Overview

The Occupational Safety and Health Administration (OSHA) enacted the Bloodborne Pathogens Standard in 1991. Its purpose is to promote safe work practices, and to ensure that all workers are protected from exposure to the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and other disease causing pathogens in human blood, body fluids, and tissues. Environmental Health and Safety (EHS) has prepared this plan to be used as a guide in developing department specific procedures for reducing exposures to bloodborne pathogens in the workplace.

Purpose

It is the policy of Boston University to maintain a safe and healthy workplace for all employees who must work with human, including but not limited to human blood and other potentially infectious materials. The provisions of the OSHA Bloodborne Pathogen Standard and Biosafety Manual are the basis for the Boston University compliance program and all employees, contractors and visitors are required to follow the requirements described in this Exposure Control Plan. The Boston Medical Center has a separate Exposure Control Plan for Hospital employees and operations.

Scope

This manual applies to all BU research activities involving biological agents. All faculty, staff, students, and visitors who work on BU or BMC-sponsored projects or at BU facilities are included in the scope of this manual.

This Exposure Control Plan applies to all Boston University (BU) personnel with occupational exposure to human, body fluids or tissues, or other potentially infectious materials as defined by OSHA. Established cultured human are also included as potential blood borne pathogens, whether characterized to be free of contamination or not. Occupational Exposure is any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of the employee’s duties. For additional information on other blood borne pathogens, employees should consult the Boston University Biosafety Manual, their Principal Investigator, Supervisor, or Research Occupational Health Program on either campus where information is available upon request.

Additional requirements and training beyond this program may be required by the IBC. Additional requirements such as permitting and registration, inspection, specialized procedures and training are required for BSL3 and higher laboratories.

Bloodborne Pathogens are defined as:

- Human Blood
- Human Blood Components
- Products made from human blood
- Semen
- Vaginal secretions

- Cerebrospinal fluid
- Synovial fluid
- Pericardial fluid
- Amniotic fluid
- Saliva in dental procedures

Additional pathogens include:
Exposure Control Plan (ECP)

- Any body fluid that is visibly contaminated with blood, and all bodily fluid in situations where it is difficult or impossible to differentiate between body fluids.
- Any unfixed tissue or organ (other than intact skin) from a human (living or deceased)
- HIV-containing cell or tissue cultures, organ cultures, and HIV-, HBV- or HCV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals with HIV, HBV or HCV
- Any other potentially infectious material of human origin
Methods of Compliance

A written Exposure Control Plan must be developed and implemented for all employees with potential for exposure to blood borne pathogens. The following elements are essential to the effectiveness of the BU blood borne pathogen compliance program:

Roles and Responsibilities
The PI/laboratory director/employee supervisor must conduct an Exposure Determination to identify employees under his or her supervision who may be at risk. Upon identifying these employees, the supervisor must: (NOTE: A model Exposure Control Plan is provided as Appendix A.)

- Reduce potential risk by providing personal protective clothing and equipment.
- Provide HBV vaccinations at no cost to the employee (available through the Research Occupational Health Program).
- Train the employees.
- Develop an effective written hazard communication program.
- Ensure that engineering controls, such as biological safety cabinets or sharps containers are available.
- Develop safe work practices and procedures, as well as internal notification procedures to report accidents.
- In conjunction with the academic department, review the list of at-risk employees on an annual basis to ensure that the list is current.
- The Model Exposure Control Plan should be used to ensure that the above steps are implemented.

Exposure Determination
Jobs within the work environment must be evaluated, and specific work tasks and procedures that may lead to occupational exposure to blood borne pathogens must be listed. Occupational exposure means any reasonably anticipated eye, skin, mucous membrane, or parenteral contact (i.e., needlestick) with blood or other potentially infectious materials). An example would be a lab technician who processes blood samples or other potentially infectious materials.

Job classifications where all have occupational exposure
Boston University has determined that all researchers working directly with human materials/subjects and personnel working in laboratories using human source materials and/or subjects have occupational exposure.

