

WYSS INSTITUTE FOR BIOLOGICALLY INSPIRED  
ENGINEERING

EXPOSURE CONTROL PLAN

July, 2018

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## List of Abbreviations, Acronyms and Definitions

<b>BBP</b>	Bloodborne pathogen
<b>CFR</b>	Code of Federal Regulations
<b>COMS</b>	Harvard Committee on Microbiological Safety
<b>ECP</b>	Exposure Control Plan
<b>EH&amp;S</b>	Environmental Health and Safety
<b>HBV</b>	Hepatitis B virus
<b>HCV</b>	Hepatitis C virus
<b>HIV</b>	Human immunodeficiency virus
<b>HUPD</b>	Harvard University Police Department
<b>IACUC</b>	Institutional Animal Care and Use Committee
<b>IRB</b>	Institutional Review Board
<b>OPIM</b>	Other potentially infectious material
<b>OSHA</b>	U.S. Occupational Safety and Health Administration
<b>PHS</b>	U.S. Public Health Service
<b>PI</b>	Principal Investigator
<b>PIM</b>	Potentially infectious material
<b>PPE</b>	Personal Protective Equipment
<b>rDNA</b>	Recombinant DNA
<b>Wyss Institute</b>	Wyss Institute for Biologically Inspired Engineering

## Contact Information and Useful Websites

Name/Title	Phone Number	E-mail
Wyss Institute EH&S		<a href="mailto:wyss_EHS@wyss.harvard.edu">wyss_EHS@wyss.harvard.edu</a>
Bob Rasmussen, Wyss Biosafety Officer & Director of Research Operations	617-432-1651 617-935-9188 (c)	<a href="mailto:robert.rasmussen@wyss.harvard.edu">robert.rasmussen@wyss.harvard.edu</a>
Michael Carr, Wyss Laboratory Manager	617-432-8234 203-710-4224 (c)	<a href="mailto:michael.carr@wyss.harvard.edu">michael.carr@wyss.harvard.edu</a>
Harvard Radiation Safety Office	617-496-3797	<a href="mailto:radiation_protection@harvard.edu">radiation_protection@harvard.edu</a>
emergency After-Hours	617-495-5560	
Harvard University EH&S	617-432-1720	
Emergency After-Hours Number	617-495-5560	
Occupational Health Departments: Harvard Medical School (HMS)	617-432-1370	
Harvard University – Cambridge	617-495-5711	
Boston Children’s Hospital (BCH)	617-355-7580	
Beth Israel Deaconess Medical Center (BIDMC)	617-632-0710	
Dana-Farber Cancer Institute (DFCI)	617-632-3016	
Harvard University Police Department (HUPD)	617-432-1212	
Center for Life Sciences Building Security - Biomed Realty Trust	617-232-0102 or 617-202-8957	
Janitronics (Biological Waste/Sharps Pickup)	617-632-7243	Pager #90598
Able Engineering (Building Maintenance)	617-735-4399	

## Emergency Reporting

For medical emergencies, call 911 and the Harvard University Police Department (HUPD) at 617-432-1212. Provide them with the exact location of the emergency.

For any serious, life-threatening or personal safety emergency, contact the Harvard University Police Department (HUPD) at 617-432-1212.

## Emergency Hospitals

In the event of an occupational exposure to human materials during normal working hours, go to your respective institution's Occupational Health Department.

In the event of an occupational exposure to human materials during off hours, go to the Emergency Department of the following hospitals/medical centers:

- **BWM** for personnel affiliated with Harvard Medical School, Children's Hospital Boston, Brigham and Women's Hospital (BWH) and Dana-Farber Cancer Institute
- **BIDMC** for personnel affiliated with Beth Israel Deaconess Medical Center (BIDMC)

### WEBSITES

Department / Resource	Webpage
Laboratory Animal Use - Harvard Center for Comparative Medicine (HCCM)	<a href="https://hccm.med.harvard.edu/welcome">https://hccm.med.harvard.edu/welcome</a>
Harvard Committee on Microbiological Safety (COMS)	<a href="https://hms.harvard.edu/departments/committee-microbiological-safety">https://hms.harvard.edu/departments/committee-microbiological-safety</a>
National Institutes of Health (NIH)/Centers for Disease Control and Prevention (CDC) <i>Biosafety in Microbiological and Biomedical Laboratories (BMBL) handbook</i>	<a href="https://www.cdc.gov/biosafety/publications/bmbl5/">https://www.cdc.gov/biosafety/publications/bmbl5/</a>
U.S. Occupational Safety and Health Administration OSHA Bloodborne Pathogens BBP Standard	<a href="http://www.osha.gov/SLTC/bloodbornepathogens/index.html">http://www.osha.gov/SLTC/bloodbornepathogens/index.html</a>

