



UNIVERSITY *of* HOUSTON

Biological Safety Manual

*Requirements and Guidelines for the Safe Handling of Biological Materials
Recombinant DNA Molecules
Bloodborne Pathogens*



Environmental Health and Risk Management Department

2006

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 the Biological Safety Manager.

HELPFUL TELEPHONE NUMBERS AND CONTACT INFORMATION

Environmental Health and Risk Management Department	(713) 743-5858
	Fax (713) 743-8035
Biological Safety Manager	(713) 743-1200
Laboratory Safety Officer (for Biosafety)	(713) 743-5899
University Health Center	(713) 743-5151
University of Houston Police Department	(713) 743-3333

EHRM 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 www.uh.edu/plantops/ehrm.

For inquires, call EHRM during business hours, after normal office hours you may leave pertinent information on the EHRM telephone mail system.

After business hours contact the University of Houston Police Department for hazardous biological agent emergencies. The Environmental Health and Risk Management Department maintains an on-call mechanism to provide expertise in the event of an after hours situation requiring assistance.

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I. POLICIES AND RESPONSIBILITIES

A. Campus Policy

1. The use of biological agents in teaching and research shall be in a manner that will guarantee 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 and require approval by the Institutional Biosafety Committee (IBC). A Memorandum of Understanding and Agreement (MUA) application form must be submitted to the IBC.
4. All research and teaching involving recombinant DNA technology shall be treated as prescribed by the most recent edition of NIH's Guidelines for Research Involving Recombinant DNA Molecules (copies are available from Centers for Disease Control and Prevention (CDC) website) and as directed by law. All Projects involving recombinant DNA molecules require approval by the Institutional Biosafety Committee (IBC). A Memorandum of Understanding and Agreement (MUA) application form must be submitted to the IBC.
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 EHRM for additional registration information and assistance.
7. 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.
8. Newly isolated or recognized infectious agents of unknown pathogenicity shall be treated as Biosafety Level 2 or greater infectious agents.
9. The University of Houston Biosafety 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:

- Obtaining approval from the different committees relevant to the project. For example, the Institutional Biosafety Committee (submit MUA) and the Institutional Animal Use and Care Committee if the project involves the use of biological agents, recombinant DNA technology and animals.
- Developing specific protocols to ensure the safe use of biological agents and recombinant DNA technology. The protocols must outline proper emergency procedures in the case of an accidental exposure of students, personnel, and/or the environment to the biological agents.
- Verifying attenuated forms of select agents and Risk Groups 3 and 4 organisms upon arrival to the laboratory through PCR test validation. Test results must be maintained on file and a copy must be sent to the Biological Safety Manager.
- Complying with the safety protocol, this manual, campus policy and any applicable federal and state laws and regulations.
- Training all personnel involved in the project so that they have a complete understanding of the hazards involved, safety procedures required and the emergency protocols in place. 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 EHRM at 3-5858 to arrange general training.
- Verifying that any persons working in a Biosafety Level 2 research project that are not employees at UH have medical insurance. For clarification, University-paid Teaching Assistants and Research Assistants are employees and are covered by workers compensation. Students and Postdoctoral Fellows, whether or not they are paid stipends, are not university employees and therefore must maintain their own medical insurance.
- Notifying the Institutional Biosafety Committee of any changes in biological agents, procedures, personnel or protocols stated in the approved Memorandum of Understanding and agreement.
- 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.
- Complying with proper shipping of infectious and diagnostic material by following recommendations in this manual, campus policy, and any applicable federal and state laws and regulations.

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 of whether or not they work directly with them.
- Knowing all emergency procedures established by the Principal Investigator.
- Completing training and verifying documentation of appropriate 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:

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

4. The Office of Environmental Health & Risk Management (EHRM) 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 DNA technology 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 for the use of biological agents and submitting the Memorandums of Understanding and Agreement to the Institutional Biosafety Committee (IBC).
- Assuring department and user compliance with the IBC's recommendations.
- Scheduling and performing laboratory assessments and inspections of facilities.
- Monitoring completion of projects through updates of protocols.
- Keeping records and copies of applicable laws and regulations.
- Providing training materials and classes upon request.
- Advising generators on proper biological hazardous waste handling, treatment, and disposal methods in accordance with federal, state, and university standards.
- Providing assistance and training for the proper shipment of biohazardous material.

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

- Assuring the safe use of recombinant DNA technology, biological agents, and bloodborne pathogens at the University of Houston.

- Reviewing and recommending acceptance or rejection of all proposed projects requiring authorization or registration 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 EHRM 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.
- Reviewing recommending and approving the content of the biological safety manual and safety training materials.
- Consulting, when necessary, with an Occupational Health Physician and establishing the level of medical surveillance for each program after reviewing his recommendations.

6. The Director of Animal Care is responsible for the following:

- Advising investigators and managers of animal facilities as to the recommended procedures for containment of biohazards in experimental animals.
- Serving in the Institutional Biosafety Committee as an animal expert to evaluate protocols that involve the use of biological agents, bloodborne pathogens, and recombinant DNA in the animal facility.

II. Requirements for working with Biological Material

A. Introduction and general requirements:

1. Registration of Biological Material: 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.

- Biological agents.
- Recombinant DNA and/or recombinant vector technology.
- 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 approval for the safe handling of a biological or chemical product.
- The IBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these six areas (e.g. nanotechnology). When it is unclear as to whether a material constitutes a potential biohazard, the IBC must be consulted. Questions must be directed to Environmental Health and Risk Management (EHRM).

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

- MUAs at Biosafety Level 1 are approved for two years and PIs must submit a renewal MUA (Appendix A) one month prior to expiration.
- MUAs at Biosafety Level 2 are approved for one year and PIs must submit a renewal MUA (Appendix A) one month prior to expiration.
- Any changes or additions to approved protocols must be submitted to the Institutional Biosafety Committee for review and approval prior to implementation.

3. 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 maintain proper annual cabinet certification.
- Medical Insurance: PIs must verify that any persons working in a Biosafety Level 2 research project that are not employees at UH must have medical insurance. For clarification, University-paid Teaching Assistants and Research Assistants are employees and are covered by workers compensation. Students and Postdoctoral Fellows, whether

or not they are paid stipends are not university employees and therefore must maintain their own medical insurance.

- Training: all staff and students working in a Biosafety Level 2 project must receive biosafety training from EHRM. Staff and students working with bloodborne pathogens must receive bloodborne pathogens training from EHRM annually.
- Attenuated forms of select agents and Risk Groups 3 and 4 organisms: these organisms must be verified upon arrival to the laboratory through PCR test validation or other equivalent/appropriate techniques. Test results must be maintained on file and a copy must be sent to the Biological Safety Manager.

4. Audits: Laboratories where research with biological hazards is ongoing will be audited at least once every year for compliance with general laboratory practices and 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 infectious agents

1. Classification of the biological agents:

Biological agents are those pathogenic bacteria, viruses, 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 section III and Appendix B. If the agent is not listed, contact EHRM. 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. Select agents require special registration with the Centers for Disease Control and Prevention (CDC). The list of select agents is in Appendix C. Please contact EHRM for further information and registration forms.

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 the Biological Safety Manager for distribution to the Institutional Biosafety Committee. 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 for each laboratory in which biological agents are 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. The PI must ensure compliance by all workers and students.

