UNIVERSITY of HOUSTON

ENVIRONMENTAL HEALTH & LIFE SAFETY

# Biological Safety Manual

**Revised January 2016**

## FOREWORD

The safety of all members of the campus community is a primary concern of the University of Houston. The university demonstrates this concern through compliance and enforcement of federal, state, local, and University of Houston System rules and regulations to which the university is subject. The purpose of this manual is to further promote safety through the proper management of potentially hazardous biological materials. In addition to policies, responsibilities and requirements for working with biological materials, this manual contains helpful information for the day to day management of your laboratory. For additional information or clarification of the contents of this manual please contact Biological Safety.

## HELPFUL TELEPHONE NUMBERS AND CONTACT INFORMATION

| | | |
|---|---|---|
| Environmental Health and Life Safety (EHLS) | | (713) 743-5858 |
| | Fax | (713) 743-8035 |
| Biological Safety Manager | | (713) 743-1200 |
| Safety Specialists (for Biosafety) | | (713) 743-4055 |
| | | (713) 743-3324 |
| University Health Center | | (713) 743-5151 |
| University of Houston Department of Public Safety | | (713) 743-3333 |

Environmental Health and Life Safety (EHLS) office hours: Monday through Friday 8:00 a.m. – 5:00 p.m.

For biological waste pick up, fill an Online Hazardous Waste Pickup Request Form at http://www.uh.edu/ehs/ .

For inquires, call Environmental Health and Life Safety (EHLS) during business hours or submit questions to ehs@uh.edu . After normal office hours, you may leave pertinent information on the EHLS voicemail system.

After business hours, contact the Department of Public Safety for hazardous biological agent emergencies. Environmental Health and Life Safety maintains an on-call mechanism to provide expertise in the event of an after-hours situation requiring assistance.

**TABLE OF CONTENTS**

## I. POLICIES AND RESPONSIBILITIES

### A. Campus Policy

1. The use of biological agents in teaching and research shall be in a manner that will ensure the safety, health, and well-being of faculty, staff, students, visitors, neighboring populations, wild and domestic animals and the environment.

2. The U.S. Public Health Service publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL) current edition, has been adopted as the University standard for the use of biological agents.

3. All Projects and courses involving biological agents must follow guidelines in the BMBL current edition. Approval is required by either the Biological Safety Officer or Institutional Biosafety Committee (IBC) based on the nature of the project. Contact Environmental Health and Life Safety (EHLS) Biosafety for questions and to submit forms for project registration.

4. All research and teaching involving recombinant or synthetic nucleic acid molecules shall be treated as prescribed by the most recent edition of NIH's Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (copies are available from Centers for Disease Control and Prevention (CDC) website) and as directed by law. All Projects involving Recombinant or synthetic nucleic acid molecules molecules require approval by the Institutional Biosafety Committee (IBC). A Memorandum of Understanding and Agreement (MUA) application form must be submitted to EHLS-Biosafety.

5. Research involving organisms in Risk Groups 3 and 4 is NOT permitted at the University of Houston. Biosafety Level 3 or 4 facilities are NOT available on campus.

6. Select agents and toxins require special registration with the Centers for Disease Control and Prevention (CDC) or the United States Department of Agriculture (USDA). Contact EHLS for additional registration information and assistance.

7. The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC) outlines the criteria for what qualifies as Dual Use Research of Concern (DURC), listing specific agents and toxins and descriptions of types of experiments, which when combined, define the parameters for research considered as DURC and subject to oversight under the policy. Contact EHLS for assistance with DURC potential research.

8. All research and courses involving human blood, cell lines, body fluids, and/or unfixed human tissue, and other primate cells must be conducted at Biosafety Level 2 according to the guidelines in Appendix H of the BMBL.

9. Newly isolated or recognized infectious agents of unknown pathogenicity shall be treated as Biosafety Level 2 or greater infectious agents.

10. All Visiting Researchers and Minors working in the laboratory must be registered with EHLS-Biosafety and complete all applicable training prior to initiating laboratory work. Contact EHLS-Biosafety to register Visiting Researchers and Minors working in the laboratory.

11. The University of Houston Biological Safety Manual will be the basis for general safety guidelines in the laboratory. Laboratory personnel will be expected to follow practices outlined in this manual, the BMBL publication, as well as the prudent practices specific to the project(s) in which they are involved.

**B. Responsibilities**

1. The Principal Investigator (PI) of a research project or teaching laboratory is responsible for the following:

- Being adequately trained in good microbiological techniques.
- Ensuring the integrity of physical containment (i.e. biosafety cabinets) and biological containment (i.e. purity and genotypic and phenotypic characteristics).
- Obtaining approval from the different committees relevant to the project. For example, the Institutional Biosafety Committee (IBC) and the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) and the Radiation Safety Committee (RSC) if the project involves the use of biological agents, recombinant or synthetic nucleic acid molecules, animals, human subjects/samples and radioactive materials.
- Developing specific protocols to ensure the safe use of biological agents and recombinant or synthetic nucleic acid molecules. The protocols must outline potential biohazards, necessary precautions and proper emergency procedures in the case of an accidental exposure of students and personnel.
- Verifying attenuated forms of select agents and Risk Groups 3 and 4 organisms upon arrival to the laboratory through PCR (Polymerase chain reaction) test validation. Test results must be maintained on file and a copy must be sent to the Biological Safety Manager.
- Informing the laboratory staff of the reasons and provision for any precautionary medical practices advised or requested (i.e. vaccinations or serum collection).
- Complying with the safety protocol, this manual, campus policy and any applicable federal and state laws and regulations.
- Registering Visiting Researchers and Minors working in the laboratory with Environmental Health and Life Safety.
- Training all personnel involved in the project so that they have a complete understanding of the hazards involved, safety procedures/practices/techniques required and the emergency protocols in place for dealing with accidents. This includes Animal Care personnel not directly supervised by the PI, who provide care for infected animals. Documentation of training must be kept on file. Contact EHLS (Environmental Health and Life Safety) at 713-743-5858 or visit http://www.uh.edu/ehls/training/ to register for laboratory safety training.
- Supervising laboratory staff to ensure that the required safety practices and techniques are employed.
- Correcting work errors and conditions that may result in the release of biohazardous agents and recombinant or synthetic nucleic acid molecules.

- Verifying that any persons working on Biosafety Level 2 research projects that are not personnel at UH have medical insurance. For clarification, Students and Postdoctoral Fellows, who do not receive monetary compensation from the University payroll are usually not considered University personnel and therefore must maintain their own medical insurance.
- Notifying EHLS(Environmental Health and Life Safety)-Biosafety of any changes in biological agents, procedures, personnel or protocols stated in the approved Memorandum of Understanding and Agreement by submitting an amendment to the MUA.
- Monitoring the access of laboratory visitors and assuring their safety and the security of biological agents and toxins.
- Complying with proper handling of biological waste by following recommendations in this manual, campus policy, and any applicable federal and state laws and regulations.
- Adhering to IBC-approved emergency plans for handling accidental spills and personnel contamination.
- Complying with proper permit and shipping of infectious and diagnostic material by following recommendations in this manual, campus policy, and any applicable federal and state laws and regulations.
- Reporting any accidents or adverse events to the Biosafety Office.

2. Laboratory staff, students and postdoctoral fellows who work in the laboratory are responsible for the following:

- Being familiar with all protocols and organisms used in the laboratory, regardless if the organism is handled directly. Knowing all emergency procedures established by the Principal Investigator.
- Completing training and verifying documentation of required laboratory safety training.
- Following all appropriate laboratory practices as outlined in this manual, the BMBL publication, and all additional practices outlined in the laboratory safety protocol.

3.The Department Chair or Director is responsible for the following:

- Ensuring the health and safety of personnel, visitors, students and postdoctoral fellows, while in departmental facilities.
- Ensuring departmental compliance with applicable laws, regulations and guidelines covering the use of biological agents in research.

4. Environmental Health & Life Safety (EHLS) - is responsible for the following:

- Providing information to the University of Houston community regarding procedures and regulations for the safe use of biological agents, bloodborne pathogens, and recombinant or synthetic nucleic acid molecules in research.

- Providing consultation in the development of safety protocols as requested by the Principal Investigators or Department Chairs.
- Providing application materials for working with biological agents upon request.
- Reviewing all applications (new, renewal and amendment) for the use of biological agents and submitting the Memorandums of Understanding and Agreement to the Institutional Biosafety Committee (IBC) for approval.
- Assuring department and user compliance with the IBC's recommendations.
- Scheduling and performing periodic laboratory assessments or audits of academic and research locations.
- Monitoring completion of projects through updates of protocols.
- Providing training materials and classes as needed.
- Advising generators on proper biohazardous waste handling, treatment, and disposal methods in accordance with federal, state, and University Hazardous Waste Standards.
- Pickup and arrange appropriate disposal of biological waste.
- Providing assistance and training for the proper shipment of biohazardous material.
- Biosafety consultations and technical assistance
- Record keeping and retention in accordance with applicable laws and regulations

5.The Institutional Biosafety Committee (IBC) is responsible for the following:

- Assuring the safe use of recombinant or synthetic nucleic acid molecules, biological agents, and bloodborne pathogens at the University of Houston.
- Reviewing and recommending acceptance or rejection of all proposed projects requiring registration and authorization through the Memorandum of Understanding and Agreement process.
- Formulating and recommending changes in campus policy for the safe use of biological agents and complying with federal and state laws, regulations and guidance standards.
- Authorizing EHLS to terminate or curtail any project or any teaching program involving the use of biological agents when it is in the best interest of the health and safety of the University of Houston community.

## II.Requirements for working with Biological Material

### A. Introduction and general requirements:

1. Registration of Biological Agents: Projects involving material(s) included in any of these categories must submit a Memorandum of Understanding and Agreement (MUA) form (Appendix A) for Institutional Biosafety Committee (IBC) review and approval.

- Potentially biohazardous biological agents.
- Recombinant or synthetic nucleic acid molecules Human blood and blood products, human body fluids, human cell cultures, and/or human tissue.
- Biological toxins.
- Pathogenic organisms carried by experimental animals that may pose significant risk to human health.
- Whenever a contractual agreement or grant proposal requires Institutional Biosafety Committee and or the Biosafety Officers approval for the safe handling of a biological material.
- When it is unclear as to whether a material constitutes a potential biohazard, EHLS-Biosafety should be consulted.

2. Approvals, renewals and amendments: Projects evaluated by the Institutional Biosafety Committee and or the Biosafety Officer receive approval as follows:

- MUAs at Biosafety Level 1 & 2 are approved for five years.
- PIs must submit a renewal MUA (Appendix A of the University of Houston Biosafety Manual) at least three months prior to expiration to EHLS-Biosafety.
- If any changes or additions are made to approved protocols, an MUA amendment must be submitted to EHLS-Biosafety for review and approval prior to implementation.

2. Biosafety Level 1: All staff and students working at BSL1 must complete EHLS Biosafety Training. Refresher Biosafety training will be required when biosafety protocols are renewed.

4. Biosafety Level 2: Projects approved at Biosafety Level 2 must comply with the following requirements:

- Biosafety Cabinets: Research that has the potential for the production of aerosols must be conducted in a certified biosafety cabinet. Please contact EHLS Biosafety for annual cabinet certification or information about repairs or if the biosafety cabinet is relocated.
- Medical Insurance: PIs must verify that any persons working on a Biosafety Level 2 research project and are not personnel at UH, must have medical insurance. For clarification, Students and Postdoctoral Fellows, who do not receive monetary compensation from the University payroll are usually not considered University personnel and therefore must maintain their own medical insurance.

Training: All staff and students working on a Biosafety Level 2 project must complete the Biosafety Training with Bloodborne Pathogens from EHLS. In addition to completing the Biosafety Training with Bloodborne Pathogens, personnel working with bloodborne pathogens

must complete the online Bloodborne Pathogens Refresher Training annually. Please access the Bloodborne Pathogens Refresher training by accessing http://www.uh.edu/ehls/training/. Refresher Biosafety training will also be required when biosafety protocols are renewed.