## Policy

The Wyss Institute is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this goal, the following Exposure Control Plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens during research activities in accordance with OSHA Standards “Occupational Exposure to Bloodborne Pathogens” and “Needlesticks and Other Sharps Injuries, Final Rule”. These standards are found at:

<https://www.osha.gov/SLTC/bloodbornepathogens/index.html> - summaries are shown here:



### Regulations (Standards - 29 CFR)

#### Final Rule on Occupational Exposure to Bloodborne Pathogens

- **Publication Date:** 12/06/1991
- **Publication Type:** Final Rules
- **Fed Register #:** 56:64004
- **Standard Number:** [1910.1030](#)

**SUMMARY:** OSHA is promulgating a standard to eliminate or minimize occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens. The standard became effective on 3/6/92. Based on a review of the information in the rulemaking record, OSHA has determined that employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials because they may contain bloodborne pathogens, including hepatitis B virus which causes Hepatitis B, and human immunodeficiency virus, which causes Acquired Immunodeficiency Syndrome (AIDS). The Agency further concludes that this exposure can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, Hepatitis B vaccination, signs and labels, and other provisions.

#### Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries; Final Rule

- **Publication Date:** 01/18/2001
- **Publication Type:** Final Rules
- **Fed Register #:** 66:5317-5325
- **Standard Number:** [1904](#); [1904.6](#); [1910](#); [1910 Subpart Z](#); [1910.1000](#); [1910.1001](#); [1910.1002](#); [1910.1018](#); [1910.1029](#); [1910.1030](#); [1910.1200](#); [1911](#); [1915.1030](#)

**SUMMARY:** The Occupational Safety and Health Administration is revising the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act

directs OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; to require that Exposure Control Plans reflect how employers implement new developments in control technology; to require employers to solicit input from Employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

## Scope of Exposure Control Plan (ECP)

The ECP is a key document to assist The Wyss Institute in implementing and ensuring compliance with the Bloodborne Pathogen Standard in research activities. This ECP includes:

- Duties and responsibilities for administration of the program
- Determination of employee exposure risk
- Methods of exposure control, including:
  - Standard precautions
  - Engineering and work practice controls
  - Personal protective equipment
  - Lab management
- Hepatitis B vaccination, post-exposure evaluation and follow-up
- Communication of hazards to employees and training
- Recordkeeping
- Procedures for evaluating circumstances surrounding an exposure incident

The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.

## Program Administration

Responsibility for implementation of this plan is as follows:

- **EH&S:** Wyss Institute EH&S, in conjunction with Harvard University EH&S, has overall responsibility for overseeing the implementation of the Exposure Control Plan and for providing training and advising on appropriate policies and practices needed to support the effective implementation of this Plan. Wyss EH&S assures provision of all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, biohazard bags, etc. as required by the Standard. Wyss EH&S is also responsible for

documentation of training and making the written ECP available to employees, OSHA, and NIOSH representatives.

- **Principal Investigators** are responsible for the execution of the ECP in all activities that may result in occupational exposure to bloodborne pathogens or other potentially infectious materials (OPIM). Principal Investigators are also responsible for the following:
  - Ensure that all personnel who have occupational exposure to human blood, body fluids or tissues, or OPIM comply with the procedures and work practices outlined in this plan.
  - Provide personnel with all requisite personal protective equipment, engineering controls, labels and other items required under this ECP and ensure that adequate supplies of this equipment are available to staff.
  - Ensure that medical actions required by the standard are performed and that appropriate employee health and OSHA records are maintained.
  - Provide training and ensure the ECP is available to employees, OSHA and NIOSH.
  - Offer workers the Hepatitis B vaccine if there is potential for exposure.
- **Wyss Institute Biosafety Officer** maintains, reviews, and updates the ECP at least annually, and whenever necessary to include new or modified tasks and procedures.
- **Institute Administrators and the Facility Manager:** Support for the program administration duties of Wyss EH&S and Wyss PIs is provided by Institute Administrators and the Facility Manager. Guidance to these individuals will be provided by EH&S.
- **Laboratory Supervisors and Advance Technology Team:** Supervisors and members of the Wyss Advance Technology Team are responsible for ensuring proper work practices (e.g., universal precautions, use of PPE) are followed by all laboratory staff on a day to day basis. Supervisors of laboratories working with human specimens or OPIM are required to maintain adequate supplies of the personal protective equipment in the appropriate sizes for laboratory staff. Guidance to these individuals is provided by EH&S.
- **Employees:** All individuals working at the Wyss Institute are responsible for participating in annual training sessions, understanding which tasks have the potential for occupational exposure and employing appropriate safe work practices in the performance of their duties. Staff who have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.
- **Occupational Health Departments:** For most Wyss Institute employees, Harvard University Health Services ensures that all medical actions required by the program are