The individual laboratory safety plan can include information from this manual, National Research Council's Biosafety in the Laboratory, CDC/NIH's Biosafety in Microbiological and

Biomedical Laboratories, OSHA's Occupational Exposure to Bloodborne Pathogens (29 CFR Part 1910.1030), IATA's Shipping Infectious Substances/Diagnostic Specimens Regulations, and the CFR 49 Part 73; Select Agents. These, and other documents, are available from EHRM.

4. Training of Laboratory Staff and Students:

Training of employees and students is an extremely important safety factor in the laboratory. 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 research in Biosafety Level 2 laboratories must attend the EHRM Biosafety course. If you need assistance or training materials for biological safety please contact EHRM. Biosafety courses available through EHRM are described in section IV of this manual. All training must be documented through training log books or certificates.

5. Illness prevention 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. Employees 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 the UH Student Health Center (if a student) or the EHRM claims coordinator (if an employee). If the employee or 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/EHRM claims coordinator can be contacted for consultation. All employees and students that will work with, or will be in the laboratory where biological agents are in use, must be immunized against those agents if a vaccine is available.

6. Restrict access to the biological agents:

For the safety and security of the UH community short-term students and visitors to the laboratory must not be exposed to potentially infectious biological agents 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 agents may be present.

C. Requirements and procedures for the safe use or recombinant DNA technology

1. Classification of the biological material and the recombinant DNA/vector technology procedures:

In the context of the NIH Guidelines, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i).

It is the policy of UH that research and teaching programs utilizing recombinant DNA technology 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 DNA molecules can be found in the latest edition of the NIH Guidelines

for Research Involving Recombinant DNA Molecules. Copies can be obtained from CDC/NIH on the EHRM Website. Please consult the NIH guide 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 DNA 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, host organisms and cell lines, vectors, DNA inserts, experimental protocols, and safety procedures. The PI is encouraged to remain in communication with the IBC 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 for each laboratory in which recombinant DNA 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. 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 problems with recombinant DNA projects must be reported immediately to EHRM 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 employees and students is an extremely important safety factor in the laboratory. Responsibility for training laboratory staff may be carried out by the PI. The institution is responsible for ensuring that the PI is adequately trained in proper microbiological techniques and safe methods of conducting recombinant DNA research. 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 research in Biosafety Level 2 laboratories must attend the EHRM Biosafety course. If you need assistance or training materials for biological safety please contact EHRM. Biosafety courses available through EHRM are described in section IV of this manual. All training must be documented through training log books or certificates.

5. Illness prevention related to work with recombinant DNA:

The IBC requires that all students working at BSL-2 have appropriate medical coverage before they start working in the laboratory. Employees and students must be familiar with signs and

symptoms of illnesses caused by the agents and recombinant DNA technologies used in the laboratory. A person that develops an illness that could be of laboratory origin must inform his/her supervisor and report to the UH Student Health Center (if a student) or the EHRM claims coordinator (if an employee). If the employee or 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/EHRM claims coordinator 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 employees, 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 DNA technology:

For 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 DNA technology 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 DNA may be present.

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 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 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 disinfection before discarding.
- All employees 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.
- All employees and students working with bloodborne pathogens must attend the EHRM bloodborne pathogens training annually.

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 of 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 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 EHRM website and in Appendix D 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 EHRM.

4. Training of Laboratory Staff and Students:

All employees and students working with bloodborne pathogens are required to attend the EHRM bloodborne pathogens training annually. The training of employees 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 EHRM are described in section IV of this manual. All training must be documented through training log books or certificates.

5. Illness prevention related to work with bloodborne pathogens:

Employees 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 employees 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 must be offered during 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. The employees receive the vaccine at the University Health Center. If an employee declines vaccination she/he must sign a declination statement (available in the ECP Appendix D). 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 an employee incurs an exposure incident, the employee must report to the Environmental Health and Risk Management's Claims Coordinator (713-743-8024) for referral to a physician.

Students are not covered in the ECP. EHRM 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.

E. 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 DNA 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 use 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 recommend to seek the assistance of the UH Director of Animal Care 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 employees 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
- Receive additional training as needed to conduct animal manipulations
- Take the Bloodborne pathogens course from EHRM if working with human products
- Take the Biosafety course from EHRM if working under Biosafety Level 2 practices
- 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. At a minimum this includes wearing personal protective equipment such as gloves and a dedicated laboratory coat when handling the animals and agents.
- Follow all safety precautions and occupational health programs required by the Director of the Animal Care Unit.

4. Illness prevention related to work with animals and biohazard

The IBC requires that all students working at BSL-2 have appropriate medical coverage before they start working in the laboratory and animal facility. Employees and students must be familiar with signs and symptoms of illnesses caused by the agents and animals they are working with. 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 plan. PIs 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 employees, 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.

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.

F. Projects Using Select Agents and Toxins

A Principal Investigator (PI) may not possess or use, receive from outside the United States, or transfer from 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 by the University's Institutional Biosafety Committee and EHRM and have been granted a certificate of registration by the DHHS Secretary or the USDA Secretary.

- Prior to possession, use or transfer of any Select Agent, a PI must register with the appropriate federal agency (CDC and/or the Animal and Plant Health Inspection Service (APHIS)). Application packets are available at their websites.
- For additional information and assistance with the registration process please contact the Biological Safety Manager at EHRM.

G. Biological Waste Disposal Procedures

- The Environmental Health and Risk Management Department (EHRM) operates the biological waste program for campus.
- Biological waste pickups are scheduled through the online form found on the EHRM website.
- Biological waste can be rendered inactive prior to pickup by EHRM. Autoclaving or chemical decontamination are appropriate methods.
- All biological waste must be placed in orange or red bags with the biohazard symbol or in a designated biological sharps container.
- All sharp and contaminated objects 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 must be incinerated. Contact the Director of Animal Care for further information.
- Section III of this manual describes waste minimization practices and waste management techniques such as on-site treatment and disposal for small quantities of biological waste.
- Please contact EHRM or the Biological Safety Manager for ways to reduce waste and local disposal of small quantities of biological waste.

H. Transportation and Shipping of Infectious Agents and Diagnostic Materials

- 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 and shipment regulations before shipping any infectious substance or diagnostic specimen. Please contact EHRM/Biological Safety to schedule training and/or for assistance with shipping.

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 a real or potential risk to the well-being of humans, animals, or plants. Infectious agents include, but are not limited to conventional pathogens, recombinant DNA research involving pathogenic vectors, agents carried in human tissue, and inherent and experimental infections of laboratory animals.

Molecular Biology and Microbiology laboratories are special, 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 DNA 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 see Appendix B of this manual.

3. 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.

Biosafety Level 1 (BSL-1):

- Appropriate for work done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans.
- It represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand-washing.

Biosafety Level 2 (BSL-2):

- Applicable to work done with a broad spectrum of indigenous, moderate-risk agents present in the community and associated with human disease of varying severity.
- Agents can be used safely on the open bench, provided the potential for producing splashes or aerosols is low.
- Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures or ingestion of infectious materials.

- Procedures with high aerosol or splash potential must be conducted in primary containment equipment such as biosafety cabinets.
- Primary barriers such as splash shields, face protection, gowns and gloves must be used as appropriate. Secondary barriers such as hand-washing and waste decontamination facilities must be available.