Job classifications where some may have exposure
Additionally, job classifications in which some workers may have a potential for occupational exposure include Principal Investigators, Research Assistants, Laboratory technicians, Public Safety Officers, Custodians, Emergency Responders, and Plumbers.

Training
Each PI or manager must ensure that they and all their employees with the potential for occupational exposure participate in a training program provided by EHS at no cost to the employee during working hours. Training must be given upon initial assignment, and on an annual basis thereafter, or whenever
modification of an existing job description may affect the employee’s potential for occupational exposure.

HIV/HBV research laboratories must ensure that their employees demonstrate proficiency in standard microbiological procedures prior to being allowed to work in the laboratory.

Training must include a comprehensive discussion of this standard, including epidemiology, symptoms and transmission of bloodborne diseases; the Exposure Control Plan; the uses, limitations of, and procedures for using Personal Protective Equipment (PPE); a discussion of the HBV vaccination (including the benefits of vaccination and efficiency of the vaccine to prevent disease); emergency procedures involving blood exposure or contamination and post-exposure follow-up procedures; hazard communication; and a question-and-answer discussion opportunity.

**Vaccination and Post-exposure evaluation**

Under the OSHA Bloodborne Pathogen Standard, the hepatitis B vaccine must be offered to all employees at risk within 10 days of starting their work assignment.

Employees must be informed of the vaccine’s benefits and risks, and if they choose not to receive it at the initial evaluation, they must sign a declination form.

If the employee has had the vaccine previously, but has not had a blood antibody titer to confirm his or her immunity, the employee will be offered the opportunity to have a titer drawn. An employee who declines the vaccine may at any time elect to have the vaccine if his or her job tasks or work setting continue to have the risk of potential exposure to bloodborne pathogens.

Any person present in a BU laboratory who has an incident involving potential exposure to an infectious agent is offered **immediate** access to a medical evaluation from the Research Occupational Health Program (listed below) or the BMC Emergency Department (after hours, holidays, and weekends). For immediate medical attention, on the Charles River Campus please call Boston University Police Department 617-353-2121, On the Boston University Medical campus, please contact Public Safety at 617-414-4444. An immediate evaluation is important, as efficacy of post-exposure medication for HIV and other infectious agents may be less effective if the initiation of treatment is delayed.

**Contacting Research Occupational Health Program:**

On Boston University Medical Campus/Boston Medical Center, Research Occupational Health Program is available via telephone 24 hours per day / 7 days per week. Contact ROHP at (617) 414-7647.

On the Charles River Campus, Research Occupational Health Program may be reached 24 hours per day / 7 days per week by telephone at (617) 414-7647.

**BMC East Newton Campus Emergency Department** is available after hours, on holidays, and during weekends. Contact Research Occupational Health Program at (617) 414-7647.

Questions may be directed to: Research Occupational Health Program at (617) 414-7647.
Personal Protective Equipment (PPE)
All blood borne pathogens are presumed to be infectious, (the concept of “universal precautions”), and appropriate PPE, such as gloves, safety glasses, and lab coats must be worn when handling blood or other potentially infectious materials, otherwise known as OPIM in the OSHA Blood borne Pathogen Standard. All PPE must be used, maintained and disposed of as specified in the Boston University Biosafety Manual, and Laboratory-specific Standard Operating Procedures (SOPs).

Gloves
Must be worn when it is reasonably anticipated that there may be hand contact with blood, potentially infectious materials, mucous membranes, non-intact skin and/or when touching potentially contaminated surfaces.

Eye protection
Eye protection devices such as safety glasses with side shields, or goggles must be used whenever there is potential for splash, spray, splatter of potentially infectious material.

Body protection
Lab coats, face shields, gowns, aprons, and other protective garments may be required based upon the task and the degree of exposure anticipated.

Additional protective equipment, including respirators may be required based on the Department/Lab-specific exposure determination.