performed and that appropriate employee health and OSHA records are maintained. Some personnel conducting research at the Wyss Institute are employed by multiple institutions, including but not limited to Harvard University, Boston University, Children's Hospital, Dana-Farber Cancer Institute and Beth Israel Deaconess Medical Center. Each individual institution's Occupational Health Department has responsibility for establishing and implementing the vaccination program and the post-exposure incident medical evaluation and follow-up as per OSHA mandate.

In addition to their responsibilities under this ECP, it is also the responsibility of PIs and researchers to ensure that their research is registered with Committee on Microbiological Safety (COMS), the Institutional Review Board (IRB), and Institutional Animal Care and Use Committee (IACUC), as appropriate. All laboratory research with human materials, including cell lines, must be registered with COMS. Work with clinical specimens requires an IRB registration. Work involving the use of live animals requires an IACUC registration. Contact Wyss EH&S for further information.

## Determination of Employee Exposure

An exposure determination must be made for anyone who has a reasonable chance of encountering human blood, body fluids and OPIM while performing their normal job duties. At the Wyss Institute, some employees work with human materials such as, but not limited to, human blood and human cell lines.

This exposure determination is made without regard to the use of PPE (i.e., persons are considered to be exposed even if they wear PPE) and is required to list all job classifications in which one may be expected to incur an occupational exposure.

At the Wyss Institute, the following job classifications are in this category:

- Principal Investigators
- Faculty
- Laboratory Technicians/Research Assistants
- Graduate Students
- Postdoctoral Fellows
- Glassware Washers/Laboratory Aides

- Advanced Technology Team Engineers/Scientists
- Visiting and Clinical Scientists
- Consultants working in Institute laboratories
- Managers of Institute facilities (imaging, tissue culture, etc.)
- Students/Interns

Associated tasks for these categories are as follows:

- Centrifugation of blood samples or OPIM.
- Separation of blood components or OPIM.
- Transferring blood or other body fluids between containers.
- Washing contaminated glassware.
- Disposing used needles and biohazardous waste.
- Working with human and non-human primate blood, body fluids, unfixed tissues and organs, and primary cells.
- Working with virus-producing cell lines and non-human primate cells.
- Administering recombinant deoxyribonucleic acid (rDNA) molecules or infectious microbiological agents into animals or animal or human cell lines.

## Methods of Compliance

### **Standard Precautions, Body Substance Isolation Precautions or Universal Precautions**

All staff will utilize Standard Precautions developed by the Centers for Disease Control and Prevention (CDC), consistent with Biosafety Level 2 practices, as a minimum standard for procedures involving human specimens and OPIM. **All human blood or other human source materials will be considered potentially infectious for HIV, HBV, HCV, and other bloodborne pathogens, regardless of the perceived "low risk" status of the source individual.** Additional safety practices may be required for specific research activities with human specimens and for work with OPIM.

Employees covered by the standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time on the Wyss website, or by contacting the Biosafety Officer, 432-1651. If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

The **Wyss Biosafety Officer (BSO)** is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The institute identifies any need for changes in engineering controls and work practices through regular attendance by the BSO at meetings of each platform, employee interviews and review of OSHA and CDC records.

## Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize BBP exposures. At Wyss Institute facilities, the following engineering and work practice controls are used:

- Hands and any other skin will be washed with soap and water, and eyes or mucous membranes will be flushed with water immediately or as soon as feasible following contact of such body areas with blood or OPIM.
- Contaminated needles and other contaminated sharps will not be bent, recapped, or removed from their syringe.
- After use, sharps (e.g., needles, scalpels, razor blades, glass
- Pasteur pipettes, etc.) are placed in red, fluorescent orange or orange-red leak-proof, rigid, puncture-resistant, shatterproof containers that that are marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color.
- Eating, drinking, chewing gum, smoking, applying cosmetics, and handling contact lenses is prohibited in work areas where exposure to infectious materials may occur.
- Food and drink is not be kept in refrigerators, freezers, on countertops, or in other storage areas where blood or OPIM are present.