Biosafety Level 3 (BSL-3):

- Applicable to work done with indigenous or exotic agents with a potential for respiratory transmission and which may cause serious and potentially lethal infection.
- Primary hazards to personnel working with these agents (i.e., *Mycobacterium tuberculosis*, St. Louis encephalitis virus and *Coxiella burnetii*) include autoinoculation, ingestion and exposure to infectious aerosols.
- Greater emphasis is placed on primary and secondary barriers to protect personnel in adjoining areas, the community and the environment from exposure to infectious aerosols.
- For example, all laboratory manipulations must be performed in a biosafety cabinet or other enclosed equipment.
- Secondary barriers include controlled access to the laboratory and a specialized ventilation system (e.g., HEPA filters, incinerators, etc.) that minimizes the release of infectious aerosols from the laboratory.

Biosafety Level 4 (BSL-4):

- Applicable for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease that may be transmitted via the aerosol route and for which there is no available vaccine or therapy.
- All manipulations of potentially infected materials and isolates pose a high risk of exposure and infection to personnel, the community and the environment.
- The facility is a specially designed building with specialized ventilation and waste management systems to prevent release of viable agents to the environment.
- UH does not have BSL-4 facilities.

Vertebrate Animal Biosafety Levels (ABSL):

- There are four Animal Biosafety Levels, designated Animal Biosafety Level 1 through 4, for work with infectious agents in mammals.
- The levels are combinations of practices, safety equipment and facilities for experiments on animals infected with agents that produce or may produce human infection.
- In general, the Biosafety Level recommended for working with an infectious agent in vivo and in vitro is comparable.

TABLE 1. Summary of Biological Safety Levels: describing the classification of agents, laboratory practices, safety equipment, and facilities (from CDC website).

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Primary barriers = Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhausted air not recirculated Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs <u>in combination with</u> full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decon systems Other requirements outlined in the text

TABLE 2. Summary of Animal Biological Safety Levels: describing the classification of agents, laboratory practices, safety equipment, and facilities (from CDC website).

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy human adults.	Standard animal care and management practices, including appropriate medical surveillance programs	As required for normal care of each species.	Standard animal facility No recirculation of exhaust air Directional air flow recommended Handwashing sink recommended
2	Associated with human disease. Hazard: percutaneous exposure, ingestion, mucous membrane exposure.	ABSL-1 practices plus: Limited access Biohazard warning signs Sharps precautions Biosafety manual Decontamination of all infectious wastes and of animal cages prior to washing	ABSL-1 equipment plus primary barriers: containment equipment appropriate for animal species; PPE: laboratory coats, gloves, face and respiratory protection as needed.	ABSL-1 facility plus: Autoclave available Handwashing sink available in the animal room. Mechanical cage washer used
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious health effects.	ABSL-2 practices plus: Controlled access Decontamination of clothing before laundering Cages decontaminated before bedding removed Disinfectant foot bath as needed	ABSL-2 equipment plus: Containment equipment for housing animals and cage dumping activities Class I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols. PPEs: appropriate respiratory protection	ABSL-2 facility plus: Physical separation from access corridors Self-closing, double-door access Sealed penetrations Sealed windows Autoclave available in facility
4	Dangerous/exotic agents that pose high risk of life threatening disease; aerosol transmission, or related agents with unknown risk of transmission.	ABSL-3 practices plus: Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting All wastes are decontaminated before removal from the facility	ABSL-3 equipment plus: Maximum containment equipment (i.e., Class III BSC or partial containment equipment in combination with full body, air-supplied positive-pressure personnel suit) used for all procedures and activities	ABSL-3 facility plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum and decontamination systems Other requirements outlined in the text

4. Summary of the NIH guidelines for the use of recombinant DNA technology

This summary only serves as a guide to the [NIH Guidelines for Research Involving Recombinant DNA Molecules](#). It is the responsibility of each Principal Investigator (PI) to make sure that his/her laboratory is in compliance. At UH all recombinant 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 register with the Institutional Biosafety Committee

TABLE 3. Outline for the registration of recombinant DNA experiments currently allowable by the NIH Guidelines.

<p>Must be Registered & Approved PRIOR to Initiation:</p>	<ol style="list-style-type: none"> 1. Cloning of DNA encoding molecules toxic to vertebrates within LD50 <100ng/kg body weight. 2. Cloning of DNA from all Class 2, 3, or 4 human or animal pathogens (including HIV and related viruses, and human tumor viruses). 3. Experiments using as vectors more than two-thirds of the genome of infectious animal or plant viruses or defective recombinant viruses grown in the presence of a helper virus. 4. Cloning using human or animal pathogens as host-vector systems. 5. All experiments that may generate transgenic animals or plants which may extend the host-range of human or animal pathogen, or that require BL-2 or greater containment. 6. All human gene transfer experiments.
<p>Require Registration Simultaneous with Initiation:</p>	<ol style="list-style-type: none"> 1. Cloning of all other DNA in E. coli K12, S. cerevisiae, and B. subtilis host-vector systems (with the exception of DNA from Class 2, 3, or 4 pathogens). 2. Introduction into cultured cells of any recombinant DNA containing less than half of a eukaryotic viral genome (with the exception of Class 2, 3, or 4 pathogens). 3. Experiments using as vectors less than two-thirds of the genome of defective animal or plant viruses, free of helper virus. 4. Cloning of DNA for more than one-half of the genome of Class 1 or Class 2 human or animal pathogens, or cloning of known oncogenes. 5. Generation of transgenic animals requiring ABSL-1 containment. 6. Experiments involving whole plants. 7. Experiments not specified on this sheet.
<p>Are Exempt and Do Not Require Registration:</p>	<ol style="list-style-type: none"> 1. Purchase or transfer of transgenic rodents.

In the context of the *NIH Guidelines*, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

The following is a synopsis of Section III of the NIH Guidelines describing some of the most common experiments and the registration procedures. Please consult the full text of the NIH Guidelines if your experiment is not described or if you need additional information.

a. Section III-A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review and NIH Director Approval Before Initiation:

- Section III-A-1-a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by RAC.

b. Section III-B. Experiments That Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation:

- Section III-B-1. Experiments Involving the Cloning of Toxin Molecules with LD₅₀ of Less than 100 Nanograms per Kilogram Body Weight: Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD₅₀ of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin).

c. Section III-C. Experiments That Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment:

- Section III-C-1. Experiments Involving the Deliberate Transfer of Recombinant DNA, or DNA or RNA Derived from Recombinant DNA, into One or More Human Research Participants: For an experiment involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (human gene transfer), no research participant shall be enrolled until the RAC review process has been completed. For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled at the clinical trial site until the following documentation has been submitted to NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the principal investigator(s) (not more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

d. Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation: Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information: (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the

containment conditions that will be implemented as specified in the *NIH Guidelines*. For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee. The Institutional Biosafety Committee shall review and approve all experiments in this category prior to their initiation.

