
41	IV-B-7-d-(2)	Does the institution provide resources to investigators to assist them in conducting training for laboratory staff regarding laboratory safety and the implementation of the <i>NIH Guidelines</i> ?	The <i>NIH Guidelines</i> require that institutions ensure appropriate training for laboratory staff regarding laboratory safety and implementation of the <i>NIH Guidelines</i> . Many institutions offer a standard general biosafety course (including material addressing requirements under the <i>NIH Guidelines</i>) to assist investigators with the training requirements.	

42	IV-B-7-d(2)	How do PIs instruct and train laboratory staff in the procedures for dealing with research-related accidents/illnesses in the laboratory?	PIs are required to train their laboratory staff in the practices and techniques required to ensure safety and the procedures for dealing with accidents. IBC-approved written policies for dealing with accidents involving recombinant or synthetic nucleic acid molecules in the laboratory should be available to all applicable personnel.	
43	IV-B-1-h	Does the institution conduct training with respect to the <i>NIH Guidelines</i> (e.g. content, format, timing, requirements) for PIs and laboratory staff?	The <i>NIH Guidelines</i> require that the institution ensure appropriate training for PIs and laboratory staff regarding laboratory safety and implementation of the <i>NIH Guidelines</i> . Furthermore, institutions should provide training to PIs regarding the responsibilities and expectations of PIs under the <i>NIH Guidelines</i> . NIH OSP has an informational brochure available that institutions can use to instruct their investigators in the requirements of the <i>NIH Guidelines</i> .	
44	IV-B-1-h	How are animal handlers informed of the risks associated with research involving recombinant or synthetic nucleic acid molecules used with animals? Are there postings in the rooms/cages etc?	It is the responsibility of the PI to ensure that laboratory staff and others involved in the conduct of research with recombinant or synthetic nucleic acid molecules are sufficiently trained regarding laboratory safety and the <i>NIH Guidelines</i> . Training programs should be in place that fulfill these expectations	

45	Recommended Practice	Does the institution keep records documenting the training individual personnel have undergone relative to the <i>NIH Guidelines</i> ?	NIH OSP recommends keeping records of training that individual personnel have undergone relative to the <i>NIH Guidelines</i> . This includes laboratory specific training given by the PI.	
SURVEILLANCE, EMERGENCY PLANNING, AND RESPONSE				
46	IV-B-1-i	Does the institution have a health surveillance program for laboratory workers conducting research with recombinant or synthetic nucleic acid molecules?	The institution shall determine the necessity for health surveillance of personnel conducting research with recombinant or synthetic nucleic acid molecules; and if appropriate, establish a health surveillance program for such projects. The institution must establish and maintain a health surveillance program for personnel engaged in large-scale research or activities involving viable organisms containing recombinant or synthetic nucleic acid molecules which require BL3 or higher containment.	
47	IV-B-1-i	Does the institution have a health surveillance program for animal care workers involved in high containment research with recombinant or synthetic nucleic acid molecule research?	The institution must establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant or synthetic nucleic acid molecules that require BL3 or higher laboratory containment.	

48	IV-B-1-j	<p>Does the institution report significant incidents, violations and research-related accidents and illnesses to NIH OSP?</p> <p>Are such incidents reported to NIH OSP in the appropriate time frame?</p>	<p>The <i>NIH Guidelines</i> require that <u>significant</u> incidents, violations and research-related accidents and illnesses be reported to NIH OSP within thirty days or immediately depending on the nature of the incident.</p> <p>For information regarding incident reporting requirements please refer to our Incident Reporting FAQs.</p>	
49	IV-B-2-b-(5)	<p>Does the IBC keep track of all protocols falling under the <i>NIH Guidelines</i> currently registered with the IBC?</p>	<p>Section IV-B-2-b-(5) of the <i>NIH Guidelines</i> requires IBCs to periodically review research with recombinant or synthetic nucleic acid molecules conducted at the institution. By having mechanisms for tracking currently registered protocols, the institution can ensure compliance with this requirement.</p>	