Engineering and Work Practice Controls
As outlined in the Boston University Biosafety Manual, standard microbiological practices such as frequent glove changing and hand washing, restricting sharps handling and establishing safe procedures for disposal, work area restrictions including limited access, specimen handling and transit, posting and labeling, and frequent decontamination must be followed to prevent exposure. All potentially contaminated equipment and areas must be labeled with the Universal Biohazard Symbol

Engineering controls include biological safety cabinets, mechanical pipettes, self-sheathing needles, enclosed containers, safety centrifuge cups, and other engineered solutions designed to minimize exposure to biological agents.

Biological safety cabinets are the most important safety equipment for protection of personnel in the laboratory environment, and most will also provide product protection. Workers must be trained on the proper use of such equipment and the equipment must be regularly inspected and maintained.

Housekeeping
Bench tops, counters and all other equipment used to work with blood and OPIM must be disinfected at the end of each work day, when work surfaces are contaminated, or after a spill. The Boston University Biosafety Manual provides additional guidance on these topics.

Waste
All regulated blood borne pathogen contaminated waste must be disposed of properly as biohazardous waste, consistent with the Boston University and Commonwealth of Massachusetts waste rules. All biohazardous waste must be segregated from other wastes (general, chemical and radioactive) to protect
Exposure Control Plan (ECP)

Use with Appendix L of the Boston University Biosafety Manual

employees, the general public and the environment. The Boston University Biosafety Manual and Department and Lab-specific SOPs provide specific guidance and direction.

References

BU/BMC Biosafety manual Appendix L
DPH Waste Regulations 105 CMR 480.000
Boston University
Model Exposure Control Plan

Template for Laboratories

This is a model for developing your written blood borne pathogens exposure control plan. It needs to be adapted to fit your specific needs. Be sure to consult the Boston University Biosafety Manual, Blood borne Pathogen Standard, and the IBC for requirements that apply to your workplace.

Each Principal Investigator/Manager (PI/supervisor) must complete an Exposure Control Plan based on the nature of the work being carried out in their facilities.

Once completed, keep the plan on file in a central location within the laboratory/work place along with the Boston University Biosafety Manual for all personnel to access.
EXPOSURE CONTROL PLAN

*Pi/Department Name*

is committed to providing a safe and healthful work environment for our entire staff. This is our plan to eliminate or minimize occupational exposure to blood borne pathogens (BBP). This exposure control plan is designed to minimize or eliminate employee exposure to blood borne pathogens.

Employees who have occupational exposure to blood or other potentially infectious material (OPIM) must follow the procedures and work practices in this plan. Employees can review this plan at any time.

This Exposure Control Plan and the *Boston University Biosafety Manual* describe how to eliminate or minimize exposure of Boston University personnel to human/primate blood or human/primate blood products that might contain blood borne pathogens. This plan is in compliance with OSHA Blood borne Pathogens Standard.

All employees must receive initial and annual BBP training, and be offered the hepatitis B vaccination.

__________________________  __________________
Signature of Pi/Supervisor    Date

__________________________  __________________
Signature of EHS Departmental Safety Advisor Date

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<tr>
<th>PI/Supervisor</th>
<th>Department</th>
<th>Building/Room</th>
<th>Lab Contact</th>
<th>Phone</th>
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*Boston University Exposure Control Plan*
Workplace Exposure Determination The following checked procedures and materials in the laboratory/workplace are potential sources of BBP exposure to personnel. Note that this evaluation does not take into consideration the use of personal protective equipment (PPE). Many of the potential materials are listed here.

[ check all that apply]

- All human substances, including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, and other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations, such as emergency response, where it is difficult or impossible to differentiate between body fluids.
- Any unfixed human or primate tissue or organ (other than intact skin) from a human (living or dead).
- Any HIV, HBV, HCV-containing cell or tissue culture, organ cultures, and medium or other solutions, and blood, organs, or other tissues from experimental animals containing HIV, HBV, or HCV.
- Other procedures or materials (describe)_________________________________________________________________
_________________________________________________________________

Job Categories/Names of personnel who may reasonably be expected to have contact with BBP’s. [Identify the job titles and names of worker for which this section is relevant].