- Section III-D-1. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems
- Section III-D-1-a. Experiments involving the introduction of recombinant DNA into Risk Group 2 agents will usually be conducted at Biosafety Level (BSL) 2 containment. Experiments with such agents will usually be conducted with whole animals at ABSL-2 containment.
- Section III-D-1-b. Experiments involving the introduction of recombinant DNA into Risk Group 3 agents will usually be conducted at Biosafety Level (BSL) 3 containment. Experiments with such agents will usually be conducted with whole animals at ABSL-3 containment.
- Section III-D-2. Experiments in Which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
- Section III-D-2-a. Experiments in which DNA from Risk Group 2 or Risk Group 3 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BSL-2 containment. Many experiments in this category are exempt from *NIH Guidelines*.
- Section III-D-3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems Caution: Special care should be used in the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of viral vectors under conditions that permit a productive infection. In such cases, serious consideration should be given to increasing physical containment by at least one level.
- Section III-D-3-a. Experiments involving the use of infectious or defective Risk Group 2 in the presence of helper virus may be conducted at BSL-2.
- Section III-D-3-b. Experiments involving the use of infectious or defective Risk Group 3 in the presence of helper virus may be conducted at BSL-3.
- Section III-D-3-e. Experiments involving the use of infectious or defective viruses in the presence of helper viruses which are not covered in Sections III-D-3-a through III-D-3-d may be conducted at BSL-1.
- Section III-D-4. Experiments Involving Whole Animals: This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BSL-1 containment. A minimum containment of BSL-2 is required. Caution – Special care should be used in

the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions.

- Section III-D-4-a. Recombinant DNA, or DNA or RNA molecules derived from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BSL-1 and appropriate to the organism under study. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BSL-1 or ABSL-1 and appropriate to the organism under study.
- Section III-D-4-c. Exceptions under Section III-D-4, *Experiments Involving Whole Animals*
- Section III-D-4-c-(1). Experiments involving the generation of transgenic rodents that require BSL-1 containment are described under Section III-E-3, *Experiments Involving Transgenic Rodents*.
- Section III-D-4-c-(2). The purchase or transfer of transgenic rodents is exempt from the *NIH Guidelines* under Section III-F, Exempt Experiments.
- Section III-D-6. Experiments Involving More than 10 Liters of Culture: The appropriate containment will be decided by the Institutional Biosafety Committee. Where appropriate, Appendix K, *Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules*, shall be used.

e. Section III-E. Experiments that Require Institutional Biosafety committee Notice Simultaneous with Initiation: Experiments not included in Section III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section III-E. All such experiments may be conducted at BSL-1 containment. For experiments in this category, a registration document shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated. The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required.

- Section III-E-1. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus: Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical) may be propagated and maintained in cells in tissue culture using BSL-1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III-D-3, *Experiments Involving the Use of Infectious Animal or Plant DNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems*, should be used. The DNA may contain fragments of the

genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

- Section III-E-3. Experiments Involving Transgenic Rodents: This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BSL-1 containment are covered under this section; experiments that require BSL-2, BSL-3, or BSL-4 containment are covered under Section III-D-4, *Experiments Involving Whole Animals*.

f. Section III-F. Exempt Experiments: Although the following recombinant DNA molecules are exempt from the *NIH Guidelines*, registration with the IBC is required:

- Section III-F-1. Those that are not in organisms or viruses
- Section III-F-2. Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, through one or more of the segments may be a synthetic equivalent.
- Section III-F-3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or closely related strains of the same species), or when transferred to another host by well established physiological means.
- Section III-F-4. Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- Section III-F-5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.
- Section III-F-6. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-6* for other classes of experiments which are exempt from the *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 D) 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 and no cure. 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), handwashing, 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 employees and students may be exposed to biological hazards such as infectious microorganisms, recombinant DNA, human tissue and body fluids, and experimental animals. In addition, all employees 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 recombinant DNA, 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.
 - Children are not permitted in laboratory work areas.
 - 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.
- Employees must not use work surfaces as seats.
- Employees 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.
- Employees are required to keep their hair at an appropriate length, covered, or tied in such a manner so that it does not become contaminated.
- Employees must wash their hands after all procedures involving animals and potentially contaminated materials. Employees 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 employees/students working with potentially infectious materials are required to wear personal protective equipment such as laboratory coats, gloves, safety glasses, etc.
- 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 clean up.
- All spills and other accidents, with overt or potential exposure to infectious materials, must be reported immediately to the laboratory supervisor and EHRM/Biological Safety Manager.
- A written record of such incidents must be maintained in the laboratory or department.

2. *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, 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.

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

- 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 are not 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.

TABLE 4. Comparison of Biosafety Cabinets (from BMBL)

Type	Face velocity (lfpm)	Airflow Pattern	Radionuclides/ Toxic Chemicals	Biosafety Level(s)	Product Protection
Class I* open front	75	In at front; rear and top through HEPA filter	No	2,3	No
Class II Type A	75	70% recirculated through HEPA; exhaust through HEPA	No	2,3	Yes
Type B1	100	30% recirculated through HEPA; exhaust via HEPA and hard ducted	Yes (Low levels/volatility)	2,3	Yes
Type B2	100	No recirculation; total exhaust via HEPA and hard ducted	Yes	2,3	Yes
Type B3	100	Same as IIA, but plenum under negative pressure to room and exhaust air is ducted	Yes	2,3	Yes
Class III	NA	Supply air inlets and exhaust through 2 HEPA filters	Yes	3,4	Yes

b. Personal Protective Equipment

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 EHRM. 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. 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.
- 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 Biosafety Level 2 and 3 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. Housekeeping

- 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 °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.

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 Appendix E.

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.

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 Health (25 TAC § 1.131-1.137) are:

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

The two most common methods utilized at 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 are required for each location that treats over 50 pounds of waste monthly and 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 ampoule or strip containing the spore *Bacillus stearothermophilus*.
- All autoclaves should be tested at least weekly.
- 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, or generate large amounts of waste, an off-site treatment option is available. Please contact EHRM or fill the on-line form for biological waste pick up.

- EHRM collects the waste and a commercial firm is in charge of incineration or land disposal.
- Infectious waste should be pre-treated by autoclaving or chemical disinfection and 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 approved by the Texas Department of Health.
- If the storage of infectious material is necessary, it should be stored in a rigid, leakproof container and bear the universal biohazard symbol.
- Infectious waste may be stored at room temperature until the storage container is full, but no longer than 30 days from the date of generation.
- Frozen waste may be kept up to 90 days from the date of generation.

- If infectious waste becomes putrescence during storage, it should be 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, or in fully enclosed carts, 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 20 minutes contact time.
- 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 or turning cabinet off.

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.
- Wear a disposable gown, shoe covers, eye protection, N95 respirator 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 EHRM for assistance.
- 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 EHRM. After business hours call 911.

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.

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 911 for emergency assistance, and inform responders of biohazards that may be a threat.
- For spills in BL-2 laboratories, evacuate the room close the doors.
- After evacuating the area, wait to assist emergency responders.
- Notify EHRM about a spill or exposure to a biohazardous agent outside of containment.
- Report exposures and injuries to EHRM Occupational Claims Coordinator.
- Report the Accident to the Biological Safety Manager 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 EHRM. Several EHRM courses are offered during the calendar year. To supplement this training, videotapes and printed materials are also available. Specifics on any of these resources may be obtained by contacting EHRM Biological Safety Manager at 713-743-1200.