- Exempt quantities, attenuated forms of Select Agents and Risk Groups 3/ 4 organisms: These organisms must be verified upon arrival to the laboratory through PCR. (Polymerase chain reaction) test validation or other equivalent/appropriate techniques. Test results must be maintained on file and a copy must be sent to EHLS-Biosafety.

4. Inspections: Laboratories with research involving the use of all biological agents will be periodically inspected for compliance with general laboratory practices, as well as specific biological safety practices and procedures. PIs are expected to comply with all statements of the safety plan approved by the IBC in the submitted MUAs.

**B. Requirements and procedures for the safe use of biological agents**

1. Classification of the biological agents:

Biological agents are those pathogenic bacteria, viruses (including viral vectors), fungi, and parasites that can be transmitted to a person or animal, directly or indirectly, and are capable of causing disease in the new host. Biological agents classified according to risk are listed in ABSA risk group classifications-http://www.absa.org/riskgroups/bacteria.html. If the agent is not listed, contact EHLS-Biosafety. Biological agents classified as Risk Groups 3 and 4 (BSL-3 & BSL-4) are currently prohibited at UH. Select agents are a group of organisms designated by the U.S. government as being potential precursors of biological weapons.

2. Registration through the Memorandum of Understanding and Agreement (MUA) form:

An MUA form includes information regarding personnel, biological agent, project protocol, and safety procedures. This form, found in Appendix A, must be submitted to EHLS Biosafety for distribution to the Institutional Biosafety Committee (IBC). The research protocol must be approved by the IBC prior to introducing the organism into the laboratory.

3. Written Standard Operating Procedures including a Safety Plan:

Written laboratory safety procedures must be prepared by the PI or designee for each laboratory in which biological agents are used for teaching or research purposes. These procedures must be included in the safety plan of the Memorandum of Understanding and Agreement or Human Products Registration Form. Research conducted at Biosafety Level 2 that has the potential for the production of aerosols must be conducted in a certified biosafety cabinet. The PI must ensure all laboratory personnel comply with laboratory standard operating procedures and safety plan. The individual laboratory safety plan must be based on actual laboratory safety practices. Suggested reference material for laboratory safety plans are: EHLS Biological Safety Manual, National Research Council's Biosafety in the Laboratory, CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories (BMBL), Texas Department of State Health Services Bloodborne Pathogens Standard (Title 25 Part 1 Chapter 96), IATA's Shipping Infectious Substances/Diagnostic Specimens Regulations (49 CFR Part 173) and Select Agent Registry.

4. Medical Surveillance related to work with biological agents:

The IBC requires that all students working at BSL-2 have appropriate medical coverage before they start working in the laboratory. Personnel and students must be familiar with signs and symptoms of illnesses caused by the agent(s) used in the laboratory. A person that develops illness that could be of laboratory origin must inform his/her supervisor and report to EHLS, the UH Student Health Center (students only) and the Risk Management Claims Coordinator. All personnel and students that will work with, or will be in the laboratory where biological agents are in use, should be immunized against those agents if a vaccine is available.

5. Restrict access to the biological agents:

To ensure the safety and security of the UH community; short-term students and visitors, must not be exposed to biological agents unless they are trained in safe operating procedures and familiarized with the safety plan of the laboratory. Non-essential visitors and children are not allowed access to laboratories where infectious agents may be present. Persons working in the laboratory who are not affiliated with the University must be registered with EHLS by completing either the Visiting Research or Minors in Laboratories application prior to performing lab activities http://www.uh.edu/ehls/.

6. Report any injuries, overt exposures or adverse events:

## C. Requirements and procedures for the safe use or Recombinant or Synthetic Nucleic Acid Molecules

1. Classification of the biological material and the Recombinant or Synthetic Nucleic Acid Molecules procedures:

In the context of the NIH Guidelines, recombinant or synthetic nucleic acids are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant or synthetic nucleic acid molecules; (ii) 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, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above.

It is the policy of UH that research and teaching programs utilizing recombinant or synthetic nucleic acid molecules will be conducted in full compliance with federal and state laws and regulations regardless of the source of funding for the research. Classification and containment requirements for use of recombinant or synthetic nucleic acid molecules can be found in the latest edition of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Copies can be obtained from CDC/NIH by clicking on the hyperlink or visiting the helpful links page on the EHLS website. Please consult the NIH guidelines to classify the etiological agents on the basis of hazard, as well as to determine the section under which your specific experiments are described and covered by the NIH guidelines.

2. Registration through the Memorandum of Understanding and Agreement (MUA) form:

All use of recombinant or synthetic nucleic acid molecules requires the submission of a completed typed MUA, which is reviewed by the IBC and remains on file for reference. You can find the form in Appendix A of the Biosafety Manual. The MUA contains information regarding personnel, host organisms and cell lines, vectors, DNA inserts, experimental protocols, and safety procedures. The PI is encouraged to remain in communication with EHLS-Biosafety throughout the review process and the duration of the project. The IBC will review containment levels required by the guidelines and will assess facilities, procedures, practices, personnel training, and personnel expertise, as appropriate.

3. Written Standard Operating Procedures including a Safety Plan:

Written laboratory safety procedures must be prepared by the PI or designee for each laboratory in which recombinant or synthetic nucleic acid molecules is used for teaching or research purposes. Research conducted at Biosafety Level 2 that has the potential for the production of aerosols must be conducted in a certified biosafety cabinet. Please maintain proper cabinet certification through EHLS. The PI must ensure compliance by all staff and students.

Prior to initiation of the research project, the PI must provide the laboratory staff copies of written safety protocols that describe potential hazards and precautions to be taken routinely and in the event of an accident. Ensure that a copy of the safety protocol is maintained in the laboratory. Significant safety issues with recombinant or synthetic nucleic acid molecules projects must be reported immediately to EHLS and the chairperson of the IBC. The IBC will then be responsible for investigating the incidents and reporting appropriate details to the NIH Office of Biotechnology Activities within 30 days.

4. Training of Laboratory Staff and Students:

Training of personnel and students is an extremely important safety factor in the laboratory. The institution is responsible for ensuring that the PI is adequately trained in conducting research safely. PIs are responsible for ensuring that laboratory personnel attend the required EHLS laboratory safety training, in addition to providing protocol specific training and closely supervising the laboratory personnel to ensure that procedures are being properly conducted. Personnel conducting research in Biological laboratories must attend the EHLS Biosafety course. If you need assistance or training materials for biological safety, please visit http://www.uh.edu/ehs/ or contact EHLS. Biosafety courses available through EHLS are described in section IV of this manual and http://www.uh.edu/ehs/. All training must be documented through training log books of course completion.

5. Illness prevention related to work with Recombinant or Synthetic Nucleic Acid Molecules

IBC requires that all students working at BSL-2 have appropriate medical insurance before they start working in the laboratory. Personnel and students must be familiar with signs and symptoms of illnesses caused by the agents and recombinant or synthetic nucleic acid molecules technologies used in the laboratory. If a person that develops an illness, that could be of laboratory origin, he/she must inform his/her supervisor and report to the UH Student Health Center (if a student), EHLS or the Risk Management Claims Coordinator (if an employee). If the student prefers to visit a private physician, he/she must advise the physician of a potential laboratory infection so that the UH Student Health Center can be contacted for consultation. The PI must inform the staff and students of reasons and provisions for precautionary medical practices (e.g. vaccinations, serum collection) advised or requested. Primary consideration must

be given to the protection of the health of personnel, students, and the public, the protection of animal populations, and the protection of the environment. Adopt emergency plans covering accidental spills and personnel contamination. Maintain copies of these plans for ready access in the event of an accident.

6. Restriction of access to the Recombinant or Synthetic Nucleic Acid Molecules:

To ensure the safety and security of the UH community, short-term students and visitors to the laboratory must not be exposed to potentially infectious biological material resulting from work with recombinant or synthetic nucleic acid molecules unless they are trained in safe procedures and familiarized with the safety plan of the laboratory. Non-essential visitors and children must not be allowed access to a laboratory where infectious biological agents and recombinant or synthetic nucleic acid molecules may be present. Persons working in the laboratory who are not affiliated with the University must be registered with EHLS by completing either the Visiting Researcher or Minors in Laboratories application prior to performing lab activities http://www.uh.edu/ehls/ .

**D. Requirements and procedures for the safe use of bloodborne pathogens: human cells, tissue, and body fluids**

1. Determine if you are working with a bloodborne pathogen - follow BSL-2 practices:

According to the current edition of the BMBL, "The potential laboratory hazards associated with human cells and tissue include the bloodborne pathogens HBV and HIV, as well as agents such as *Mycobacterium tuberculosis* that may be present in human lung tissue. Other primate cells and tissue also present risks to laboratory workers. Potential hazards to laboratory workers are presented by cells transformed with viral agents, such as SV-40, EBV, or HBV, as well as cells carrying viral genomic material. Tumorigenic human cells also are potential hazards as a result of self-inoculation."

The following current edition of the BMBL recommended practices are mandatory at UH for work with bloodborne pathogens:

- Human and other primate cells (commercial lines as well as patient isolates) must be handled using Biosafety Level 2 practices and containment.
- All procedures that can result in the production of aerosols must be performed in a certified biosafety cabinet.
- All material must be decontaminated by autoclaving or chemical disinfection before discarding.
- All personnel working with human cells and tissue must be enrolled and must work under the policies and guidelines established by the University's Exposure Control Plan (see Appendix B).
- All personnel and students working with bloodborne pathogens must complete the EHLS Bloodborne Pathogens Training annually. Personnel and staff who have completed the instructor led course, can take all subsequent annual refreshers online at http://www.uh.edu/ehls/training/eh13w/

2. Registration through the Memorandum of Understanding and Agreement (MUA) form:

All research involving human cell lines, body fluids, and unfixed human tissue, must be conducted at Biosafety Level 2. The use biological material that may cause potential bloodborne pathogens requires the submission of a completed typed MUA which is reviewed by the IBC and remains on file for reference. You can find the form in Appendix A. The MUA contains information regarding personnel, cell lines, tissue, body fluids, experimental protocols, and safety procedures. The IBC and EHLS will review containment levels required by the guidelines and will assess facilities, procedures, practices, personnel training, and personnel expertise, as appropriate.

3. Exposure Control Plan - Written Standard Operating Procedures and Safety Plan:

Universal Precautions and guidelines set by the Public Health Service & Centers for Disease Control and Prevention must be followed. In accordance with Texas Administrative Code; Health and Safety Code, Chapter 81, Subchapter H, and analogous to OSHA Bloodborne Pathogens Standard, the University of Houston has implemented an Exposure Control Plan (ECP) that must be followed by all personnel potentially exposed to bloodborne pathogens in the work place. It is a requirement that PIs read, instruct staff and students, and follow the ECP. You can find the University of Houston Exposure Control Plan on the EHLS website and in Appendix B of this manual.

Written laboratory safety procedures must also be prepared by the PI for each laboratory in which bloodborne pathogens are used for teaching or research purposes. The PI must ensure compliance by all staff and students. Prior to initiation of the research project, provide the laboratory staff copies of written safety protocols that describe potential hazards and precautions to be taken routinely and in the event of an accident. Ensure that a copy of the safety protocol is maintained in the laboratory. Significant safety problems with bloodborne pathogens must be reported immediately to EHLS.

4. Training of Laboratory Staff and Students:

All personnel and students working with bloodborne pathogens are required to complete the EHLS online bloodborne pathogens refresher training annually. The refresher training can be found online at http://www.uh.edu/ehls/training/. The training of personnel and students is an extremely important safety factor in the laboratory. Responsibility for training laboratory staff in project specific safety procedures may be carried out by the PI. The responsible faculty member will provide protocol specific training and then closely supervise the laboratory staff and students to ensure that procedures are being properly conducted. Additional biosafety courses available through EHLS are described in shipping and transport section IV of this manual. All training must be documented through training log books of course completion.

5. Illness prevention related to work with bloodborne pathogens:

Personnel and students must be familiar with signs and symptoms of illnesses caused by the agents present in human products used in the laboratory. The PI must follow the ECP for the University and ensure that all personnel who have been identified as having occupational exposure to blood or other potentially infectious materials are offered the hepatitis B vaccine, at

the expense of the employee's department. The personnel receive the vaccine at the University Health Center. If an employee declines vaccination she/he must sign a declination statement on the Hepatitis B vaccination form (available in the ECP Appendix B). An employee who initially declines the vaccine but who later elects to receive it may then have the vaccine provided to the employee at the expense of the employee's department.