Exposed Personnel

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All of the above personnel must be offered the hepatitis B vaccination and receive initial and annual BBP training

Tasks and Procedures: The following procedures used in the work place may create a risk of BBP exposure [check off all that might apply].

- Phlebotomy or venipuncture of humans or primates
- Injections into humans or animals using primate or human specimens
- Other use of needles with human or primate specimens
- Handling human or primate tissue, including preparation, dissection, cutting
- Pipetting, mixing, or vortexing human or primate blood, fluid, or tissue
- Centrifuging human or primate blood, fluid, or tissue
- Handling tubes or other container or human or, fluid, or tissue
- Handling contaminated sharps or other contaminated waste
- Cleaning spills of human or primate blood or other body fluids
- Preparing or handling primary human or primate cell cultures
- Other ________________________________________________________________
Methods of Compliance

Information and Training
All personnel listed as “exposed personnel” must receive general laboratory safety training and Blood borne Pathogen (BBP) training provided by Environmental Health and Safety. BBP training is required upon initial assignment, on an annual basis thereafter, and whenever modification of the job description may affect the employee’s potential for occupational exposure.

Laboratory/workplace specific training will be provided by the PI/supervisor and will include specific safety training for each person’s duties, including specific equipment usage and procedures. Laboratory and workplace – specific training shall be documented and the records maintained by the PI/supervisor (or department) for at least three years.

Written Exposure Control Plan
Upon completion of this laboratory specific plan, the PI/supervisor must file it in a central location within the laboratory along with the Boston University Biosafety Manual for all personnel to access. This plan will be reviewed and revised annually or whenever changes in procedure or personnel occur. Additional copies of the template plan are available through EHS and on www.bu.edu/research/compliance web site.

Engineering and Work Practice Controls Engineering and work practice controls must be used to eliminate or minimize exposure to individuals. The following engineering and work practice controls will be utilized:

Personal Protective Equipment (PPE)
Personal protective equipment (PPE) is provided without cost to all individuals who are at risk of occupational exposure to blood borne pathogens. All PPE must be inspected, cleaned, or replaced as needed. PPE will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the individual's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

All PPE must be selected with the goal of providing protection from a hazard. And as specified by the IBC. Selection of alternate choices of PPE should be considered if the user is at risk of discomfort (such as contact dermatitis from latex gloves or asthma from wearing certain face masks).
Proper training on the wearing and function of personal protective equipment is required PRIOR to using PPE. Consultation or advice on PPE is provided by EHS.

Eye protection
Protective eye wear must be worn in the laboratory when it is reasonably anticipated that blood or other potentially infected material may make contact with the mucous membranes of the eye. Face shields may be required as additional protection if there is a potential for splashes, sprays, or aerosols to the face.
Lab coats and uniforms
Laboratory coats, gowns, smocks, aprons, or uniforms must be worn while in the laboratory; long sleeves are required. Sandals, open-toed shoes and shoes which do not completely cover the feet are not permitted. Before leaving the laboratory for non-laboratory areas (e.g., cafeteria, administrative offices), all protective clothing must be removed and left in the laboratory.

Gloves
All personnel engaged in activities that may involve skin contact with potentially infectious fluids or tissues must wear gloves. Gloves are also required for laboratory workers with dermatitis or other lesions on the hands who may have direct or indirect contact with potentially infectious materials. Hand washing with soap and water must be a routine practice immediately after direct contact with potentially infectious materials and on completion of work, even when gloves are worn. Gloves should be removed before touching common equipment (phone, computer, appropriate laboratory equipment) to prevent contamination.