Courses:

- Biological Safety Levels 1 and 2: This three hour course is mandatory for all personnel and students working under Biosafety Level 2 practices and procedures. 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 DNA.
- Bloodborne Pathogens: This is a one hour course mandatory for all faculty, staff, and graduate students working with bloodborne pathogens. This course must be attended every year. The content of the course fulfills all the training requirements established by the Texas Administrative Code regarding work with Bloodborne Pathogens.

2. Online Biosafety Resources

- [NIH Guidelines for Research Involving Recombinant DNA Molecules](#)
- [Biosafety in Microbiological and Biomedical Laboratories, 4th 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 \(CDC\)](#)
- [Interstate Shipment of Etiologic Agents \(CDC\)](#)
- [Laboratory Registration/ Select Agent Transfer Program \(CDC\)](#)
- [Packaging and Shipping of Biomedical Material \(CDC\)](#)
- [Proceedings of the 4th National Symposium on Biosafety: Working Safely w/Animals \(CDC\)](#)
- [Risk Group Classification for Infectious Agents \(ABSA\)](#)
- [Selection, Installation and Use of Biosafety Cabinets \(NIH\)](#)
- [7 CFR 340.0 Introduction of Genetically Engineered Organisms \(NIH\)](#)
- [CDC's Bioterrorism and Response Page](#)
- [Association for Professionals in Infection Control and Epidemiology, Inc.](#)
- [Texas Department of State Health Services – Bloodborne Pathogens](#)
- [NIEHS Biological Safety Page](#)

APPENDIX A

Memorandum of Understanding and Agreement (MUA) Form

To be completed by Biosafety Manager
 MUA No.: _____
 Approval Date: _____

University of Houston
 Memorandum of Understanding and Agreement
 Registration of Biohazardous Materials and Recombinant DNA Experiments

SECTION A Principal Investigator and personnel information (please type or print)		
<i>P.I. Name:</i>	<i>Title:</i>	<i>Dept:</i>
<i>Phone No:</i>	<i>Fax:</i>	<i>Mail code:</i>
<i>Building and Lab Room No(s):</i>	<i>E-mail:</i>	
All laboratory personnel working at BSL-2 are required to have medical insurance. <i>Name, title and insurance carrier of personnel working with registered material at Biosafety Level 2</i>		
<i>Title of the protocol:</i>		
<i>Granting agency and I.D. number:</i>		
<p><i>Principal Investigator Acknowledgment</i></p> <p>I accept responsibility for:</p> <p>The safe use of all potentially infectious organisms at Biosafety Level _____ and have informed all personnel of the risks of exposures while working with these organisms and/or toxins.</p> <p>The conduct of this research in accordance with Section IV-B-5 of the NIH Guidelines for Research Involving Recombinant DNA Molecules.</p> <p>The safe use of human blood, body fluids, tissue, and/or cell lines using Biosafety Level 2 practices and procedures. All personnel have been informed of potential risks, and proper laboratory practices for working safely with HIV and other bloodborne pathogens and have had or have been given the opportunity for vaccination.</p>		
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Principal Investigator (Signature)Date		

Please send signed MUA to: Rocio Harrelson, Biological Safety Manager, Environmental Health and Risk Management Department, Mail Code 1005.

For information contact Ms. Harrelson at arharrelson@uh.edu or (713) 743-1200.

University of Houston

Memorandum of Understanding and Agreement Registration of Biohazardous Materials and Recombinant DNA 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 should follow the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidelines (4th Edition-1999).

Experiments using recombinant DNA technology should follow the NIH Guidelines for Research Involving Recombinant DNA (rDNA) Molecules, (April 2002).

The Principal Investigator (PI) is responsible for completing the appropriate parts of this registration document. The UH Institutional Biosafety Committee (IBC), in conjunction with the Environmental Health and Risk Management Department (EHRM), maintains a registry of all laboratories and personnel working with human pathogens, and/or toxins, human blood, body fluids, and tissue, and recombinant DNA technology.

The PI is also responsible for notifying EHRM 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.

This registration document is to be forwarded to EHRM (Biological Safety Manager) prior to the initiation of work. Each individual listed should be informed of the potential hazards associated with this work, the appropriate safety practices to be used, the availability of medical programs, and applicable training requirements.

EHRM conducts an annual survey of registered laboratories to review practices and procedures. The survey is not intended to negate the responsibilities of the PI in supervising work with potentially infectious or hazardous materials.

RISK GROUPS AND BIOSAFETY LEVELS should be determined using the BMBL and the NIH rDNA Guidelines. Additional information for infectious agents can be found in the American Biological Safety Association (ABSA) website (<http://www.absa.org/resriskgroup.html>)

SECTION B *Brief description of the research understandable to scientist working in different fields* - This summary should include: (a) hypothesis; (b) types of biological agents and toxins, their quantity, duration of experiment, and/or the rDNA technology to be applied; (c) significance of the project; (d) additional information to clarify experimental procedures, design, etc.

This project will use: **Biohazardous Material** **Biological Toxins** **Recombinant DNA**

Title of the protocol:

Description of research:

(a) Hypothesis

(b) Types of biological agents and toxins, their quantity, duration of experiment, and/or the rDNA technology to be applied

(c) Significance of the project

(d) Please include any additional information that may assist the IBC in the review of this protocol (e.g. description of experimental design, procedures, etc)

SECTION C Use of recombinant DNA technology				<input type="checkbox"/> Not Applicable
<i>Prokaryotic Hosts/ Eukaryotic Cells</i> <i>List Strains</i>	<i>Vector</i>	<i>DNA Insert</i>	<i>Relevant section of NIH Guidelines</i>	<i>Physical Containments</i>
<i>If viral vector is to be used will infectious virus be generated?</i> Yes				<input type="checkbox"/> No
<i>Will studies include attempts to obtain expression of a foreign gene, other than those used for selection purposes?</i> <input type="checkbox"/> No <input type="checkbox"/> Yes what protein _____				

SECTION D Potential human pathogens and/or toxins (please provide information for each microorganism and or toxin used, use additional space if needed)				<input type="checkbox"/> Not Applicable
<i>Organism:</i>	<i>Strain:</i>	<i>Volume used:</i>	<i>Risk Group:</i>	
<i>Biological Toxins:</i>		<i>Volume used:</i>	<i>Risk Group:</i>	
<i>Is organism concentrated?</i> <input type="checkbox"/> No <input type="checkbox"/> Yes <i>Specify methods:</i> <input type="checkbox"/> centrifugation <input type="checkbox"/> filtration <input type="checkbox"/> Precipitation <input type="checkbox"/> Other _____				
<i>Containment equipment available:</i> <input type="checkbox"/> Biological Safety Cabinet: Class _____ Last Certified: _____ <input type="checkbox"/> Fume Hood <input type="checkbox"/> Containment Centrifuge <input type="checkbox"/> Other _____				

SECTION E Use of animals

Are animals used in this project? No Yes Date IACUC Approval (if applicable)

<i>List all animals used in the project</i>	<i>Organism, toxin, or rDNA introduced</i>	<i>Routes of administration</i>

Types of animal tissue handled and/or animal cell lines

SECTION F Handling of Human Products (requires BSL-2 practices)

Are Human samples used in this project? No Yes Date IRB Approval (if Applicable)

Type of human samples manipulated

Cell lines Blood Tissue Urine Spinal Fluid Serum Feces Semen

Other _____ Specify _____

Type of manipulations:

Centrifugation Bleeding/Mixing Dissection Sonication Pipetting

Other _____

SECTION G. Training, Safety and Security Plan: State your safety, security, and personnel training procedures for the work

described in this MUA (e.g. PPE, locks, etc) – use the BMBL as a guide to write your safety procedures.