When personnel incur an exposure incident, the employee must report to EHLS and the Risk Management Claims Coordinator (713-743-5865) for referral to a physician.

Students not employed by the University are not covered in the ECP. EHLS recommends PIs to inform the students in the laboratory that they are not covered by the ECP. The IBC requires that all students working at BSL-2 have appropriate medical coverage before they start working in the laboratory.

6. Restriction of access to the bloodborne pathogens:

For the safety and security of the UH community, short-term students and visitors to the laboratory must not be exposed to bloodborne pathogens unless they are trained in safe procedures and familiarized with the safety plan of the laboratory. Non-essential visitors and children must not be allowed access to a laboratory where bloodborne pathogens may be present. Biosafety Level 2 practices require that the PI set restriction standards for the laboratory. Persons working in the laboratory who are not affiliated with the University must be registered with EHLS by completing the Visiting Researcher application prior to performing lab activities http://www.uh.edu/ehls/.

**E. Projects Using Non Hazardous Animal Samples**

An Animal Sample Registration Form must be completed for all projects involving animal samples that are not registered by the IACUC or the IBC (cell lines, body fluids and tissues) that neither are infected nor involve the use of recombinant or synthetic nucleic acid molecules. To register your project with the EHLS-Biosafety office, please submit the Animal Sample Registration form in Appendix C of this manual.

**F. Projects Using Human Products**

A Human Products Registration Form must be completed for all projects that only utilize human products (no recombinant or synthetic nucleic acid molecules or other biological material). To register your project with the EHLS-Biosafety, please submit the Human Products Experiments form in Appendix D of this manual.

**G. Projects Using Experimental Animals**

1. Registration of projects using experimental animals and biohazards:

All projects involving the use of animals in conjunction with microbial agents, biological toxins, bloodborne pathogens, and/or recombinant or synthetic nucleic acid molecules must be registered with the Institutional Biosafety Committee (IBC), as well as the Institutional Animal Care and Use Committee (IACUC). To register with the IBC please submit the MUA form in Appendix A of this manual.

2. Written Standard Operating Procedures and Safety Plan:

Laboratory animals have been shown to carry agents infectious for humans and, therefore, laboratory safety plans must be developed for all projects that use animals. It is recommended to seek the assistance of Animal Care Operations and the Institutional Animal Care and Use Committee (IACUC). The following types of work must be addressed in the safety plan:

- Transplantation or injection of human tissue into animals.
- The use of nonhuman primates.
- The use of nonhuman primate tissue.
- The use of retroviruses and other infectious organisms from any species.
- The use of dangerous chemical such as carcinogens in the animal facility.

3. Training of Laboratory Staff and Students:

Training of personnel and students is an extremely important safety factor in the laboratory. Responsibility for training laboratory staff may be carried out through the PI. The responsible faculty member will provide protocol specific training and then closely supervise the laboratory staff and students to ensure that procedures are being properly conducted.

Personnel conducting animal research must:

- Take the appropriate institutional animal research training courses- species specific
- Receive additional training as needed to conduct animal manipulations
- Take the Bloodborne Pathogens course from EHLS if working with human products
- Take the Biosafety course conducted by EHLS
- Be aware of the occupational hazards associated with the animals and the research.
- Take proper precautions to minimize hazards in the laboratory and animal facility. Please consult with ACO for PPE regulations.
- Follow all safety precautions and occupational health programs required by Animal Care Operations.

4. Illness prevention related to work with animals and biohazard

The IBC requires that all personnel working at BSL-2 have appropriate medical insurance before working in the laboratory and animal facility. Personnel must be familiar with signs and symptoms of illnesses caused by the agents and animals. A person that develops an illness that could be of laboratory origin must inform his/her supervisor. All personnel working in the animal facility must be enrolled in the Animal Care Occupational Health Program. PIs must inform the personnel of reasons and provisions for precautionary medical practices (e.g. vaccinations, serum collection) advised or requested. Primary consideration must be given to the protection of the health of personnel, students, and the public, the protection of animal populations, and the protection of the environment.

5. Restriction of access to the laboratory and animal facility:

For the safety and security of the UH community, short-term students and visitors to the laboratory must not be exposed to experimental animals and biohazards unless they are trained in safe procedures and familiarized with the safety plan of the laboratory and animal facility. Non-essential visitors and children must not be allowed access to the animal facility or a laboratory where animals are present. Biosafety Level 2 practices require that the PI set restriction standards for the laboratory. Persons working in the laboratory who are not affiliated with the University must be registered with EHLS by completing either the Visiting Researcher or Minors in Laboratories application prior to performing lab activities http://www.uh.edu/ehls/ .

**H. Projects Using Select Agents and Toxins**

A Principal Investigator (PI) may not possess, use, receive (from outside the United States), or transfer (within the United States), any biological agent or toxin listed as a Select Agent by the Department of Human Health Services (DHHS) or the United States Department of Agriculture (USDA), until they have been approved to use the biological agent or toxin.

- A list of Select Agents can be accessed by visiting http://www.selectagents.gov/ . Please contact EHLS Biosafety for Select Agent and Toxins potential research.
- It is the responsibility of the Principal Investigator to identify his or her research involving one or more of the agents or toxins listed on the Select Agent Registry and notify the IBC.

**I. Projects Involving Agents and/or Toxins of Dual Use Research of Concern Projects Involving Agents and/or Toxins of Dual Use Research of Concern**

Dual Use Research of Concern (DURC) is life sciences research which, based on current understanding, can reasonably be anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC) outlines the criteria for what qualifies as Dual Use Research of Concern (DURC), listing specific agents and toxins and descriptions of types of experiments, which when combined, define the parameters for research considered as DURC and subject to oversight under the policy.

Currently, there are 15 non-attenuated agents and toxins listed under this policy and all are prohibited from use at the University of Houston:

- **Agents/Toxins-**

- Avian influenza virus (highly Pathogenic)
- Bacillus anthracis
- Botulinum neurotoxin
- Burkholderia mallei
- Burkholderia pseudomallei

- Ebola virus
- Foot-and-mouth disease virus
- Francisella tularensis
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of Clostridium botulinum
- Variola major virus
- Variola minor virus
- Yersinia pestis

➢ **Categories of experiments-**

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

➢ It is the responsibility of the Principal Investigator to identify his or her research involving one or more of the agents or toxins listed in IODURC Section 6.2.1 and notify the IBC.

## J. National Biosafety Stewardship

In 2014, the NIH and other Department of Health and Human Services agencies announced National Biosafety Stewardship month as a new initiative to promote stewardship of the life sciences and biosafety awareness. National Biosafety Stewardship Month is a period during which institutions are encouraged to reinforce their attention to biosafety policies, practices and procedures. **Please note National Biosafety Stewardship month will occur annually during the month of October.** All laboratories are expected to review their biological agents' inventory and ensure that appropriate biosafety policies, practices and procedures are in place.
http://www.nih.gov/research-training/national-biosafety-stewardship-month

## K. Transportation and Shipping of Infectious Substances and Exempt Specimens

- Any movement or transport of biological hazards within laboratories or buildings must be performed in such a manner as to prevent any spills and/or leakage.
- Use primary containers with closed lids, closed plastic secondary containers, and carts to prevent spills and accidents when transporting biohazards in the laboratory.

- Materials must be transported in containers that can be sealed. If the outside of the primary container is contaminated, a secondary container must be used. If the transported material could puncture the primary container, a secondary, puncture-resistant container must be used.
- Any contaminated equipment must be contained or decontaminated prior to movement maintenance, and/or repair.
- Laboratory personnel must be trained and certified on transportation regulations prior to transporting any infectious substance or diagnostic specimen. Please contact EHLS/Biological Safety to schedule training and/or for assistance with transporting.

.

- Infectious Substances are substances which are known to contain or reasonably expected to contain pathogens. For shipping purposes, Infectious Substances are divided in to two categories.
  - Category A Infectious Substances- infectious substances in a form that, when exposure occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. They are assigned the following UN numbers and proper shipping names:
    - UN2814 – Infectious Substance, affecting humans
    - UN2900 – Infectious Substance, affecting animals
  - Category B Infectious Substances- infectious substances that do not meet criteria for inclusion in Category A. They are assigned the proper shipping name:
    - UN3373 – Biological Substance, Category B
- Infectious Substances to be shipped must have triple layer packaging
  - Primary container- must be leak proof (test tube)
  - Secondary container- must contain absorbent material capable of absorbing full and contain a lid/be sealed volume of liquid contents
  - Rigid outer packaging- must have proper labeling

### L. Principal Investigator Check-Out Procedure

In the event a PI moves laboratories or leaves the University of Houston, and check out must be completed by an EHLS representative. Contact EHLS biosafety to schedule a laboratory check out at least two weeks prior to move. Please refer to Principal Investigator Checkout Procedure in Appendix E.

## III. BIOLOGICAL SAFETY GUIDELINES AND PROCEDURES

### A. General Information

#### *1. Risk Assessment:*

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

Molecular Biology and Microbiology laboratories are often unique work environments that may pose identifiable infectious disease risks to persons in or near them. Infections have been contracted in the laboratory throughout the history of research. To prevent infection, PIs must make an initial risk assessment based on the Risk Group (RG), followed by a thorough consideration of the agent itself and how it is to be manipulated.

Factors to be considered in determining the level of containment include agent factors such as:

- virulence
- pathogenicity
- infectious dose
- environmental stability
- potential routes of exposure
- communicability
- laboratory procedures
- quantity
- availability of vaccine or treatment
- gene product toxicity
- physiological activity
- allergenicity

Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain. The containment level required may be equivalent to the Risk Group classification of the agent or it may be raised or lowered as a result of the above considerations.

The Institutional Biosafety Committee must approve the risk assessment and the biosafety containment level designated by the PI in the MUA.

***2. Infectious Agent Risk Group Classification:***

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

- RG1: Agents not associated with disease in healthy adult humans.
- RG2: Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
- RG3: Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).
- RG4: Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Appendix B) contains a comprehensive list of agents classified by Risk Group. For additional information, consult the BMBL and the American Biological Safety Association (ABSA) website. For a list of organisms and their Risk Group, please visit http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

***3. Summary of Biological Safety Levels of Practices and Containment:***

There are four Biosafety Levels that consist of combinations of laboratory safety practices and techniques, safety equipment and laboratory facilities. Each combination is specifically appropriate for the operations performed, for the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity. The recommended Biosafety Level for an organism represents the conditions under which the agent can be ordinarily handled safely. Please consult this link for recommended biosafety levels: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

***4. Summary of the NIH Guidelines for the Use of Recombinant or Synthetic Nucleic Acid Molecules technology***

This summary only serves as a guide to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines . It is the responsibility of each Principal Investigator (PI) to make sure that his/her laboratory is in compliance. At UH all recombinant or synthetic research requires registration, check the Guidelines for the appropriate biosafety level and relevant section. All PIs with human pathogenic material or potentially pathogenic material (human tissue and blood products) must also register with the Institutional Biosafety Committee.

Please consult this link for guidelines for research involving recombinant or synthetic nucleic acid molecules research: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

***5. Bloodborne Pathogens (BBP)***

The State of Texas requires institutions to have written procedures that protect the rights of workers in the event of an exposure to hazardous body fluids. Hazardous body fluids include blood, and other potentially infectious materials, (OPIM) such as human and nonhuman primate organs, tissue, cell cultures, etc., which are known or assumed to be associated with the transmission of bloodborne pathogens. Please consult the University's Exposure Control Plan (Appendix B) for specific information regarding prevention and exposure control procedures.