Personnel must wear gloves, lab coat, and safety glasses whenever handling human or primate blood, fluids, or tissue. Gloves must be replaced frequently and immediately if they become contaminated or damaged in any way. In addition to above items, personnel must wear any additional PPE (apron, booties, face shield, etc.) that is needed to prevent blood or other potentially infectious material from contaminating their street cloths, skin, eyes, mouth, or other mucous membranes under normal conditions. All PPE shall be removed prior to leaving the work areas and placed in designated areas for disinfection or disposal. At no time will personnel be permitted to take home any PPE, including lab coats, for laundering or cleaning.

Hand washing
Personnel must wash their hands immediately upon removal of gloves and upon any contact with potential BBP materials.

Mouth pipetting
Mouth pipetting is prohibited.

No eating, drinking
Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are not permitted in work areas. Food and drink are not to be carried through, placed or stored in areas (refrigerators, microwaves, etc.) where potential BBP are kept or may be present.

Needles, sharps, and broken glass
Used needles and other sharps are not to be sheared, bent, broken, recapped, or resheathed by hand. Used needles are not to be removed from disposable syringes. Disposable sharps must not be reused. All sharps, contaminated or not, shall be disposed of in a puncture-resistant hard sided, labeled sharps container.

Any broken glassware must not be directly handled with a gloved or bare hand. Use a mechanical tool (tongs, dustpan and broom) to collect the pieces into a hard-sided container labeled ‘broken glass’. Contaminated broken glass must be placed in a puncture-resistant hard sided container and disposed of as biohazardous waste.
Minimization of aerosols
All procedures must be performed carefully to minimize the creation of aerosols. Biological safety cabinets or other physical containment devices must be used whenever possible while performing operations capable of creating aerosols, including but not limited to:

- centrifugation
- blending
- homogenization
- opening pressurized containers, including vacuum sealed test tubes.

If a biological safety cabinet cannot be used, the most effective means of minimizing exposure to aerosols is to contain them by using closed containers (centrifuge tubes, sealed centrifuge rotors, capped test tubes, etc.). The Boston University IBC may specify additional requirements.

Disinfection of work area and spill cleanups
Blood and blood products shall be handled in an area that can be readily decontaminated. The work area must be disinfected before and after handling microorganisms. Non-laboratory personnel should not handle equipment that has been used with potential BBP’s until it has been decontaminated. All spills must be cleaned up immediately and disinfected with a germicide by appropriate decontamination procedures determined by the laboratory supervisor. The laboratory supervisor or other laboratory personnel must immediately report laboratory accidents.

Labeling
A biohazard warning sign incorporating the universal biohazard symbol shall be posted on the access door to the laboratory work area. All human tissue, body fluid, or other potentially infectious materials must be stored in a container labeled with a biohazard symbol. Refrigerators, freezers, incubators, or other pieces of equipment where potentially infectious materials are stored or handled must also be labeled with the biohazard symbol. All signs are available from EHS.

Limited access
Access to a laboratory is limited or restricted by the laboratory supervisor when work is in progress. When work with blood or blood products is being performed, non-laboratory personnel (maintenance, administrative personnel) and non-Boston University personnel should be discouraged from entering. If they must enter a facility, the hazards of the work being performed must be fully explained. Maintenance and building services personnel may be unfamiliar with the potential hazards present in the laboratory and must be fully instructed and carefully supervised by the laboratory supervisor when working in areas where human blood and blood products are handled. Areas where maintenance work is to be performed must be evaluated and decontaminated as necessary prior to starting the work.

Transportation on Campus
Specimens of blood or other potentially infectious materials shall be placed in a primary container that prevents leakage (capped test tube, centrifuge tube, etc.) during collection, handling, and storage. If specimens are transported through hallways, the primary containers must be placed in a secondary container with absorbent material that is leak proof, shatterproof, and gasket-sealed.
Shipping of Samples
Specimens of blood or other potentially infectious materials that will be shipped to or from Boston University must be clearly identified as human/NHP blood or blood products. The material shall be placed in a sealed primary container, a leak proof secondary container, and proper outer packaging that comply with the current DOT/IATA shipping regulations. Personnel involved with shipping of biohazardous agents or potential BBPs must have documented training prior to shipping. Contact EHS for more detailed guidelines and training on shipping samples or specimens.