If you are working with animals describe in detail the safety protocol for handling infected animals in the animal care facility

Training Plan:

Safety and Security Plan:

Will ship or transport biohazardous material No Yes

Will generate biohazardous waste No Yes

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

<http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl3toc.htm> CDC - Biosafety in Microbiological and Biomedical Laboratories (BMBL)

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> NIH guidelines for work with recombinant DNA molecules

<http://www.absa.org/resriskgroup.html> ABSA - American Biological Safety Association Risk Group classification tables

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

APPENDIX B

Recommended Biosafety Level for Infectious Agents and Infected Animals

Recommended Biosafety Level for Infectious Agents and Infected Animals			
Bacterial Agents	BSL	ABSL	Comments
<i>Actinobacter calceticus</i>	2	2	
<i>Actinobacillus sp.</i>	2	2	
<i>Actinomyces sp.</i>	2	2	
<i>Aeromaonas sp.</i>	2	2	
<i>Arachnida propionica</i>	2	2	
<i>Bacillus alvei</i>	2	2	
<i>Bacillus anthracis</i> *	2/3	2/3	BMBL, vaccination recommended
<i>Bacteroides sp.</i>	2	2	
<i>Bartonella sp.</i>	3	3	
<i>Bordetella sp.</i>	2	2	
<i>Bordetella pertussis</i>	2	2/3	BMBL
<i>Borrelia sp.</i>	2	2	
<i>Brucella sp.</i> *	2/3	3	BMBL
<i>Campylobacter fetus var. jejuni</i>	2	2	BMBL
<i>Camplobacter sp.</i>	2	2	
<i>Chlamydia psittaci</i>	2	3	BMBL
<i>Chlamydia pneumoniae</i>	2/3	2	BMBL
<i>Chlamydia trachomatis</i>	3	3	
<i>Clostridium botulinum</i> *	2/3	2	BMBL
<i>Clostridium tetani</i>	2		BMBL
<i>Corynebacterium diphtheriae</i>	2	2	BMBL
<i>Corynebacterium equi</i>	2	2	
<i>Corynebacterium haemolyticum</i>	2	2	
<i>Corynebacterium pseudotuberculosis</i>	2	2	
<i>Corynebacterium pysogenes</i>	2	2	
<i>Corynebacterium renale</i>	2	2	
Enterobacteriaceae all other	2	2	
<i>Erysipelothrix rhusiopathiae</i>	2	2	
<i>Escherichia coli</i>	2	2	
<i>Escherichia coli</i> K12 derivative	1	1	
<i>Francisella tularensis</i> *	2/3	3	BMBL

Bacterial Agents - continue	BSL	ABSL	Comments
<i>Fusobacterium sp.</i>	2	2	
<i>Haemophilus sp.</i>	2	2	
<i>Klebsiella sp.</i>	2	2	
<i>Legionella pneumophilia</i>	2/3	2	BMBL
<i>Leptospira interrogans</i> all servars	2	2	BMBL
<i>Listeria sp.</i>	2	2	
<i>Moraxella sp.</i>	2	2	
<i>Mycobacterium avium</i>	2	2	
<i>Mycobacterium bovis</i>	3	3	BMBL
<i>Mycobacterium leprae</i>	2	2	BMBL
<i>Mycobacterium sp.</i>	2	2	BMBL
<i>Mycobacterium tuberculosis</i>	2/3	2/3	BMBL
<i>Mycoplasma sp.</i>	2	2	
<i>Neisseria gonorrhoeae</i>	2/3	2	BMBL
<i>Neisseria meningitidis</i>	2/3	2	BMBL
<i>Nocardia sp.</i>	2	2	
<i>Pasteurella sp.</i>	2	2	
<i>Pseudomonas mallei</i>	2/3	3	BMBL
<i>Neisseria gonorrhoeae</i>	2/3	2	BMBL
<i>Pseudomonas testoserone</i>	2	2	
<i>Rotococcus (Coryne.) equi</i>	2	2	
<i>Salmonella sp.</i>	2	2	BMBL
<i>Salmonella typhi</i>	2/3	2	BMBL
<i>Shigella sp.</i>	2	2	BMBL
<i>Staphylococcus sp.</i>	2	2	
<i>Streptococcus sp.</i>	2	2	
<i>Streptocacillus moniliformis</i>	2	2	
<i>Streptomyces somaliensis</i>	2	2	
<i>Treponema pallidum</i>	2	2	BMBL
<i>Vibrio sp.</i>	2	2	BMBL
<i>Yersinia pestis*</i>	2/3	3	BMBL, immunization recommended

BMBL - Agent summary and biosafety levels according to type of activities are listed in the CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories 4th Edition

V - Vaccination is recommended for personnel
* - Select agents

Fungal Agents	BSL	ABSL	Comments
<i>Blastomyces dermatitides</i>	2	2	BMBL
<i>Coccidioides immitis</i> *	2/3	2	BMBL
<i>Cryptococcus neoformans</i>	2	2	BMBL
<i>Epidermophyton - pathogenic sp.</i>	2	2	BMBL
<i>Histoplasma capsulatum</i>	2/3	2	BMBL
<i>Microsporium - pathogenic sp.</i>	2	2	BMBL
<i>Paracoccidioides brasiliensis</i>	2	2	
<i>Sporothrix schenckii</i>	2	2	BMBL
<i>Trichophyton - pathogenic sp.</i>	2	2	BMBL
<i>Candida albicans</i>	2	2	
Miscellaneous Molds	2		BMBL

BMBL - Agent summary and biosafety levels according to type of activities are listed in the CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories 4th Edition

V - Vaccination is recommended for personnel
* - Select agents/toxins

Parasitic Agents	BSL	ABSL	Comments
<i>Anaplasma sp.</i>	2	2	
<i>Ascaris sp.</i>	2	2	BMBL
<i>Coccidia sp.</i>	2	2	BMBL
<i>Cryptosporidia sp.</i>	2	2	BMBL
<i>Echinococcus Granulosus</i>	2	2	BMBL
<i>Ehrlichia sp.</i>	2	2	
<i>Entamoeba sp.</i>	2	2	BMBL
<i>Enterobius sp.</i>	2	2	BMBL
<i>Fasciola sp.</i>	2	2	BMBL
<i>Giardia sp.</i>	2	2	BMBL
<i>Haemobartonella sp.</i>	2	2	
<i>Hymenolepsis nana</i>	2	2	BMBL
<i>Leishmania sp.</i>	2	2	BMBL
<i>Leukocytozoon sp.</i>	2	2	

Parasitic Agents - continue	BSL	ABSL	Comments
<i>Naegleria sp.</i>	2	2	
<i>Plasmodium sp.</i>	2	2	BMBL
<i>Sarcocystis sp.</i>	2	2	BMBL
<i>Schistosoma sp.</i>	2	2	BMBL
<i>Strongyloides sp.</i>	2	2	BMBL
<i>Taenia solium</i>	2	2	
<i>Toxocara canis</i>	2	2	
<i>Toxoplasma sp.</i>	2	2	BMBL
<i>Trichinella spiralis</i>	2	2	BMBL
<i>Trypanosoma sp.</i>	2	2	BMBL
BMBL - Agent summary and biosafety levels according to type of activities are listed in the CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories 4th Edition			
V - Vaccination is recommended for personnel			
* - Select agents/toxins			