50	IV-B-2-b-(6) and B-7-a-(6)	<p>Does the institution have plans or policies for the following if recombinant or synthetic nucleic acid molecules are involved:</p> <p>A) Personnel contamination, B) Research-related illness, C) Accidental spills, D) Loss of containment, E) Violations?</p>	<p>On behalf of the institution, the IBC must adopt emergency plans covering accidental spills and personnel contamination resulting from research with recombinant or synthetic nucleic acid molecules subject to the <i>NIH Guidelines</i>.</p>	
51	IV-B-2-b-(7)	<p>What procedures are followed to ensure reporting of any significant violations of the <i>NIH Guidelines</i>, or significant research-related accidents/ illnesses to the appropriate institutional official and to NIH OSP?</p> <p>How has this policy been conveyed to the lab personnel?</p>	<p>Significant problems with, or violations of, the <i>NIH Guidelines</i> and any significant research related accidents or illnesses must be reported to NIH OSP within 30 days (or immediately depending on the nature of the incident). The most effective way to ensure this provision is met is to have a formalized institutional policy describing how these incidents will be reported to NIH OSP and by whom. This policy should be widely disseminated to PIs and laboratory staff and discussed during training.</p>	

52	IV-B-3-c-(1)	<p>Are periodic inspections conducted to ensure that laboratory standards and containment conditions required by the IBC are rigorously followed?</p> <p>If so, how often and by whom?</p> <p>Are problems communicated to the IBC?</p>	<p>The Biological Safety Officer is charged with performing periodic inspections to ensure that laboratory standards are rigorously followed. Any significant problems that are encountered as a result of these inspections should be promptly reported to the IBC.</p>	
53	Recommended Practice	<p>Does the institution have a laboratory inspection checklist?</p>	<p>Section IV-B-3-c-(1) requires periodic inspections to ensure that laboratory standards are rigorously followed. Having an inspection checklist can help ensure standardized inspection practices.</p>	
PHYSICAL CONTAINMENT – LABORATORY ENVIRONMENT				
54	IV-B-7-e-(1) and Appendix G	<p>Who determines the minimum required Personal Protective Equipment (PPE) for laboratory staff working with recombinant or synthetic nucleic acid molecules?</p> <p>Who trains personnel in the proper use of PPE?</p> <p>How is compliance monitored?</p>	<p>Determining the minimum PPE required for laboratory staff is a responsibility of the PI. Training for the proper use of PPE should also be conducted by the PI. The PI is also responsible for supervising the safety performance of the laboratory staff. This would include monitoring PPE compliance.</p>	

55	IV-B-7-e-(4)	Does the institution ensure that laboratory equipment (cabinets, HEPA filters) are properly maintained and functioning properly?	The PI is responsible for ensuring the integrity of the physical containment (e.g. biosafety cabinets) and the biological containment (e.g. purity and genotypic and phenotypic characteristics). The institution should consider a policy of periodic certification and maintenance of laboratory equipment.	
56	IV-B-2-b-(1)	Does the IBC review and approve plans for the renovation or construction of laboratories and other facilities where research with recombinant or synthetic nucleic acid molecules is conducted?	IBCs are responsible for assessments of facilities contemplating research. The IBC's review of construction plans can help ensure that new facilities comport with the conditions and containment measures described in the <i>NIH Guidelines</i> .	
57	Appendix G	How does the institution dispose of liquid and solid waste containing recombinant or synthetic nucleic acid molecules? Are there written Standard Operating Procedures (SOP) for waste disposal?	As part of standard microbiological practice, all liquid and solid laboratory waste containing recombinant or synthetic nucleic acid molecules must be decontaminated before disposal.	
58	Appendix G-II-C	Does the institution engage in research with recombinant or synthetic nucleic acid molecules at BL3 or higher? If so, has a BSO been appointed?	Appendix G-II-C discusses the standard microbiological practices, the special practices, containment equipment and laboratory facilities requirements for research being conducted at BL3. A BSO must be appointed when conducting research at BL3 or higher.	