Biological Waste Disposal
Disposal of potentially hazardous biological materials shall be performed with appropriate consideration for the personnel involved in the handling of laboratory waste, as well as the requirements of the Massachusetts Department of Public Health. The following types of waste are identified and defined as infectious or physically dangerous medical or biological waste, and are subject to the requirements of 105 CMR 480.000:

- Blood and Blood Products:
- Human anatomical parts, organs, tissues and body fluids
- Human or animal specimens or infectious cultures,
- Contaminated animal carcasses, body parts and bedding
- Sharps, including hypodermic needles and syringes, Pasteur pipettes, broken medical glassware, scalpel blades, disposable razors, and suture needles.
- Cultures and stocks of infectious agents
- Wastes from the production of bacteria, viruses, or the use of spores, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures

Specific procedures for the disposal of biological materials are available from EHS and can also be found in the Boston University Biosafety Manual. Additional requirements may be specified by the IBC.

Medical Surveillance Program
It is the PI’s responsibility to ensure that researchers, technicians, students, or volunteers who work in the laboratory and who have contact with animals, infectious agents, or blood borne pathogens are medically evaluated prior to starting work and that anyone working with blood borne pathogens is offered the hepatitis B vaccination series administered by the Research Occupational Health Program in compliance with the Blood borne Pathogen Exposure Policy for Boston University’s/Boston Medical Center.

An appointment can be made by contacting:

**On Boston University Medical Campus/Boston Medical Center**, Research Occupational Health Program is available via telephone 24 hours per day / 7 days per week. Contact ROHP at (617) 414-7647.

**On the Charles River Campus**, Research Occupational Health Program may be reached 24 hours per day / 7 days per week by telephone at (617) 414-7647.
BMC East Newton Campus Emergency Department is available after hours, on holidays, and during weekends. Contact Research Occupational Health Program at (617) 414-7647.

Questions may be directed to: Research Occupational Health Program at (617) 414-7647.
Exposure Control Plan (ECP)

Use with Appendix L of the Boston University Biosafety Manual

It is the PI/Supervisor’s responsibility to ensure that:

- Any person present in a BU laboratory who has an incident involving potential exposure to an infectious agent is offered immediate access to a medical evaluation from The Research Occupational Health Program (listed below) or the BMC Emergency Department (after hours, holidays, and weekends). An immediate evaluation is important, as efficacy of post-exposure medication for HIV and other infectious agents may be less effective if the initiation of treatment is delayed.
- When required, each individual completes a medical clearance for respirator use prior to fit-testing for a respirator. Personnel who develop symptoms of allergy or asthma that occur upon exposure to experimental animals are referred to Occupational Health Services for evaluation.

Under the OSHA Blood borne Pathogen Standard, BU and BMC are required to offer the hepatitis B vaccine to all employees at risk within 10 days of starting their work assignment. The employees must be informed of the vaccine’s benefits and risks, and if they choose not to receive it at the initial evaluation time, they must sign a declination form that is provided by Occupational Health Services. If the employee has had the vaccine previously, but has not had a blood antibody titer to confirm his or her immunity in the past, the employee will be offered the opportunity to have a titer drawn. An employee who declines the vaccine may at any time elect to have the vaccine if his or her job tasks or work setting continue to have the risk of potential exposure to blood borne pathogens.

**Reporting and Documenting Sharps Injuries and/or Exposure:**

For immediate medical attention please contact 617 353-2121 on the Charles River Campus 617-414-4444 on the BUMC campus. If any employee has an exposure to blood borne pathogens, he or she must also report this immediately to the Research Occupational Health Program. An immediate evaluation is important, as efficacy of post-exposure medication for HIV may be less effective if the initiation of treatment is delayed. For more information, please contact Research Occupational Health Program is available via telephone 24 hours per day / 7 days per week. Contact ROHP at (617) 414-7647.

**Contacting the Research Occupational Health Program**

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