Rickettsial Agents	BSL	ABSL	Comments
<i>Coxiella burnetii</i> *	2/3	3	BMBL
<i>Rickettsia akari</i>	2/3	2/3	
<i>Rickettsia australis</i>	2/3	2/3	BMBL
<i>Rickettsia canada</i>	2/3	2/3	BMBL
<i>Rickettsia conorii</i>	2/3	2/3	BMBL
<i>Rickettsia prowazekii</i> *	2/3	2/3	BMBL
<i>Rickettsia rickettsii</i> *	2/3	2/3	BMBL
<i>Rickettsia siberica</i>	2/3	2/3	BMBL
<i>Rickettsia tsutsugamushi</i>	2/3	2/3	BMBL
<i>Rickettsia typhi (R. mooseri)</i>	2/3	2/3	BMBL
Rickettsial Agents - continue	BSL	ABSL	Comments
<i>Rochalimaea quintana</i>	2	2	
<i>Rochalimaea vinsonii</i>	2	2	
Spotted Fever Group - other	2/3	2/3	
BMBL - Agent summary and biosafety levels according to type of activities are listed in the CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories 4th Edition			
V - Vaccination is recommended for personnel			
* - Select agents/toxins			

Viral Agents	BSL	ABSL	Comments
Adenoviruses	2	2	
Adenoviruses - animal - all	2	2	
Aleutian Disease Virus	2	2	
Arboviruses - certain	2	2	BMBL
Arboviruses - certain	3	3	BMBL
Arboviruses - certain	4	4	BMBL
Arenaviruses - certain	3	3	BMBL
Arenaviruses - certain	4	4	BMBL
Avian Erthyroblastosis Virus	2	2	
Avian Leucosis Virus	2	2	
Avian Lymphomatosis Virus	2	2	
Avian Myeloblastosis Virus	2	2	
Bovine Encephalomyelitis Virus	2	2	
Bovine Leukemia Virus	2	2	
Bovine Respiratory Syncytial Virus	2	2	
Bovine Rhinotracheitis (IBR)	2	2	
Cache Valley Virus	2	2	BMBL
Canine Hepatitis Virus	2	2	
Canine Distemper Virus	2	2	
Caprine Arthritis	2	2	
Coxsackie A & B Viruses	2	2	
Cytomegaloviruses	2	2	
Encephalomyelitis Virus*	2	2	
Echovirus	2	2	
Viral Agents - continue	BSL	ABSL	Comments
Dengue Virus	2	3	BMBL
Encephalomyocarditis Virus	2	2	
Epidemic Diarrhea Infant Mice	2	2	
Epstein-Barr Virus	2	2	
Feline Leukemia Virus	2	2	
Feline Sarcoma Virus	2	2	
Viral Agents - continue	BSL	ABSL	Comments

Filoviruses	2	2	
Flanders Virus	2	2	BMBL
Gibbon Ape Lymphosarcoma	2	2	
Hart Park Virus	2	2	BMBL
Hemorrhagic Fever Agents*	2	2	
Hepatitis A Virus, Hepatitis E Virus	2	2	BMBL
Hepatitis B Virus, Hepatitis C Virus, Hepatitis D Virus	2	2	BMBL
Herpesvirus - other	2	2	
Herpesvirus ateles	2	2	
Herpesvirus saimir	2	2	
Herpesvirus Simiae (B-virus)	3	3	BSL-2, -3 or -4 depending on activity, BMBL
Human Herpesviruses	2	2	BMBL
Hog Cholera Virus	2	2	
Human T-Cell Leukemia Virus I & II	2	2	
Infectious Bronchitis Virus	2	2	
Influenza Virus	2	2	BMBL
Influenza Virus Virulent Avian	3	3	
K (Rate) Virus	2	2	
Lactic Dehydrogenase Elevating	2	2	
Langat Virus	2	2	BMBL
Laryngotracheitis Virus	2	2	
Lassa Virus*	4	4	BMBL
Low Risk Oncogenic Viruses	2	2	
Lymphocytic Choriomeningitis Virus	2/3	2/3	BMBL
Marburg Virus*	4	4	BMBL
Measles Virus	2	2	
Memningopneumonitis Virus	2	2	
Mouse Encephalomyelitis Virus	2	2	
Viral Agents - continue	BSL	ABSL	Comments

Mouse Hepatitis Virus	2	2	
Mouse Leukemia Virus	2	2	
Mouse Pneumonia Virus	2	2	
Mumps Virus	2	2	
Myxomatosis Virus	2	2	
Newcastle Disease Virus	2	2	
Newcastle Disease Virus (VVND)	2	2	
Non-Defective Adenovirus 2SV40 HYB	2	2	
Papilloma Virus Shope	2	2	
Parainfluenza Virus	2	2	
Poliovirus - all types	2	2	BMBL
Polyoma Virus	2	2	
Poxvirus alastrim	2	2	
Poxvirus monkey pox	3	3	
Poxvirus - Smallpox*			restricted use by WHO
Poxvirus sp.	2	2	BMBL
Pseudorabies Virus	2	2	
Rabies Virus	2/3	2/3	BMBL
Reovirus sp.	2	2	
Respiratory Syncytial Virus	2	2	
Retroviruses, including HIV & SIV	2/3	2/3	BMBL
Rhinovirus sp.	2	2	
Rous Sarcoma Virus	2	2	
Rubella Virus	2	2	
Simian Virus - other	2	2	
Simian T-Cell Leukemia Virus	2	2	
Sindbis Virus	2	2	
Slow Viruses	2	2	
Tensaw Virus	2	2	
Tick-Borne Encephalitis Complex	4	4	
Turlock Virus	2	2	
Viral Agents - continue	BSL	ABSL	Comments

Transmissible Spongiform Encephalopathies (Creutzfeldt-Jakob, kuru, and related agents)	2	2	BMBL
Vaccinia Virus	2	2	
Venezuelan Equine Encephalitis*	3	3	
Vesicular Stomatitis - lab adapted	2	2	BMBL
Vesicular Somatitis Virus	3	3	BMBL
Woolly Monkey Fibrosarcoma	3	3	
Yaba Virus	2	2	
Yellow Fever Virus 17D Strain*	2	2	BMBL
Yellow Fever Virus Except 17D*	3	3	BMBL
BMBL - Agent summary and biosafety levels according to type of activities are listed in the CDC/NIH's Biosafety in Microbiological and Biomedical Laboratories 4th Edition			
V - Vaccination is recommended for personnel			
* - Select agents/toxins			

APPENDIX C.

Select Agent List

Select Agents

The United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have identified bacteria, viruses, toxins, rickettsia, and fungi that pose a potential threat to public health or welfare. These organisms are considered Select Agents and High Consequence Livestock Pathogens and Toxins.

Materials regulated as Select Agents are listed below. If you use or intend to use any of these agents, contact EHRM office at 713-743-1200. Some exemptions and prohibitions apply.