59	Appendix G-II-D	<p>Does the institution engage in recombinant or synthetic nucleic acid molecule research at BL4?</p> <p>If so, has a BSO been appointed?</p>	Appendix G-II-D discusses the standard microbiological practices, the special practices, containment equipment and laboratory facilities requirements for research being conducted at BL4. A BSO must be appointed when conducting research at BL3 or higher.	
60	Appendix G	Does the institution have policies and procedures regarding the disposal of recombinant or synthetic nucleic acid molecule containing animal waste?	Appendix G-II-B-2-i and Appendix G-II-C-2-n require that all recombinant or synthetic nucleic acid molecule containing wastes (including transgenic animal carcasses) from laboratories and animal rooms are appropriately decontaminated before disposal. NIH OSP strongly recommends the institution have formalized written policies for how animal waste containing recombinant or synthetic DNA is disposed.	
61	Recommended Practice	Does the institution have any autoclave verification program?	Autoclave verification programs should be employed in order to ensure that autoclaves are working properly and effectively. The institution should consider having a written SOP detailing the methodology and frequency of testing.	

PHYSICAL CONTAINMENT – LARGE SCALE RESEARCH

62	Appendix K	<p>Does the institution engage in large-scale research or production activities involving organisms containing recombinant or synthetic nucleic acid molecules?</p> <p>What is the largest volume? What BL is used?</p> <p>If the institution does conduct Large Scale Research has a BSO been appointed?</p>	<p>Appendix K specifies physical containment guidelines for large scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant or synthetic nucleic acid molecules. Appendix K applies to large scale research or production activities as specified in Section III-D-6 of the <i>NIH Guidelines</i>. If the institution is performing large scale research, a BSO must be appointed.</p>	
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EXPERIMENTS REQUIRING IBC, RAC REVIEW, AND NIH DIRECTOR APPROVAL

63	III-A-1-a	<p>Does the institution conduct any experiments that involve the deliberate transfer of a drug resistance trait to microorganisms not known to acquire that trait naturally?</p>	<p>Experiments involving the deliberate transfer of a drug resistance trait to microorganisms not known to acquire that trait naturally that could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, must be reviewed by the RAC and approved by the NIH Director before initiation. Additional information on Major Actions can be found in the Major Action FAQs.</p>	
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EXPERIMENTS REQUIRING NIH AND IBC APPROVAL

64	III-B-1	Does the institution conduct research involving the deliberate formation of recombinant or synthetic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD50 of less than 100 ng/kg of bodyweight?	Experiments involving the deliberate formation of recombinant or synthetic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD50 of less than 100 ng/kg of bodyweight must be reviewed and approved by both NIH OSP and the IBC before initiation. A list of specific experiments already approved under Section III-B-1 may be obtained by contacting NIH OSP at: NIHGuidelines@od.nih.gov .	
65	III-B-2	Does the institution wish to conduct an experiment previously approved as a Major Action under Section III-A-1-a of the <i>NIH Guidelines</i> ?	NIH OSP may determine that a proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director. An experiment will only be considered equivalent if, as determined by NIH OSP, there are no substantive differences and pertinent information has not emerged since submission of the initial III-A-1-a experiment that would change the biosafety and public health considerations for the proposed experiments. If such a determination is made by NIH OSP, these experiments will not require review and approval under Section III-A, but will instead be subject to Section III-B.	

EXPERIMENTS INVOLVING HIGHLY PATHOGENIC INFLUENZA				
66	III-D-7	Does the institution conduct research involving Highly Pathogenic Influenza?	<p>Research involving influenza viruses containing the H2 HA segment must be conducted at BL3 enhanced containment, while experiments with H2 HA gene in cold- adapted, live attenuated vaccine strains may be conducted at BL2 (III-D-7-a). Experiments involving influenza viruses containing a majority of genes and/or segments from HPAI H5N1 must be conducted at BL3 enhanced containment. Experiments with a minority of genes and/or segments from HPAI H5N1 influenza virus must be performed at BL3 enhanced unless a risk assessment determines that the can be safely conducted at BL2 (III-D-7-b). Experiments involving influenza viruses containing any gene or segment from 1918 H1N1 must be performed at BL3 enhanced containment (III-D-7-c).</p>	
EXPERIMENTS INVOLVING HUMAN GENE TRANSFER				
67	Appendix M	Does the institution participate in or sponsor research with recombinant or synthetic nucleic acid molecules involving human subjects?	The requirements of Appendix M apply to human gene transfer research conducted at or sponsored by an institution that receives any support for research with recombinant or synthetic nucleic acid molecules from NIH.	