Direct contact with someone's blood or OPIM carrying a bloodborne pathogen is not necessary for an exposure. Staff or students who perform tasks such as handling clinical specimens,

biohazardous trash, blood or body fluid soaked laundry, or needles or other sharps should be aware and careful of exposure to bloodborne pathogens.

a. Potential Hazards:

In the Laboratory, the potential hazards associated with human blood, cells, and tissue include the following bloodborne pathogens:

- Hepatitis B virus (HBV): This virus causes Hepatitis B and has been found in all body secretions and excretions, with blood and semen being the most infectious. HBV infections are a major cause of liver damage, cirrhosis, and liver cancer. Routine vaccinations have declined the number of HBV infections significantly. HBV can cause acute or chronic infections depending on the body's response to the virus. Those who develop chronic HBV infections do not develop antibodies and carry the virus with the potential to infect other for decades. The HBV vaccine is the best protection against this disease.
- Hepatitis C virus (HCV): This virus causes Hepatitis C and is found in blood. HCV does not always cause serious health problems. Many carriers may present liver damage with no symptoms. In others, cirrhosis of the liver may develop, resulting in eventual liver failure. In the laboratory, the primary risk of HCV infection is via direct contact with infectious blood through an accidental needle-stick or injury with other sharps. Currently there is no vaccine available for HCV however there is a cure approved by the Food and Drug Administration (FDA). Therefore, preventive measures are very important.
- Human immunodeficiency virus (HIV): This virus causes acquired immunodeficiency syndrome (AIDS) and is found in blood and OPIM. Often HIV infected persons are asymptomatic. AIDS damages cells that are essential for immune functions, causing susceptibility to opportunistic infections that might become fatal. No vaccine is currently available for HIV, and there is no cure for AIDS. Therefore, preventive measures are very important.

Primate cells and tissue also present other risks to laboratory workers, some examples are:

- *Mycobacterium tuberculosis* that may be present in human lung tissue.
- Cells transformed with viral agents, such as SV-40, EBV, or HBV.
- Cells carrying viral genomic material.
- Tumorigenic human cells as a result of self-inoculation.

b. Risks of Infection:

The risk of infection following an exposure to blood or other potentially infectious material (OPIM) depends on many factors, including these:

- Whether the pathogens are present in the source blood or OPIM
- The number of pathogens present
- The type of injury or exposure (how the infectious material gets into the body)
- The current health and immunization status of the exposed person

This means that even if the source blood or OPIM do contain pathogens, you are not necessarily infected. To be safe, however, always assume an exposure is potentially infectious and follow all recommended measures to prevent exposures from occurring, such as working in a certified biosafety cabinet.

c. Prevention of BBP Infections:

Occupational exposure to BBP can be reduced by following the University's Exposure Control Plan and using the following four strategies:

- Engineering controls: devices that isolate or remove the BBP hazard from the workplace. These devices include needleless systems, eye wash stations, handwashing facilities, biohazard labels, and biosafety cabinets.
- Work practice controls: controls to reduce the likelihood of exposure by altering the manner in which a task is performed. Depending upon the environment, the controls might include the use of personal protective equipment (PPE), hand washing, decontaminating and sterilizing equipment and areas, safely handling sharps, correctly disposing of wastes, safely handling laundry, and good personal hygiene habits.
- Personal protective equipment: consists of barriers such as gloves, scrubs, aprons, gowns, eye shields or goggles, face masks or shield, caps and booties that can be worn to prevent exposure to blood and OPIM.
- Universal precautions: safety guidelines in which all blood and OPIM are handled as if they are contaminated. Under universal precautions, you treat all materials as if they are infected with bloodborne pathogens. Following universal precautions means using PPE and following all the safe work practice controls described in this manual.

## B. Laboratory practices and containment

### *1. Laboratory Safety Procedures*

Principal Investigators must maintain written laboratory safety procedures for each research and teaching laboratory where personnel and students may be exposed to biological hazards such as infectious microorganisms, recombinant or synthetic nucleic acid molecules, human tissue and body fluids, and experimental animals. In addition, all personnel and students working in a research or teaching laboratory with potential exposure to biological hazards must be appropriately trained in Biosafety and laboratory techniques and records of the training must be available.

The following list of safety procedures can serve as a guide to develop and implement a safety plan. Please use the BMBL, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the Texas Administrative Code regulations governing exposures to bloodborne pathogens as reference for your specific plan.

a. Set requirements for access to the laboratory

- Only persons who have been advised of potential hazards and who meet specific entry requirements (e.g., training, occupational medical clearance, immunization) must be allowed to enter the laboratory working area.
- Minors under the age of 18 are not permitted in laboratory work areas unless registered and approved by EHLS.

- Laboratory doors must be kept closed when work is in progress.
- Access to laboratories where animals are present must be restricted to authorized personnel.
- Animals not involved in the work being performed shall not be in the laboratory.

b. Set standards for appropriate behavior in the laboratory

- Eating, drinking, smoking, storing food, applying cosmetics, and handling contact lenses is not permitted in the laboratory or animal work area.
- Personnel must not use work surfaces as seats.
- Personnel with wounds that are weeping or purulent (pus-exuding) must not work in the laboratory or animal care areas whenever infectious agents might be present.
- Personnel are required to keep their hair at an appropriate length, covered, or tied in such a manner so that it does not become contaminated.
- Personnel must wash their hands after all procedures involving animals and potentially contaminated materials. Personnel are encouraged to shower and change clothes after working with animals.

c. Set standards for minimizing contamination with biohazardous materials when procedures are in progress.

- Determine the level of personal protective equipment for your specific procedures. All laboratory personnel/students working with potentially infectious materials are required to wear personal protective equipment (ex. lab coat, long pants/skirt, close-toed shoes, protective eyewear, respiratory protection and gloves)
- All technical procedures must be performed in a manner that minimizes the creation of aerosols.
- Biosafety cabinets must be certified annually and must be used when working with bloodborne pathogens, and when performing procedures with Risk Group 2 agents that might create aerosols.
- Specimens containing infectious materials to be centrifuged must be covered. A safety centrifuge cabinet or a safety centrifuge cup must be considered for infectious materials.
- Mouth pipetting is not permitted for any materials or reagents. Mechanical pipetting devices will be utilized.

d. Enforce procedures to minimize the risk of sharps injuries.

- Standard procedures for needle stick and other injuries, animal bites/scratches, and occupational illness must be incorporated into individual procedures, as needed.
- Hypodermic needles and syringes must be used only for parenteral injection and aspiration of fluids from patients, laboratory animals, and bottles sealed with a diaphragm.
- Hypodermic needles and syringes must not be used as a substitute for automatic pipetting devices in the manipulation of potentially infectious fluids.

- Needles used in collection of potentially infectious material must not be recapped after use.
- All syringes, needles, and other sharps must be placed into red plastic puncture resistant containers labeled as containing "sharps" and "infectious material."

e. Set procedures for routine decontamination, accidental spill cleanup, disposal of contaminated materials, and emergencies.

- All liquid or solid materials containing potentially infectious material must be decontaminated before disposal.
- Work surfaces, which may have contact with potentially infectious material, must be decontaminated with a disinfectant at the beginning and end of the day and after any spill of potentially dangerous material. Soak up the disinfectant and contaminated material with an absorbent material (such as paper towels) and dispose of these materials in a double plastic bag or sealed container. Gloves must be worn for cleanup.
- All spills and other accidents, with overt or potential exposure to infectious materials, must be reported immediately to the laboratory supervisor and EHLS/Biological Safety Manager.
- A written record of such incidents must be maintained in the laboratory or department.

### *1. Warning Signs and Postings*


- The universally accepted biological hazard-warning symbol must be used throughout the institution to notify workers about the presence of infectious agents. The warning symbol must be removed when the hazardous agent is no longer in use or present.
- The location of the posting is determined by the access to the area where biological hazards are used.
- Doors to any laboratory containing a designated infectious agent must be posted.
- Postings must be displayed in other areas such as biosafety cabinets, freezers, or other specially designated work and storage areas or equipment where biological hazards are used.
- All individual containers of biological hazards must be labeled to identify the content and any special precautionary measures that must be taken.
- Universal biohazard labels must be affixed to containers of regulated waste, and refrigerators and freezers containing blood or other infectious materials.
- Labels must be affixed to other containers used to store, transport, or ship blood or other potentially infectious materials.
- Acceptable color-coded (red or orange) bags or containers may be substituted for labeling requirement.

### *3. Safety Equipment*

Safety equipment includes biosafety cabinets, enclosed containers and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The biosafety cabinet (BSC) is the principal engineering control used to provide containment of infectious splashes or aerosols generated by many microbiological procedures.

Safety equipment also may include items for personal protection such as personal protective clothing, respirators, face shields, safety glasses or goggles. Personal Protective Equipment (PPE) is often used in combination with other safety equipment when working with biohazardous agents. In some situations, personal protective clothing may form the primary barrier between personnel and the biohazardous agents.

a. Biosafety Cabinets

Biosafety cabinets are used to provide primary containment in the laboratory when using potentially infectious materials and can be used for manipulation of sterile cultures. BSCs must be used in Biosafety Level 2 laboratories if aerosol-generating procedures are conducted, a high concentration of infectious agents are used or if large volumes of infectious agents are used.

BSCs must be tested and certified annually or after installation, relocations, alterations or maintenance. Testing and certification of BSCs will be performed by an outside contractor. Tests are conducted in accordance with the most recent edition of NSF's International Standard No. 49, Class II (Laminar Flow) Biohazard Cabinetry. If the BSC location changes within nine months of certification, it may not be used until recertified and payment for recertification will be the responsibility of the PI or department.

Biosafety cabinets must be decontaminated before the following can take place:

- Any maintenance work requiring disassembly of the air plenum, including filter replacement
- Cabinet recertification
- Movement of the cabinet to a new laboratory
- Discarding or salvaging

Biosafety cabinet certification must be performed when the following takes place:

- After they are received and installed (before use with infectious materials);
- After filter changes;
- After being moved (even a few feet); and
- Annually

There are three types of BSCs as defined by CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories. Types of biosafety cabinets

- The Class I BSC provides personnel and environmental protection but no product protection. It is similar in function to a chemical fume hood but has a HEPA filter in the exhaust system to protect the environment. The Class I BSC is not commonly used on campus.

- Class II BSC (Types A, B1, B2 and B3) are designed for work involving microorganisms assigned to Biosafety Levels 1, 2 and 3. These cabinets provide the microbe-free work environment necessary for cell culture propagation and may be used for nonvolatile chemotherapeutic drug preparation.
- The Class III BSC is designed for work with Biosafety Level 4 microbiological agents and provides maximum protection to the operator and the environment.

Horizontal and vertical laminar-flow clean-air benches <u>are not</u> BSCs. They discharge HEPA-filtered air across the work surface and toward the user. These devices provide only product protection.

For specific instructions on how to properly operate your biosafety cabinet please contact the manufacturer or a contracted certifier.

b. <u>Personal Protective Equipment</u>

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

- Gloves must be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin and when handling or touching contaminated items or surfaces. In some instances double gloves are required Disposable single use gloves shall be replaced as soon as possible when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised. Hands must be washed each time gloves are removed. Disposable gloves shall never be washed or disinfected for reuse. Utility gloves may be disinfected for reuse if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibiting any sign of deterioration.
- Safety goggles must be worn when it can be reasonably anticipated that the employee may perform tasks that could generate splashes or spatters and containment equipment is not required. Safety glasses must be worn when the anticipation of splashes and spatters have been eliminated by the use of containment equipment or tasks performed will not generate splashes or spatters.
- Masks and eye protection shall be worn whenever splashes, spray, droplets, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or mouth contamination.
- Laboratory coats, gowns, aprons, clinic jackets, or similar outer garment must be worn in situations where there is a potential for exposure to infectious agents.
- All PPE shall be removed immediately upon leaving the work area or as soon as possible if overtly contaminated and placed in an appropriately designated area for decontamination or disposal.

- The PI is responsible for arranging and enforcing laundering and disposal procedures for PPE. When PPE is removed, it must be placed in an appropriately designated area or container for storage, washing, decontamination, or disposal.

### *4. Facility Design*

The design of a facility is important in providing a barrier to protect people working inside and outside the laboratory and to protect people or animals in the community from infectious agents that may be accidentally released in the laboratory. Facilities must be commensurate with the laboratory's function and the recommended Biosafety Level for the agent being manipulated.

The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in BSL-1 and BSL-2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments. Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave), and hand washing facilities.