Viruses

- African horse sickness virus¹
- African swine fever virus¹
- Akabane virus¹
- Avian influenza virus (highly pathogenic)¹
- Blue tongue virus (exotic)¹
- Camel pox virus¹
- Cercopithecine herpes virus (Herpes B virus)³
- Classical swine fever virus¹
- Crimean-Congo haemorrhagic fever virus³
- Eastern equine encephalitis virus²
- Ebola viruses³
- Foot and mouth disease virus¹
- Goat pox virus¹
- Japanese encephalitis virus¹
- Lassa fever virus³
- Lumpy skin disease virus¹
- Malignant catarrhal fever¹
- Marburg virus³
- Menangle virus¹
- Monkey pox virus¹
- Newcastle disease virus (exotic)¹
- Nipah and Hendra complex viruses²
- Peste des petits ruminants¹
- Plum pox potyvirus⁴
- Rift Valley fever virus²
- Rinderpest virus¹
- Sheep pox¹
- South American haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)³
- Swine vesicular disease virus¹
- Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern --Tick-borne encephalitis, Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)³
- Variola major virus (Smallpox virus) and Variola minor (Alastrim)³
- Venezuelan equine encephalitis virus²
- Vesicular stomatitis virus (exotic)¹

Prions

- Bovine spongiform encephalopathy agent ¹

Toxins

- Abrin ³
- Botulinum neurotoxins ²
- *Clostridium perfringens* epsilon toxin ²
- Conotoxins ³
- Diacetoxyscirpenol ³
- Ricin ³
- Saxitoxin ³
- Shigatoxin and Shiga-like ribosome inactivating proteins ²
- *Staphylococcal* enterotoxins ²
- Tetrodotoxin ³
- T-2 toxin ²

Bacteria

- *Bacillus anthracis* ²
- Botulinum neurotoxin producing strains of *Clostridium* ²
- *Brucella abortus* ²
- *Brucella melitensis* ²
- *Brucella suis* ²
- *Burkholderia mallei* ²
- *Burkholderia pseudomallei* ²
- *Coxiella burnetii* ²
- *Cowdria ruminantium* (Heartwater) ¹
- *Francisella tularensis* ²
- *Liberobacter africanus*, *Liberobacter asiaticus* ⁴
- *Mycoplasma capricolum* / *M. F38* / *M. mycoides capri* (contagious caprine pleuropneumonia agent) ¹
- *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia agent) ¹
- *Ralstonia solanaceanon Race 3* ⁴
- *Rickettsia prowazekii* ³
- *Rickettsia rickettsii* ³
- *Xanthomonas oryzae pv. oryzicola* ⁴
- *Xylella fastidiosa* (citrus variegated chlorosis strain) ⁴
- *Yersinia pestis* ³

Fungi

- *Coccidioides immitis* ²
- *Coccidioides posadasii* ³
- *Peronoscleospora philippinensis* ⁴
- *Phakopsora pachyrhizi* ⁴
- *Sclerophthora rayssiae var zea* ⁴
- *Synchytrium endobioticum* ⁴

¹USDA High Consequence Livestock Pathogens or Toxin

²USDA/HSS Overlap Agent

³HHS Select Infectious Agent

⁴APHIS Plant Pathogens (Animal and Plant Health Inspection Service, a division of USDA)

APPENDIX D.

Exposure Control Plan – Bloodborne Pathogens

UNIVERSITY OF HOUSTON
ENVIRONMENTAL HEALTH AND RISK MANAGEMENT
BIOLOGICAL SAFETY PROGRAM

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 Health Bloodborne Pathogens Exposure Control Plan requires employers to perform an exposure determination for employees 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 employees 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 employees. 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 employees, 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 employees 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, employees wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water. If employees

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, leakproof 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, employees 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 employees, service representatives, and/or the manufacturer, as appropriate.

Personal Protective Equipment

All personal protective equipment used is provided without cost to employees. 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, eyewear with side shields, gowns, lab coats, aprons, shoe covers, face shields, and masks. All personal protective equipment is fluid resistant.

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 employees will have hand contact with blood, other potentially infectious materials, non-intact skin, and mucous membranes. Latex sensitive employees 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, glasses with solid side shield, 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 and commonsense storage and processing of clean and 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:

Imperial Linen Service	(713) 223-1365
Pilgrim Cleaners	(713) 394-9665
MW Cleaners	(713) 667-7474

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 employees is conducted prior to initial assignment to tasks where occupational exposure may occur. All employees also receive annual refresher training. Training is offered by the University every spring and fall semester or upon departmental requests.

Training for employees 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 employees 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.
- Employees receive the vaccine at the University Health Center.
- Employees who decline the Hepatitis B vaccine sign a declination statement (see attached copy).
- Employees 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 Environmental Health and Risk Management's Claims Coordinator (713-743-8024) for referral to a physician. All employees 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.

- The Environmental Health and Risk Management department 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 the Biological Safety Manager (713-743-1200) in the Environmental Health and Risk Management Department. The Department of Environmental Health and Risk Management 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

EXPOSURE TO BLOODBORNE PATHOGENS - HEPATITIS B VACCINE

NAME: _____

TITLE: _____

DEPARTMENT: _____

TELEPHONE: _____ E-MAIL: _____

Please check the appropriate box, fill all information requested, and if appropriate sign the declination statement.

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

I received the Hepatitis B vaccine at a previous place of employment
Name of Institution: _____
Date of vaccination: _____

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 _____

Please fill out one form for each staff member and fax or mail this form to the Environmental Health and Risk Management Department, Attention Biological Safety Manager, Mail Code 1005, Fax # 713-743-8035

APPENDIX E.

List of Disinfectants

Chemical Disinfectant List

Chlorine Compounds

5000 ppm concentration needed
contact time: 10 to 30 minutes
wide spectrum germicidal
sanitizing properties
no residue
low toxicity
bronchial irritant and skin irritation from extended contact
good for disinfecting surfaces
solution must be made fresh (at least monthly) since chlorine will off-gas
light contact (accelerates decomposition) prevented by using opaque containers

Quaternary Ammonium Compounds

0.1 to 2% concentration of active ingredient needed
contact time: 10 to 30 minutes
soluble in water
excellent for vegetative bacteria (gram +), lipo viruses, and HIV
good detergent properties
relatively non-toxic
not effective with spores and poor response with Pseudomonas
best for routine disinfecting of surfaces

Alcohol (ethyl or isopropyl)

60-95% concentration needed
contact time 10 to 30 minutes
effective on vegetative bacteria
no residue formation
non-toxic (generally)

Formaldehyde

4-8% concentration needed
contact time: 10 to 30 minutes
wide spectrum germicide
active in organic matter
can cause allergic dermatitis and is a suspected carcinogen
not recommended for routine use

Iodophor Compounds

0.47% concentration of iodine needed
contact time: 10 to 30 minutes
relatively non-toxic
wide spectrum germicide
fairly safe to use
not stable above 54°C

Phenolics

0.2 to 3.0% concentration effective
contact time: 10 to 30 minutes
wide spectrum antimicrobial agent
excellent sanitizing agent
toxic compound and a poor sporicidal agent

Glutaraldehyde

mode of action is alkylation
used in a 2% dilution
contact time: 10 to 60 minutes
a chemosterilizer and high level disinfectant
typically used for medical equipment such as endoscopes