68	Appendix M	<p>Has a PI at the institution ever submitted a human gene transfer protocol to the NIH OSP?</p> <p>Did the protocol undergo in-depth public review at one of the RAC meetings?</p>	<p>Research proposals involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human subjects must be registered with NIH OSP and may undergo review by the RAC if specific criteria are met. The IBC may not give final approval of a protocol until the registration process is complete. For protocols that undergo RAC review, the registration process is not complete until RAC review has occurred. This is to ensure that the PI and the IBC take the RACs recommendations into consideration before the protocol is approved.</p>	
69	Appendix M	<p>Does the institution have written policies for reporting serious adverse events on human gene transfer trials to the IBC?</p>	<p>Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format and time frame for reporting, respectively. NIH OSP recommends written policies and procedures be in place for reporting serious adverse events to the IBC.</p>	

70	Appendix M	<p>Does the institution have written policies for reporting serious adverse events that are associated with the use of human gene transfer products to NIH OSP?</p> <p>What is the required time frame for reporting serious adverse events as well as the threshold for determining what is a reportable event to NIH OSP?</p>	<p>Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format, and time frame for reporting, respectively. NIH recommends institutions have written policies and procedures in place for reporting serious adverse events to NIH OSP and other required entities.</p>	
71	Appendix M	<p>Does the IBC review informed consent documents to ensure that human subjects are adequately informed of the possible risks, discomforts, and side effects that are associated with the use of gene transfer agents?</p>	<p>Section III-C of the <i>NIH Guidelines</i> requires that the IBC approve human gene transfer protocols prior to subject enrollment. As part of this approval process IBCs should review the informed consent documentation from the perspective of risks associated with the use of recombinant or synthetic nucleic acid molecules.</p>	
72	Recommended Practice	<p>Does the institution encourage the use of the GeMCRIS database for the submission of annual reports and the reporting of adverse events on human gene transfer trials to NIH OSP?</p>	<p>For additional information, visit the GeMCRIS page on the NIH OSP Web site.</p>	

PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RESEARCH INVOLVING PLANTS

73	Appendix P	Does the institution engage in research with recombinant or synthetic nucleic acid molecules involving plants subject to Appendix P of the <i>NIH Guidelines</i> ?	Appendix P of the <i>NIH Guidelines</i> specifies the physical and biological containment conditions and practices suitable to the greenhouse conduct of plant experiments involving recombinant or synthetic nucleic acid molecules.	
74	Appendix P	Does the institution have policies and procedures regarding the proper disposal of transgenic plants?	Transgenic plants and associated organisms must be decontaminated in accordance with the requirements of Appendix P of the <i>NIH Guidelines</i> . NIH OSP recommends having formalized written policies describing procedures to be followed when disposing of transgenic plants. These plans should be approved by the IBC.	
75	Appendix P	Has the institution ever allowed the field release of a transgenic plant? If so, was authorization obtained from the proper agency?	The <i>NIH Guidelines</i> address contained research only. Experimental field releases require proper authorization from a responsible federal agency.	

PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RESEARCH INVOLVING ANIMALS

76	Appendix Q	Does the institution engage in research with recombinant or synthetic nucleic acid molecules involving large animals subject to Appendix Q of the <i>NIH Guidelines</i> ? (Large animals subject to Appendix Q include transgenic animals and animals into which viable modified recombinant or synthetic nucleic acid molecules have been introduced).	If the institution engages in recombinant or synthetic nucleic acid molecule experiments involving large animals then the institution is required to follow the procedures of Appendix Q of the <i>NIH Guidelines</i> . Appendix Q pertains to research involving animals of a size or having growth requirements that preclude the use of containment for laboratory animals.	
77	Appendix Q-1-B-2	Does the institution inventory and track large animals subject to Appendix Q to ensure proper disposal?	The <i>NIH Guidelines</i> require that institutions keep a permanent record of the experimental use and disposal of animals covered under Appendix Q.	
78	Appendix Q	Does the institution have policies and procedures regarding the proper disposal of transgenic animals covered under Appendix Q?	Large animals must be disposed of in accordance with the procedures of Appendix Q of the <i>NIH Guidelines</i> . NIH OSP recommends that the institution have formalized, IBC approved policies describing how large animals are to be disposed.	