As the risk for aerosol transmission increases, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features could include specialized ventilation systems to assure directional airflow, air treatment systems to decontaminate or remove agents from exhaust air, controlled access zones, airlocks at laboratory entrances, or separate buildings or modules for isolation of the laboratory.

## C. Waste management

The following concepts and procedures can help to handle the biological waste generated by laboratories in a safe and efficient way. Methods of how to process biological waste on-site are particularly useful to minimize waste pickups and to handle small quantities of biological waste generated during research.

### *1. Maintenance*

- Areas where designated infectious agents are used should be cleaned on a regular basis by trained laboratory personnel with an appropriate disinfectant.
- Personal protective equipment such as gloves must be worn throughout the entire procedure.
- All equipment and working surfaces should be cleaned and decontaminated upon completion of procedures, spills, or after contact with blood or other potentially infectious materials.
- Decontamination must be performed using an appropriate disinfectant for the agent in use.
- If an area becomes contaminated with blood or biohazardous fluids, the fluid shall be absorbed with disposable absorbent material and placed in a biohazard container or bag.
- Protective coverings, such as absorbent paper, are to be removed and replaced when overtly contaminated or at completion of procedures.

- All receptacles intended for reuse, such as bins, pails, or cans that may be contaminated should be inspected and decontaminated on a regular basis.
- Broken glassware should be cleaned up using mechanical means, such as brush, broom, dust pans, tongs, forceps, etc and placed in a sharps container for later pickup.
- Equipment that may become contaminated with blood or other potentially infectious materials shall be checked routinely and prior to servicing or shipping and shall be decontaminated as necessary.

***2. Sterilization and Disinfection***

a. Sterilization

- Sterilization is a method or process to remove all viable microorganisms from an object or material.
- The process must consistently produce objects that are negative to chemical and biological indicators of contamination.
- Achieving sterility of the finished product depends on the number and type of organisms present, the temperature, and the length of contact time.
- Steam sterilization (autoclaving) will kill most microorganisms when steam under pressure is applied at $121^{\circ}$C for a minimum of 45 minutes.
- Sterilization will not be complete if steam does not reach all surfaces of the object, for example on items that have a high soil load and densely packed materials.
- Spore strips (*B. stearothermophilus*) can be placed at the center of the autoclave pack as a biological indicator of sterility.
- Autoclave tape is not an indicator of sterility; it simply indicates that the proper temperature has been achieved on the surface.
- Please follow the manufactures recommendation and make sure all items are autoclave able

b. Disinfection

- Disinfection must be utilized where sterilization is not practical, for instance, on tables, cabinets, and some equipment.
- Disinfection is the use of antimicrobial chemicals on inanimate objects with the purpose of destroying all non-spore forming organisms of pathogenic nature or which would compromise the integrity of the experiment.
- Disinfection does not mean the destruction of all organisms.
- Disinfectants destroy microorganisms by coagulating or denaturing proteins, injuring the cell membrane, and stopping normal enzymatic reactions.
- The range of susceptibility of microorganisms to disinfectants is relatively broad.

- The vegetative bacteria, fungi, and lipid containing viruses are highly susceptible to disinfecting agents.
- Non-lipid containing viruses are moderately resistant to these disinfecting agents.
- Spore forms are the most resistant to disinfectants.
- Use only disinfectants approved for use with a particular organism.
- There are many chemical disinfectants on the market, with the main constituent being one of the following: chlorine, quaternary ammonium compounds, alcohol, formaldehyde, iodine, phenolics, or glutaraldehyde. For a descriptive list of chemical disinfectants please see visit http://www.epa.gov/oppad001/chemregindex.htm

***3. Biological waste disposal***

a. Description of Biological Waste

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

- Microbiological waste such as discarded cultures and stocks of infectious agents and associated biological materials, discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial and industrial laboratories, discarded live and attenuated vaccines, discarded used disposable culture dishes, discarded used disposable devices used to transfer, inoculate, or mix cultures.
- Sharps, defined as contaminated scalpel blades, razor blades, suture needles, disposable razors, disposable scissors, intravenous stylets and rigid intruders, glass Pasteur pipettes, specimen tubes; blood culture bottles, microscope slides, broken glass from laboratories.
- Bulk blood, bulk human blood products, and bulk human body fluids.
- Pathological waste such as body parts, tissue, recognizable human tissue, organs, bulk blood and body fluids.
- Animal Waste.

These types of waste should always be handled in accordance with practices that minimize exposure to waste handlers and to ensure that the waste will ultimately receive the proper treatment. This can be accomplished by adhering to the following general guidelines:

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

- Environmental Health and Life Safety (EHLS) operates the biological waste program for campus. Please refer to the EHLS Hazard Waste Procedures: http://www.uh.edu/ehls/waste/procedures/
- Biological waste pickups are scheduled through the online form found on the http://www.uh.edu/ehls/waste/ Solid biological waste must be placed leak proof receptacles containing a lid and labeled with the biohazard symbol. The receptacle must be lined with orange or red bags with the biohazard symbol.
- Liquid waste must be collected in an appropriate container that is leak proof, and disinfected and allowed to stand for at least 15 minutes prior to disposal with 10% bleach solution/ dilution.
- All sharp must be placed in an approved puncture resistant "sharps" container. This container must have securely capped ends or a closable top or lid.
- Animal carcasses containing known biohazardous agents stored in the ACO freezer. Contact Animal Care Operations for further information.
- Please contact EHLS for ways to reduce waste and local disposal of small quantities of biological waste.

b. On-Site Waste Treatment and Disposal

Infectious waste is treated so as to render it noninfectious. Treatment techniques approved by the Texas Department of State Health Services are:

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

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

- Steam Sterilization (Autoclave): Steam sterilization utilizes pressurized steam at 250 to 270 °F (121 to 132 °C) to kill pathogenic organisms that are present in the infectious waste. Steam sterilization process does not destroy the waste. Instead, it renders it non-infectious. **Properly sterilized waste can be disposed of in the regular trash after placing the autoclaved bag containing the waste in a regular black household garbage bag.**

  Standard operating procedures must include the following criteria:

  - The proper bags must be utilized.
  - The temperature of the autoclave must be at least 121°C (250°F).

- The pressure must be at least 15 psi.
- Waste must be treated for a minimum of 45 minutes.
- A sterilization indicator strip that changes color when operating parameters are achieved should be run with every cycle.
- Routine biological monitoring using the appropriate Bacillus species should be conducted.
- Biological indicators can be in the form of either an ampule or strip containing the spore *Bacillus stearothermophilus*.
- All autoclaves should be tested at least once a month.
- For those autoclaves in which a continuous readout of operating procedures is available, routine parameter monitoring can be substituted for biological monitoring.
- Once the waste has been treated, it should be double bagged in 2 mL thick black liners and placed in designated garbage containers.
- Treated waste can then be disposed of into a municipal solid waste landfill.

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

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

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

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

c. Off-Site Waste Treatment and Disposal

For those departments that do not have the proper equipment to effectively treat waste, an off-site treatment option is available. Please fill out the on-line form for biological waste pick up at http://www.uh.edu/ehls/about/.

- EHLS collects the waste and a commercial firm is in charge of incineration or land disposal.
- Infectious waste should be handled as little as possible.
- The waste must incur additional handling and therefore special care should be taken when packaging it for pickup.
- Waste must be placed in biohazard bags and containers.
- If the storage of infectious material is necessary, it should be stored in a rigid, leak-proof container and bear the universal biohazard symbol.
- Infectious waste may be stored at room temperature until the storage container is full, but no longer than 30 days from the date of generation.
- Frozen waste may be kept up to 90 days from the date of generation.
- If infectious waste becomes putrescence during storage, it should be pre-treated within 24 hours.
- Storage of waste should be in a manner that affords protection from theft, vandalism, human or animal exposure, rain, water, and wind.
- Infectious waste should be stored separate from chemical and radioactive waste.
- Transporting biohazard waste through the hallways or between buildings should be conducted with the use of secondary containment to prevent spills or exposure to other personnel.

***4. Biological Spill Clean-Up Procedures***

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

a. For hazardous biological spills inside the biosafety cabinet:

- Wear laboratory coat, eye protection and gloves during clean-up.
- Allow cabinet to run during clean-up.
- Apply disinfectant and allow a minimum of 15-20 minutes contact time A list of recommended disinfectants can be viewed at http://www.epa.gov/oppad001/chemregindex.htm .
- Wipe up spillage with disposable disinfectant-soaked cloth or tissue.
- Wipe the walls, work surface and any equipment in the cabinet with a disinfectant-soaked cloth.
- Discard contaminated disposable materials in appropriate biohazard waste container(s) and autoclave before discarding as waste.
- Place contaminated reusable items in biohazard bags or in autoclave pans with lids before autoclaving and cleanup.
- Expose non-autoclavable materials to disinfectant and allow 20 minutes contact time before removing from the biosafety cabinet.
- Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving; if disposable, treat as biohazardous waste.

- Run cabinet 15 minutes after cleanup before resuming work

b. For hazardous biological spills in the laboratory, outside the biosafety cabinet:

- Clear area of all personnel. Wait approximately 30 minutes for the aerosols to settle before entering spill area.
- Remove any contaminated clothing and place in biohazard bag to be autoclaved; if disposable, treat as biohazardous waste
- Wear a disposable gown, shoe covers, eye protection, N95 respirator (if needed) and gloves.
- Initiate cleanup with disinfectant as follows:
  - Soak paper towels in disinfectant and place over spill.
  - Encircle the spill with additional disinfectant being careful to minimize aerosols during pouring while assuring adequate contact. Start from the periphery and work toward the center.
  - Decontaminate all items within the spill the area.
  - Allow 20 minutes contact time to ensure germicidal action of disinfectant before passing items to clean area.
  - Wipe equipment with 1:10 bleach, followed by water, then 70% ethanol or isopropanol.
  - Place disposable contaminated spill materials in appropriate biohazardous waste container(s) for autoclaving.
  - Place contaminated reusable items in biohazard bags in autoclave pans with lids or wrap in newspaper before autoclaving and cleanup.

c. For hazardous biological spills inside the centrifuge:

- Clear the immediate area of all personnel. Wait 30 minutes for aerosol to settle before attempting to clean up spill. Keep centrifuge closed.
- Wear a laboratory coat, eye protection, N95 respirator and gloves during cleanup.
- Remove rotors and buckets to nearest biosafety cabinet for clean-up.
- Thoroughly disinfect inside of centrifuge.
- After thorough disinfection of rotor or rotor cups, remove contaminated debris and place in appropriate biohazardous waste container(s) and autoclave before disposing as infectious waste.

d. For hazardous biological spills outside laboratory, during transport:

- Transport biohazardous materials in an unbreakable sealed primary container, placed inside a second unbreakable lidded container. Label the outer container with the biohazard symbol.

- Should a spill occur in a public area, do not attempt to clean it up without appropriate personal protective equipment. Call the P.I. and EHLS for assistance at 713-743-5858.
- As an interim measure, wear gloves and place paper towels, preferably soaked in disinfectant, directly on spilled materials to prevent spread of contamination. To assure adequate contact, surround the spill with disinfectant, if available, taking care to minimize aerosols.

If you are not sure about the proper procedures or need assistance, call EHLS. After business hours call UH Department of Public Safety at 713-743-3333

**D. Emergency Procedures**

All biohazard laboratories must establish written emergency procedures based on the biohazardous agents used as well as other hazards that may be present. Emergency procedures must take into consideration the use of radioactive materials and chemicals. These procedures may be outlined in your approved MUA.

The following items should be noted for the type of biohazardous agent used in the laboratory in the event of an accident, exposure, and/or spill:

- Attend to any injured personnel.
- Call DPS at 713-743-3333 for emergency assistance, and inform responders of biohazards that may be a threat.
- For spills in BSL-2 laboratories, evacuate the room close the doors.
- After evacuating the area, wait to assist emergency responders.
- Notify EHLS about a spill or exposure to a biohazardous agent outside of containment.
- Report exposures and injuries to Risk Management Claims Coordinator within 24 hours.
- Report the accident to the Biosafety Office for a review of laboratory protocols and procedures.

**IV.Training and Resources**

**A. Training**

Instruction concerning individual laboratory procedures and the development of a laboratory safety plan are the responsibility of the PI.

Training regarding basic and refresher training for laboratory safety is provided by EHLS. Several EHLS courses are offered during the calendar year. Visit for more information on training. http://www.uh.edu/ehls/training/

Courses:

- Biological Safety with Bloodborne Pathogens Training: This course is mandatory for all personnel and students working in Biosafety laboratories. The content of the course provides an understanding of the principles of biological safety up to BSL-2 and the training required for working with Bloodborne Pathogens. This course is recommended for all PIs and their staff that have a Memorandum of Understanding and Agreement for working with biohazards and/or recombinant or synthetic nucleic acid molecules. Refresher training may be required at the end of the 5-year MUA approval cycle.

- Bloodborne Pathogens: This is a one hour course mandatory for all personnel who have exposures to blood or any other bodily fluids over the course of their job duties. The content of the course fulfills all the training requirements established by the Texas Administrative Code regarding work with Bloodborne Pathogens.
- Bloodborne Pathogens Refresher Training: This course must be completed every year by all personnel who handle bloodborne pathogens or may have occupational exposures to bodily fluids. The training can be viewed online by accessing http://www.uh.edu/ehls/training/. The content of the course fulfills all the training requirements established by the Texas Administrative Code regarding work with Bloodborne Pathogens.

**B. Online Biosafety Resources**

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules
- Biosafety in Microbiological and Biomedical Laboratories, 5th ed. (BMBL - CDC)
- Biosafety (Collection from CDC)
- Laboratory Biosafety Guidelines (LCDC Canada)
- Biosafety-Related MSDS (LCDC Canada)
- American Biological Safety Association (ABSA) Biosafety Links
- Importation Permits for Etiologic Agents (CDC)
- National Select Agent Registry (CDC/APHIS)
- Packaging, Labeling Shipping of Biological Substances (IATA)
- Risk Group Classification for Infectious Agents (ABSA)
- Selection, Installation and Use of Biosafety Cabinets (CDC)
- 7 CFR 340.0 Introduction of Genetically Engineered Organisms (APHIS)
- CDC's Bioterrorism and Response Page
- Association for Professionals in Infection Control and Epidemiology, Inc.
- Texas Department of State Health Services (DSHS) – Bloodborne Pathogens
- Dual Use Research of Concern

# APPENDIX A

Memorandum of Understanding and Agreement Form

UNIVERSITY of HOUSTON
DEPARTMENT of PUBLIC SAFETY
Environmental Health & Life Safety

# Memorandum of Understanding and Agreement
# Registration of Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules Experiments

For purposes of this registration, biohazardous materials are defined as any organism known to or suspected of causing infection in humans, and a toxin is a proteinaceous poison which is highly toxic to humans. Experiments using biohazardous materials and toxins must follow the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidelines (5th Edition-2009).Experiments using recombinant DNA technology must follow the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, (April 2016).

| **SECTION A** Principal Investigator and Personnel Information (please type) | | |
|---|---|---|
| ***PI Name*:** | ***Title*:** | ***PeopleSoft ID No*:** |
| ***Office Phone No*:** | ***Lab Phone* No:** | ***Department:*** |
| ***Building and Lab Room No(s)- Location where research/activities will be conducted*:** | **E-mail:** | |
| **Please list all laboratory personnel (including students or volunteers). Laboratory personnel working at BSL-2 are required to have medical insurance if they are not paid by the University payroll. Please provide name, title and insurance carrier for non-university laboratory personnel. Please provide name, title and PeopleSoft Identification numbers for all personnel.**<br>**PEOPLESOFT # NAME TITLE INSURANCE CARRIER** | | |
| | | |
| Please send MUA to: Biological Safety Manager, Environmental Health and Life Safety, Mail Code 1005; ehs@uh.edu; (713) 743-5858. | | |

**The Principal Investigator (PI) is responsible for: (please initial each statement)**

___ Notifying the Biosafety Office when work with any potentially infectious material is terminated or

when other significant changes occur, such as changes in protocol, personnel or relocation of the laboratory.

____Reporting any adverse events, such as exposures or injuries, immediately to the Biosafety Office.

____ Informing all laboratory personnel of the potential hazards associated with this work, the appropriate safety practices to be used, the availability of medical programs, and applicable trainingrequirements.

____ Verifying medical insurance if BSL2 work is conducted in the laboratory.

____ Ensuring that all laboratory personnel handling human samples (including cell/tissue culture) have acompleted Hepatitis B Vaccination form on file with the Biosafety Office.

**SECTION B** Brief description of the research understandable to scientist working in different fields

☐ **New Protocol** ☐ **Renewal Protocol** ☐ **Amendment Protocol**

**Title of the protocol:** _____

***Granting agency and I.D. number:*** _____

**This project will use:** ☐ **Biohazardous Material** ☐ **Biological Toxins** ☐ **Recombinant/Synthetic Nucleic Acid Molecules**

**Biosafety Level** _____

B.1. General description of research (Please give a lay summary):

B.2. Please describe experimental design:

Describe the hypothesis-

Describe the general summary of experimental protocol-

Describe where safety exposure risks could occur-

Explain the manipulation of experimental/biological material in this protocol as relevant to safety (consider toxins and/ or biological agents-

B.3. Type of manipulations of samples:

☐ Centrifugation ☐ Dissection ☐ Filtration ☐ Mixing ☐ Pipetting ☐ Precipitation ☐ Sonication
☐ Other _____

**Section C** Use of recombinant or synthetic nucleic acid molecules technology (including siRNA) ☐ **Not Applicable**

Will studies include attempts to obtain expression of genes or gene products, other than those used for selection purposes (ex. Ampicillin resistance)?

☐ No ☐ Yes what protein _____

| Prokaryotic Hosts/ Eukaryotic Cells<br>List Strains | Vector | DNA Insert | Relevant section of NIH Guidelines | Biosafety Containment Level |
|---|---|---|---|---|
| | | | | |

| | | | | |
|---|---|---|---|---|
| | | | | |
| If viral vector is to be used, will infectious virus be generated? ☐ No ☐ Yes | | | | |

| **Section D** Non-pathogens, pathogens and/or toxins (please provide information for each microorganism and or toxin used, use additional space if needed) **☐ Not Applicable** | | | |
|---|---|---|---|
| Pathogenic Organism: | Strain: | Volume used: | Risk Group: |
| Non-pathogenic Organism: | Strain: | Volume used: | Risk Group: |
| Biological Toxins: | | Volume used: | Risk group: |

| **Section E** Use of Animals | | |
|---|---|---|
| Are animals used in ***this*** project? ☐ No ☐ Yes<br>If yes, please provide IACUC Approval number and date _____ | | |
| List all animals used in the project | Organism, toxin, or rDNA introduced | Routes of administration |
| | | |
| Types of animal tissue handled and/or animal cell lines: | | |

| **Section F** Handling of Human Products (requires BSL-2 practices) |
|---|
| Are Human derived samples used in ***this*** project? ☐ No ☐ Yes<br>If yes, please provide IRB Approval number and date _____ |
| Type of human samples manipulated:<br>☐ Cell lines ☐ Blood ☐ Tissues ☐ Urine ☐ Spinal Fluid ☐ Serum ☐ Feces ☐ Semen<br>☐ Other _____ Specify_____ |
| What volume will be maintained at any given time:_____ |

How long will the samples be maintained: _____

## Section G

Safety, Security, and Training Plan - Use the BMBL as a guide only to write your specific safety procedures. Follow the outline below for the items that are applicable to your project (please put N/A for the items that do not apply to your laboratory).

If you are working with animals, describe in detail the safety protocol for handling infected animals in the Animal Care Facility.

*G.1. Training Plan:*

☐ General Laboratory Safety and Hazardous Materials Orientation

☐ Biosafety Training (required initially and when protocol is renewed

)

☐ Bloodborne Pathogens Annual Refresher Training

☐ Infectious Substance Shipping/Transport Training

☐ Fit Testing (for respirator users)

☐ Other _____

Briefly Describe Laboratory Specific Training:

G.2. Security Plan (include access to both laboratory and biological agents):

G.3. Specific Laboratory Practices:

G.4. Personal Protective Equipment (PPE) Required:

☐ Lab coat ☐ Gloves ☐ Goggles/Safety glasses ☐ Closed-toe shoes ☐ Long pants

☐ Respirator/Face mask (specify) _____ ☐ Other _____

G.5. Containment Equipment:

Is containment equipment available in the laboratory? ☐ No ☐ Yes

Containment equipment used for this project:

☐ Biological Safety Cabinet: Locations:_____ Last Certified:_____

☐ Fume Hood ☐ Containment Centrifuge ☐ Other _____

G.6. Decontamination Procedures:

G.7. Spill Clean Up Procedures:

G.8. Transfer and/or Transport of Biohazards Between/Outside the Laboratories:

G.9. Handling of Hazardous Waste:

G.10. Medical Surveillance/Incident Reporting:

Will ship biohazardous material ? ☐ No ☐ Yes

Will generate biohazardous waste? ☐ No ☐ Yes

Will Select Agents be involved in this project? ☐ No ☐ Yes

Will Dual Use Research of Concern be involved in this project? ☐ No ☐ Yes

**The following websites contain information that can help you complete the MUA**

CDC - Biosafety in Microbiological and Biomedical Laboratories (BMBL)
http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html

ABSA - American Biological Safety Association Risk Group classification tables
http://www.absa.org/riskgroups/index.html

WHO 2004 Laboratory Biosafety Manual
http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf

# APPENDIX B.

Exposure Control Plan – Bloodborne Pathogens

**UNIVERSITY OF HOUSTON**

**ENVIRONMENTAL HEALTH AND SAFETY**

# BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

In accordance with Texas Administrative Code; Health and Safety Code, Chapter 81, Subchapter H, and analogous to OSHA Bloodborne Pathogens Standard, the University of Houston has implemented the following Exposure Control Plan:

## EXPOSURE DETERMINATION

The Texas Department of State Health Service's Bloodborne Pathogens Exposure Control Plan requires employers to perform an exposure determination for personnel who have occupational exposure to blood or other potentially infectious materials. The exposure determination is made without regard to the use of personal protective equipment. Job classifications that include personnel who have potential occupational exposure risks are laboratory personnel, custodial personnel, nutrition services personnel, medical personnel, law enforcement personnel, plumbing personnel, solid waste personnel, wellness center personnel and fire and safety personnel.

## IMPLEMENTATION AND METHODOLOGY

### Compliance Methods

Universal/standard precautions are observed to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious materials are considered infectious regardless of the perceived status of the source individual.

Engineering and work practice controls are used to eliminate or minimize exposure to personnel. Where occupational exposure remains after institution of these controls, personal protective equipment is used. Examples include safety design devices, sharps containers, needleless systems, sharps with engineered sharps injury protection for personnel, passing instruments in a neutral zone, etc.

Supervisors and workers examine and maintain engineering and work practice controls within the work environment on a regular schedule.

Handwashing facilities are available to the personnel who may incur exposure to blood or other potentially infectious materials.

If handwashing facilities are not available, the employer is required to provide either an antiseptic cleanser in conjunction with a clean cloth/paper towels, antiseptic towelettes or waterless disinfectant. If these alternatives are used, then the hands are to be washed with soap and running water as soon as possible.

After removal of personal protective gloves, personnel wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water. If personnel incur exposure to their skin or mucous membranes, then those areas are washed with soap and water or flushed with water as appropriate as soon as possible following contact.

## Needles

Contaminated needles and other contaminated sharps are not bent, recapped, removed, sheared, or purposely broken. The exception to this is if no alternative is feasible and the action is required by a specific medical procedure. If such action is required, then the recapping or removal of the needle must be done by the use of a device or a one-handed technique.

## Contaminated Sharps Discarding and Containment

Contaminated sharps are discarded immediately or as soon as feasible in containers that are closable, puncture resistant, leak-proof on sides and bottom, and biohazard labeled or color-coded.

During use, containers for contaminated sharps are easily accessible to personnel; located as close as is feasible to the immediate area where sharps are being used or can be reasonably anticipated to be found (e.g., laundries); maintained upright throughout use; are not allowed to overfill; and replaced routinely.