79	Appendix Q	Does the institution have policies and procedures regarding the disposal of infectious animal waste covered under Appendix Q?	Infectious animal wastes must be disposed of in accordance with Appendix Q of the <i>NIH Guidelines</i> . NIH OSP recommends that the institution have formalized, IBC approved policies describing how infectious animal wastes containing recombinant or synthetic nucleic acid molecules will be disposed.	
80	Appendix Q	Has the institution conducted the field release of a transgenic animal covered under Appendix Q? From what agency was authorization obtained?	The <i>NIH Guidelines</i> address contained research only. Experimental field releases require proper authorization from a responsible federal agency.	
RESOURCES				
81	Recommended Practice	Has the institution developed tools for communicating requirements for the conduct of research subject to the <i>NIH Guidelines</i> ?	NIH OSP recommends that the institution develop a method for disseminating information regarding the <i>NIH Guidelines</i> to those faculty and staff in need of such information. Effective methods include newsletters, email blasts and FAQ's.	
82	Recommended Practice	Does the institution encourage attendance at professional or scientific conferences related to biosafety or the <i>NIH Guidelines</i> ?	NIH OSP encourages support of professional development particularly for IBC members and staff.	

For general questions related to the *NIH Guidelines* and the submission of incident reports, please email:

NIHGuidelines@od.nih.gov

For questions related to human gene transfer protocols and all human gene transfer protocol related submissions, please email:

HGTprotocols@mail.nih.gov

Safety Procedures For Human Anatomy lab operations for Educational programs at UNTHSC

Purpose

The purpose of this document is to establish defined standard safety operating procedures for Human Anatomical lab operations for educational programs at UNTHSC

Applicability

This standard operating procedure applies to all the activities, specimen preparation, dissection and sample collection from cavaders within University of North Texas Health Science Center laboratories.

Training and PPE

- These activities should be performed by individuals who have successfully completed the Blood Borne Pathogen (BBP) training.
- Lab coats/ scrubs, gloves and eye protective gears will be used to performs the activities.

Safety Procedures

- Do not eat, drink, apply lip balm, or touch your face while in the Anatomy Lab.
- Wear examination gloves when handling specimens, cadavers, or waste material.
- Change gloves when damaged and periodically as needed.
- Wear eye protection when working with cadavers and preserved specimens.
- Wear a lab coat or scrubs when doing dissections to protect your clothes. For significant splash hazards, wear an apron over the lab coat.
- Dispose of all scalpel blades and other sharps in red "SHARPS" containers.
- Wash hands and any exposed skin immediately on contact with embalming fluid and before leaving the dissection area.
- All waste containers must be kept closed when not actively being filled. Do not overfill.
- Report injuries or problems to the tank supervisor as soon as possible.

Health Surveillance for exposure

- 1. Wash! Wash exposed areas with soap and water – for eyes and mouth, flush with large amounts of water.

- Notify your tank supervisor immediately – follow the instruction from the supervisor
- For Medical assistance, Contact Harris Occupational Health Clinic @ 1651 West Rosedale, Ste. 105, Fort Worth, TX 76104 or (817) 250-4840
- If Harris Occupational Health Clinic is not available, go to the nearest ER for blood borne pathogen exposure and follow the site protocol.
- If you need to report a needle stick, please do so at:
https://unthsc.qualtrics.com/SE/?SID=SV_6tZB8dQXVAwqZ6Z Presence of Drug Enforcement Administration (DEA) Licensee is required along with Safety Office representative to collect the Controlled Substances waste from investigators.

Waste processing and disposal

- Work surface will be decontaminated with disinfecting agents (70% alcohol, 10% freshly prepared bleach or other commercially available disinfectants recommended for clinical laboratories)
- All the waste generated from human specimen should be collected in red biohazard bags.
- All sharps used to perform any activity with human specimen should be disposed off in the sharp container ONLY.
- Custodial service should be contacted to pick up the waste.

Recordkeeping

The safety Department will maintain all annual inspection report.

Standard Operating Procedures For human specimen collection, storage and transportation

Purpose

The purpose of this document is to establish defined standard operating procedures for human specimen collection, storage and transportation.

Applicability

This standard operating procedure applies to all for human specimen collection, storage and transportation within University of North Texas Health Science Center laboratories.

Training and PPE

- These activities should be performed by licensed individuals to perform the sample collection and have successfully completed the Blood Borne Pathogen (BBP) training and other trainings requires by specific studies (eg; IATA training for storage and transportation)
- Lab coats/ scrubs, gloves and eye protective gears will be used to performs the activities

Health Surveillance for needle stick and exposure

- 1. Wash! Wash exposed areas with soap and water – for eyes and mouth, flush with large amounts of water.
- 2 hours for treatment – it is critical that you are treated within the first two hours after the injury.
- 3 red top vials of blood from the source
- Notify your supervisor immediately – keep the source of blood on site so the blood can be drawn.
- Contact Harris Occupational Health Clinic @ 1651 West Rosedale, Ste. 105, Fort Worth, TX 76104 or (817) 250-4840
- If Harris Occupational Health Clinic is not available, go to the nearest ER for blood borne pathogen exposure and follow the site protocol.
- If you need to report a needle stick, please do so at:
https://unthsc.qualtrics.com/SE/?SID=SV_6tZB8dQXVAwqZ6Z Presence of Drug Enforcement Administration (DEA) Licensee is required along with Safety Office representative to collect the Controlled Substances waste from investigators.

- **Waste processing and disposal**
- Work surface will be decontaminated with disinfecting agents (70% alcohol, 10% freshly prepared bleach or other commercially available disinfectants recommended for clinical laboratories)
- All the waste generated from human specimen should be collected in red biohazard bags.
- All sharps used to perform any activity with human specimen should be disposed off in the sharp container ONLY.
- Custodial service should be contacted to pick up the waste.

Recordkeeping

The safety Department will maintain all annual inspection report.

HUMAN BIOSPECIMENS RESEARCH

BioSafety Proposal Registration Form

Purpose

The purpose of this form is to document the **collection, storage and transportation** of human biospecimens obtained for research purposes. Human biospecimens include unfixed samples of blood, serum, plasma, saliva, urine, fecal matter, semen, vaginal secretions, earwax, buccal swabs, or any tissues or cells.

Applicability

This standard operating procedure applies to all research projects involving human specimen collection, storage and transportation within any University of North Texas Health Science Center facility or laboratory, or the collection, storage and transportation of such samples by UNTHSC personnel (faculty, staff or students).

Please provide the following information for preliminary review by the Environmental Health and Safety Department

Title of the project: _____

1. Principal investigator: Name _____
- Contact information: Email _____
- Phone _____
- Office (Room) _____

- ## 2. Brief Summary of the project:

3. UNTHSC personnel and/or facilities will ONLY be used for sample collection, storage and transportation. Yes ____ No ____
4. Location of sample collection and storage:

5. Will biospecimens be analyzed at UNTHSC in any facility or laboratory?

Yes ____ No ____

If yes, please contact the IBC office or website to submit a formal IBC protocol for review and approval

Personnel: list all personnel engaged in collection, and storage of biospecimens. Attach copies of the Blood Borne Pathogen (BBP) Training certificate for each listed person.
(Attach additional pages as needed)

Attestation: I attest that, as Principal Investigator, I assume full responsibility for all collection, storage and transportation of human biospecimens associated with this protocol, and that all activity associated with human biospecimens shall be conducted in accordance with all UNTHSC policies and procedures.

Principal Investigator:

Name _____

Signature _____

Date _____

For Environmental Health and Safety Office use only:

The project has been reviewed with following recommendation:

Site Inspection Conducted (Date):

Site/Staff Determination: Approved _____

Need additional IBC review: Yes ____ No ____

Safety Director/Biosafety Officer Name: _____

Signature: _____ Date: _____