## Work Area Restrictions

In work areas where there is a reasonable likelihood of exposure to blood or other potentially infectious materials, personnel are not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. Food and beverages are not to be kept in refrigerators, freezers, shelves, cabinets, or on counter/bench tops where blood or other potentially infectious materials are present.

Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

All procedures are conducted in a manner to minimize splashing, spraying, splattering, and generation of droplets of blood or other potentially infectious materials.

## Collection of Specimens

Specimens of blood or other potentially infectious materials are placed in a container, which prevents leakage during the collection, handling, processing, storage, transport, or shipping of the specimens. The container used for this purpose is labeled with a biohazard label or color-coded unless universal/standard precautions are used throughout the procedure and the specimens and containers remain in the facility. Specimens of blood and other potentially infectious body substances or fluids are usually collected within a hospital, doctor's office, clinic, or laboratory setting. Labeling of these specimens should be done according to the department's specimen collection procedure. This procedure should address placing the specimen in a container, which prevents leakage during the collection, handling, processing, storage, transport, or shipping of the specimens. In departments where specimen containers are sent to other institutions and/or universal precautions are not used throughout the procedure, a biohazard or color-coded label should be affixed to the outside of the container.

If outside contamination of the primary container occurs, the primary container is placed within a secondary container, which prevents leakage during the handling, processing, storage, transport,

or shipping of the specimen. The secondary container is labeled with a biohazard label or color-coded.

Any specimen, which could puncture a primary container, is placed within a secondary container, which is puncture proof.

## Contaminated Equipment

Equipment which may become contaminated with blood or other potentially infectious materials is examined prior to servicing or shipping and decontaminated as necessary unless the decontamination of the equipment is not feasible. University personnel place a biohazard label on all portions of contaminated equipment that remain to inform personnel, service representatives, and/or the manufacturer, as appropriate.

## Personal Protective Equipment

All personal protective equipment used is provided without cost to personnel. Personal protective equipment is chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment is considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of the time which the protective equipment is used. Examples of personal protective equipment include gloves, protective eyewear, gowns, lab coats, aprons, shoe covers, face shields, and masks.

All personal protective equipment is cleaned, laundered, and disposed of by the employer. All repairs and replacements are made by the employer.

All garments which are penetrated by blood are removed immediately or as soon as feasible and placed in the appropriate container. All personal protective equipment is removed prior to leaving the work area and placed in the designated receptacle.

Gloves are worn where it is reasonably anticipated that personnel will have hand contact with blood, other potentially infectious materials, non-intact skin, and mucous membranes. Latex sensitive personnel are provided with suitable alternative personal protective equipment.

Disposable gloves are not to be washed or decontaminated for re-use and are to be replaced as soon as practical when they become contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

Utility gloves may be decontaminated for re-use provided that the integrity of the glove is not compromised. Utility gloves are discarded if they are cracked, peeling, torn, punctured, exhibit other signs of deterioration, or when their ability to function as a barrier is compromised.

Masks in combination with eye protection devices, such as goggles, or chin length face shields, are required to be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can reasonably be anticipated.

Surgical caps or hoods and/or fluid resistant shoe covers or boots are worn in instances when gross contamination can reasonably be anticipated.

## Housekeeping

All contaminated work surfaces are decontaminated after completion of procedures, immediately or as soon as feasible after any spill of blood or other potentially infectious materials, and at the end of the work shift.

Protective coverings (e.g., plastic wrap, aluminum foil, etc.) used to cover equipment and environmental surfaces are removed and replaced as soon as feasible when they become contaminated or at the end of the work shift.

All bins, pails, cans, and similar receptacles are inspected and decontaminated on a regularly scheduled basis.

Any broken glassware which may be contaminated is not picked up directly with the hands.

## Regulated Waste Disposal

All contaminated sharps are discarded as soon as feasible in sharps containers located as close to the point of use as feasible in each work area.

Regulated waste other than sharps is placed in appropriate containers that are closable, leak resistant, labeled with a biohazard label or color-coded, and closed prior to removal. If outside contamination of the regulated waste container occurs, it is placed in a second container that is also closable, leak proof, labeled with a biohazard label or color-coded, and closed prior to removal.

All regulated waste is properly disposed of in accordance with federal, state, county, and local requirements.

## Laundry Procedures

Although soiled linen may be contaminated with pathogenic microorganisms, the risk of disease transmission is negligible if it is handled, transported, and laundered in a manner that avoids transfer of microorganisms to personnel and environments. Rather than rigid rules and regulations, hygienic storage and processing of soiled linen is recommended. The methods for handling, transporting, and laundering of soiled linen are determined by the departmental written policy and any applicable regulations.

Please use a service that specifically cleans lab coats or contaminated laundry. The following are suggested:

| | |
|---|---|
| Wolfe's Cleaners | (713) 227-6246 |
| Fannin Dry Cleaners | (713) 790-1774 |
| Dry Clean Planet 9 | (281) 922-6666 |

## Use of Biohazard Labels

These materials may include but are not limited to, Regulated waste, refrigerators and freezers containing blood or other potentially infectious materials, and other containers used to store, transport, or ship blood or other potentially infectious materials should have biohazard-warning labels or be placed in color-coded bags.

## Training

Training for all personnel is conducted prior to initial assignment to tasks where occupational exposure may occur. All personnel also receive annual online refresher training. Training is offered by the University bimonthly or upon departmental requests.

Training for personnel includes an explanation of the following:

- Chapter 96. Bloodborne Pathogen Control
- OSHA Bloodborne Pathogen Final Rule;
- epidemiology and symptoms of bloodborne diseases;
- modes of transmission of bloodborne pathogens;
- University's Exposure Control Plan (i.e., points of the plan, lines of responsibility, how the plan will be implemented, where to access plan, etc.);
- procedures which might cause exposure to blood or other potentially infectious materials at the workplace;
- control methods which are used at the University to control exposure to blood or other potentially infectious materials;
- personal protective equipment available at the University (types, use, location, etc.);
- hepatitis B vaccine program at the University;
- procedures to follow in an emergency involving blood or other potentially infectious
- materials;
- procedures to follow if an exposure incident occurs, to include U.S. Public Health Service Post Exposure Prophylaxis Guidelines;
- post exposure evaluation and follow up;
- signs and labels used at the University; and,
- an opportunity to ask questions with the individual conducting the training.

## Pre Exposure Hepatitis B Vaccine

- All personnel who have been identified as having occupational exposure to blood or other potentially infectious materials are offered the hepatitis B vaccine, at the expense of the employee's department.
- The vaccine is offered after bloodborne pathogens training and within 10 working days of their initial assignment to work unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or that the vaccine is contraindicated for medical reasons.
- Personnel receive the vaccine at the University Health Center.
- Personnel who decline the Hepatitis B vaccine sign a declination statement (see attached copy).

- Personnel who initially decline the vaccine but who later elect to receive it may then have the vaccine provided to the employee at the expense of the employee's department.

**Post Exposure Evaluation and Follow up**

When an employee incurs an exposure incident, the employee must report to the Risk Management Claims Coordinator (713-743-0414) for referral to a physician. The employee and supervisor must complete forms at the following websites:

- Supervisor's First Report of Injury- http://www.uh.edu/af/riskmanagement/pdf/wc_TWCC1S.pdf
- Employee's First Report of Injury- http://www.uh.edu/af/riskmanagement/pdf/wc_SORM29.pdf

All personnel who incur an exposure incident are offered a confidential medical evaluation and follow up as follows:

- Documentation of the route(s) of exposure and the circumstances related to the incident.

- Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law. After obtaining consent, unless law allows testing without consent, the blood of the source individual should be tested for HIV/HBV infectivity, unless the employer can establish that testing of the source is infeasible or prohibited by state or local law.

- The results of testing of the source individual are made available to the exposed employee with the employee informed about the applicable laws and regulations concerning disclosure of the identity and infectivity of the source individual.

- The physicians will examine the employee and order blood collection for testing of the employee's HIV/HBV serological status. The blood sample is preserved for at least 90 days to allow the employee to decide if the blood should be tested for HIV serological status. If the employee decides prior to that time that the testing will be conducted, then testing is done as soon as feasible.

- The employee is offered post exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service.

- The employee is given appropriate counseling concerning infection status, results and interpretations of tests, and precautions to take during the period after the exposure incident.

- The employee is informed about what potential illnesses can develop and to seek early medical evaluation and subsequent treatment.

- Environmental Health and Life Safety will assure that the policy outlined here is effectively carried out and maintain records related to this policy.

## Interaction with Healthcare Professionals

A written opinion is obtained from the healthcare professionals after an exposure incident. In order for the healthcare professional to adequately evaluate the employee, the healthcare professional is provided with:

- a copy of the University's Exposure Control Plan;
- a description of the exposed employee's duties as they relate to the exposure incident;
- documentation of the route(s) of exposure and circumstances under which the exposure occurred;
- results of the source individual's blood tests (if available); and,
- medical records relevant to the appropriate treatment of the employee (if available).

Written opinions are obtained from the healthcare professional in the following instances:

- when the employee is sent to obtain the Hepatitis B vaccine, or
- whenever the employee is sent to a healthcare professional following an exposure incident.

Healthcare professionals are instructed to limit their written opinions to:

- whether the Hepatitis B vaccine is indicated;
- whether the employee has received the vaccine;
- the evaluation following an exposure incident;
- whether the employee has been informed of the results of the evaluation;
- whether the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment (all other findings or diagnosis shall remain confidential and shall not be included in the written report ); and,
- whether the healthcare professional's written opinion is provided to the employee within 15 days of completion of the evaluation.

## Recordkeeping

Departments identify personnel with the potential for occupational exposure to bloodborne pathogens and other infectious materials and submit that information to EHLS-Biosafety (713-743-5858 or ehs@uh.edu ). The Department of Environmental Health and Life Safety maintains training, vaccination, and occupational exposure records for the University. Individual medical records of occupational exposures are maintained by the respective medical personnel that provided post exposure evaluation and follow-up.

UNIVERSITY of HOUSTON
DEPARTMENT of PUBLIC SAFETY
Environmental Health & Life Safety

## EXPOSURE TO BLOODBORNE PATHOGENS - HEPATITIS B VACCINE FORM

NAME: _____
*(Please provide the exact spelling of name as listed on the Cougar One Card)

TITLE: _____

DEPARTMENT: _____

PRINCIPAL INVESTIGATOR/SUPERVISOR: _____

TELEPHONE: _____E-MAIL:_____

PEOPLESOFT ID#:_____

Please check the appropriate box, fill all information requested.

☐ I would like to receive the Hepatitis B vaccine at the University of Houston Student Health Center

☐ I would like to receive the Hepatitis B Antibody Surface Test/titer

☐ I received the Hepatitis B vaccine at the University of Houston Student Health Center
Date of vaccination: _____

☐ I received the Hepatitis B vaccine at a previous place of employment

---

**If appropriate sign the declination statement**

☐ I am declining the Hepatitis B vaccine offered by the University of Houston (please read and sign the declination statement)

DECLINATION STATEMENT

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If, in the future, I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to myself.

Signature _____ Date _____

# APPENDIX C.

Animal Samples Registration Form

UNIVERSITY of HOUSTON
DEPARTMENT of PUBLIC SAFETY
Environmental Health & Life Safety

# Animal Sample Registration
# (Animal Tissue, Fluids and Cell lines Experiments)

| **SECTION A** Principal Investigator and Personnel Information (please type) | | |
|---|---|---|
| ***P.I. Name*:** | ***Title*:** | ***Dept*:** |
| ***Phone No*:** | ***Lab Phone*:** | ***Mail code:*** |
| ***Building and Lab Room No(s)*:** | **E-mail:** | |

**Please provide name, title and insurance carrier for all laboratory personnel (including students or volunteers). All persons handling human products must have medical insurance. Include PeopleSoft numbers for all personnel.**

**PEOPLESOFT #** **NAME** **TITLE**

***Title of the protocol:***

**The Principal Investigator is responsible for: (please initial each statement)**

____Training of personnel on how to correctly work with animal cell/tissue cultures.

____Limiting access to authorized users.

____ Minimizing the possibility of inadvertent ingestion or inhalation and direct skin, eye contact or accidental inoculation with the cells or tissue cultures.

____Reporting any adverse events, such as exposures or injuries, immediately to the Biosafety Office.

_____ _____
Principal Investigator (Signature) Date

_____ _____
Environmental Health and Life Safety Date

Please send Registration to: Biological Safety Manager, Environmental Health and Life Safety, Mail Code 1005; ehs@uh.edu; (713) 743-5858.

## **Section B** Experimental Design

Briefly describe experimental design:

Types of Manipulations:

☐ Centrifugation ☐ Bleeding/Mixing ☐ Dissection ☐ Sonication ☐ Pipetting
☐ Other _____

*Origin of samples:* _____

*If samples are purchased from ATCC provide ATCC number* _____

*Are the samples harvested or collected from animals infected with a pathogen?*

☐ No ☐ Yes If yes, please list _____

## **Section D** Use of live animals

Will live animals be used for this project? ☐ No ☐ Yes IACUC protocol #_____

## **Section E** Safety Plan

Training Plan:

Personal Protective Equipment (PPE) Required:

☐ Lab coat Gloves ☐ Goggles ☐ Safety glasses ☐ Closed-toe shoes ☐ Long pants
☐ Respirator (specify) _____ ☐ Face mask
☐ Other _____

Containment Equipment:

*Is containment equipment available in the laboratory?* ☐ No ☐ Yes

*Containment equipment used for this project:*

☐ Biological Safety Cabinet Location:_____ Last Certified:_____
☐ Fume Hood ☐ Containment Centrifuge ☐ Other _____

Handling of Biohazardous Waste:

Liquid-

Solid-

Spill Cleanup Procedures:

Will the samples be shipped? ☐ No ☐ Yes

# APPENDIX D.

Human Products Registration Form

UNIVERSITY of HOUSTON
DEPARTMENT of PUBLIC SAFETY
Environmental Health & Life Safety

# Human Products Registration
# Registration of Human Products Experiments

| **SECTION A** Principal Investigator and Personnel Information (please type) | | |
|---|---|---|
| ***P.I. Name*:** | ***Title*:** | ***Dept*:** |
| ***Phone No*:** | ***Lab Phone*:** | ***Mail code:*** |
| ***Building and Lab Room No(s)*:** | **E-mail:** | |

**Please provide name, title and insurance carrier for all laboratory personnel (including students or volunteers). All persons handling human products must have medical insurance. Include PeopleSoft numbers for all personnel.**

| **PEOPLESOFT #** | **NAME** | **TITLE** | **INSURANCE CARRIER** |
|---|---|---|---|

***Title of the protocol:***

**Principal Investigator Acknowledgement:**

**I accept responsibility for: (please initial each statement)**

____The safe use of human products
____All personnel have been informed of potential risks, and proper laboratory practices for working safely with human products and have had or have been given the opportunity for the Hepatitis B vaccination.
____Verification of medical insurance for laboratory personnel handling human products.
____Reporting any adverse events, such as exposures or injuries, immediately to the Biosafety Office.

The University's Biological Safety Manual is located at www.uh.edu/ehs. This manual must be supplemented with the laboratory's safety plan and must include special practices when working with human products. Also, all laboratory personnel must be familiar with safe handling practices (e.g., training with proof of training).

_____ _____
Principal Investigator (Signature) Date

_____ _____
Environmental Health and Life Safety Date

Please send Registration to: Biological Safety Manager, Environmental Health and Life Safety, Mail Code 1005; ehs@uh.edu; (713) 743-5858.

UNIVERSITY of HOUSTON
DEPARTMENT of PUBLIC SAFETY
Environmental Health & Life Safety

| **Section B** Experimental Design |
|---|
| Briefly describe experimental design: |
| Types of Manipulations:<br>☐ Centrifugation ☐ Bleeding/Mixing ☐ Dissection ☐ Sonication<br>☐ Pipetting ☐ Other _____ |
| Type of human products manipulated:<br>☐ Cell lines ☐ Blood ☐ Tissues ☐ Urine ☐ Feces ☐ Other - _____ |
| Origin of samples: _____ |
| How long will samples be maintained?_____ How much sample will be maintained at any given time?_____ |
| Are samples infected with a pathogen?<br>☐ No ☐ Yes If yes, please list _____ |
| Is the project registered with the Institutional Review Board (IRB)? ☐ No ☐ Yes<br>IRB protocol# _____ IRB date of approval:_____ |

| **Section C** Safety Plan |
|---|
| Training Plan: |
| Personal Protective Equipment (PPE) Required:<br>☐ Lab coat Gloves ☐ Goggles ☐ Safety glasses ☐ Closed-toe shoes<br>☐ Long pants<br>☐ Respirator (specify) _____ ☐ Face mask<br>☐ Other _____ |
| Containment Equipment:<br>*Is containment equipment available in the laboratory?* ☐ No ☐ Yes |

| |
|---|
| *Containment equipment used for this project:*<br>☐ Biological Safety Cabinet Location:_____ Last Certified:_____<br>☐ Fume Hood ☐ Containment Centrifuge ☐ Other _____ |
| Handling of Biohazardous Waste:<br>Liquid-<br>Solid-<br>Spill Cleanup Procedures: |
| Will the samples be shipped? ☐ No ☐ Yes |
| Will samples be transported between laboratories or outside University? ☐ No ☐ Yes<br>Hepatitis B vaccination offered to laboratory personnel (if applicable)? ☐ No ☐ Yes |

# APPENDIX E.

Principal Investigator Checkout Procedure

**UNIVERSITY OF HOUSTON**
**ENVIRONMENTAL HEALTH AND SAFETY**

**SECTION: BIOLOGICAL, CHEMICAL, RADIATION AND SAFETY**
**SUBJECT: Principal Investigator Checkout Procedure**

---

PURPOSE

All Principal Investigators (PIs) are required to complete this checkout procedure 30 days prior to the completion of their association with the University of Houston. PIs must ensure that all hazardous chemical, biological and radioactive materials under their authorization/supervision are properly disposed, transferred to another laboratory, shipped, or removed to storage. Strict adherence to this policy will reduce the likelihood of accumulating orphaned chemicals, some of which may become dangerously unstable. Uncontrolled inventories of hazardous chemical, biological or radioactive materials eventually lead to storage problems, increased waste disposal costs, contamination and other potentially unsafe conditions. **The failure of any PI to complete or properly follow this checkout procedure will require that their departmental chairperson assume such responsibility.**

***Please note:***
***Radioactive material transfer must receive prior approval of the Radiation Safety Officer.***

***Registrants authorized by DEA to possess Controlled Substances must follow agency guidelines regarding transfer and disposal of controlled drugs. EHLS is not authorized and will not receive controlled drugs for disposal in any form.***

1. Environmental Health and Safety (EHLS) must be given written notification of a PI's departure from the University of Houston by their department at least 30 days prior to his/her exit date. The written notification is to be sent to: EHLS-1005 or ehs@uh.edu . Advance notice is required to allow adequate time for the scheduling of laboratory clean outs and compliance with regulatory requirements. The attached PI Advance Notification form is provided to the PI for completion and submittal to EHLS as required.

2. The PI must include the following items in the written notification of departure:
   a. Forwarding mailing address
   b. Department
   c. Departmental chairperson's name
   d. Room numbers for all laboratories under that PI's supervision
   e. Date of departure
   f. Contact telephone number before and after departure
   g. Name of individual who will take responsibility of transferred chemicals, biological materials and/or radioisotopes

3. Chemicals that will remain in the laboratory must have proper labels that include the chemical name, hazards, reactivity and date received or last utilized. Radioactive materials and radioactive samples must also have labels which include the radioisotope, activity, and date. Biological material remaining in the laboratory must be placed in leak proof or breakage

resistant receptacles with the name and hazards associated with the microbial agent on the specimen container.

**1.** Radioactive materials/samples to be taken with the PI to another licensed institution must be properly shipped through EHLS. All outstanding radioisotopes still in inventory must be accounted for prior to leaving. Please consult with the Radiation Safety Officer for assistance with shipping of radioactive materials.

**2.** Chemicals will not be shipped through EHLS; outside vendors may be contacted to arrange legal shipments of such materials. However, our department will inspect all chemical hazardous products prior to shipping to ensure that they are properly packaged for transport.

**3.** All biological materials that need to be shipped or relocated must be packed and transported following the Department of Transportation (DOT) and the International Air Transport Association (IATA) rules and regulations. Please contact EHLS so that trained and certified personnel can assist you with the transportation of your biological materials.

**It is ultimately the responsibility of the department to make sure that all of the hazardous materials are shipped to a licensed institution in accordance to state and federal laws.**

**4.** All equipment and laboratory ware used with radioactive materials must be identified and properly labeled for disposal or transfer to another approved PI. All such equipment and laboratory ware to be taken with the PI to another licensed institution must be adequately decontaminated prior to removal. Documentation of decontamination must be provided to EHLS. Please see http://www.uh.edu/plantops/services/disposal-of-appliances/index.php to submit the Laboratory Equipment Safety Clearance form.

**5.** All radiation laboratories and remaining equipment (i.e. refrigerators, centrifuges, incubators, etc.) must be decontaminated to the approved levels by the PI prior to leaving. Copies of the PI's final surveys and wipe tests must be sent to EHLS. EHLS will confirm decontamination with their own surveys and wipe tests. All radiation labels and signage will be removed during the EHLS closeout procedures and the laboratories will then be released to other PIs for use.

**6.** All radiation badges must be returned to EHLS prior to the PI's departure or the department will be held responsible for financial reimbursement.

**7.** All containment equipment such as biosafety cabinets, fume hoods, or centrifuges that were used with infectious agents at Biosafety Level 2 must be properly cleaned and decontaminated with an appropriate disinfectant for the agents used. Please see http://www.uh.edu/plantops/services/disposal-of-appliances/index.php to submit the Laboratory Equipment Safety Clearance form.

**UNIVERSITY OF HOUSTON**
**ENVIRONMENTAL HEALTH AND SAFETY**

# PRINCIPAL INVESTIGATOR CHECKOUT CHECKLIST

---

The PI Checkout Checklist is provided to assist the PI with properly withdrawing from the University of Houston.

1. Completed and submitted form for 30 days advance notification_____
   (Provide accurate and detailed information)

2. Chemicals & samples properly labeled & packaged_____
   (PI should consider donating unwanted new and reusable chemicals
   to fellow investigators with the help of EHLS)

3. Biologicals materials properly labeled & packaged by EHLS staff _____
   trained in shipping infectious agents and diagnostic materials

4. Radioactive materials & samples properly labeled & packaged_____
5. Submit EHLS Hazardous Waste Pickup Request Form online at the following website:
   (As needed for radioactive, chemical, and biological waste) _____
   http://vnet.uh.edu/vrecord_data/web_forms/College_of_Natural_Sciences_&_Mathematics/NSM_Dean/waste_pickup_req/add.lasso

6. Laboratory cleanout completed_____

7. Equipment & laboratory ware properly decontaminated_____

8. Final radiation laboratory surveys & wipe tests completed_____

9. Copies of surveys & wipe tests sent to EHLS -1005_____

10. Radiation badges returned to EHLS_____

11. Hazardous Chemicals inspected prior to shipping _____

12. Radioactive materials properly shipped through EHLS_____

13. Controlled Substance and Dangerous Drugs properly disposed/transferred____

Please submit completed checklist to EHLS-1005 or ehs@uh.edu .

**UNIVERSITY OF HOUSTON**
**ENVIRONMENTAL HEALTH AND SAFETY**

**PRINCIPAL INVESTIGATOR'S 30 DAYS ADVANCE NOTIFICATION PRIOR TO DEPARTURE FROM UH**

---

This is to officially notify the Environmental Health and Safety Department of my intent to leave the University of Houston. This written notification is submitted to: EHLS -1005 or ehs@uh.edu, 30 days prior to my departure from UH. The following information is provided as required in the Principal Investigator Checkout Procedure.

PI: _____

Date of Departure: _____

Department: _____

Department Chair: _____

Room Numbers of all laboratories under PI: _____

Contact Phone Numbers:
Before Departure: _____

After Departure: _____

Name of Responsible Individual(s) receiving transferred Chemicals, Biologicals, and/or

Radioactive Materials: _____

_____