- Procedures involving blood or OPIM are performed carefully to minimize splashing, spraying, splattering, and producing droplets or aerosols of blood or OPIM.
- Centrifugation of blood, blood-products or OPIM is performed using rotors with safety covers.
- Mouth pipetting/suctioning of blood or OPIM is prohibited.
- All equipment and work surfaces will be cleaned and disinfected on a routine basis and as soon as possible following spills or other exposure to blood or OPIM.
- Leak-proof, labeled containers are used for disposal of contaminated waste.
- Biosafety cabinets are re-certified annually to ANSI/NSF49 standards by qualified certifiers and are used as secondary protection (second to PPE such as laboratory coats, disposable latex or nitrile gloves, and safety glasses or face shields).
- To help reduce needlesticks and other sharps injuries the use of safer medical devices is advised.

The biosafety program of the Wyss identifies any needs for changes in engineering control and work practices through review of exposure incidents by Wyss EH&S.

New procedures or products are identified by literature review, or feedback from purchasing or researchers. Products potentially useful to more than one group are provided for a trial to other platform groups to get feedback about the usefulness of the product. This meets the requirement of involving both front line worker and management involvement. Comments are brought back to the Purchasing department for action on available products.

Wyss Operations department will ensure effective implementation of these recommendations.

## Personal Protective Equipment (PPE)

PPE is considered the required safety equipment, or “primary barrier” for protection against bloodborne pathogens. Each host institution is required to provide all necessary PPE to their employees free of cost. This equipment includes, but is not limited to:

- Disposable latex or nitrile gloves
- Laboratory coats
- Gowns/scrubs

- Goggles
- Safety glasses with side shields
- Prescription safety glasses with side shields
- Face shields/masks
- Hoods
- Shoe covers
- Respiratory protection
- Other site specific PPE as needed

Occupants are trained regarding the use of the appropriate PPE for their job classifications and tasks/procedures they perform. Training is provided by EH&S, the laboratory managers or designee, when necessary, such as when an employee takes a new position or new job functions are added to their current position.

Wyss Institute facilities adhere to the following practices to ensure that PPE is not contaminated and is in the appropriate condition to protect employees from potential exposure:

- PPE selection is reviewed by Wyss Institute EH&S or the responsible Laboratory Manager/Laboratory Safety Contact.
- Reusable PPE is properly cleaned, laundered and decontaminated, as needed.
- Single-use PPE (or equipment that cannot, for whatever reason, be decontaminated) is disposed of as biological waste.

Wyss Institute occupants are trained to adhere to the following practices to ensure that PPE is used as effectively as possible. These include, but are not limited to:

- Hands are washed immediately or as soon as feasible after removal of gloves or other PPE.
- Any garments penetrated by blood or other infectious materials are removed immediately or as soon as feasible. Grossly contaminated lab coats are placed in a sealed biohazard bag prior to adding to the soiled lab coat container.
- All PPE is removed prior to leaving a work area and is never worn in common areas of the building such as conference rooms, restrooms, and lunchrooms.
- Disposable latex or nitrile gloves are worn in the following circumstances:
  - Whenever employees anticipate hand contact with potentially infectious materials.

- When performing vascular access procedures, with reasonable likelihood of blood exposure.
- When handling or touching contaminated items or surfaces.
- Disposable latex or nitrile gloves are replaced as soon as practical after contamination, or if they are torn, punctured or otherwise lose their ability to function as an "exposure barrier."
- Utility gloves are decontaminated for reuse unless they are cracked, peeling, torn or exhibit other signs of deterioration, at which time they are disposed of.
- Full-face protection, such as masks, face shields, and eye protection (goggles, etc.) are used whenever splashes or sprays may generate droplets of infectious materials.
- Protective clothing (such as gowns, scrubs and aprons) is worn whenever potential exposure is anticipated.
- Head covers/hoods and/or shoe covers/boots are used in any instances where "gross contamination" is anticipated (such as perfusion activities).

## General Lab Safety Management

It is the responsibility of everyone who works at the Wyss Institute to ensure that the facility is maintained in a clean and sanitary condition. The following sections outline the procedures to ensure this level of cleanliness.

**Regulated waste (biohazard waste)** is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled, and closed prior to removal to prevent spillage or protrusion of contents during handling.

### Contaminated Sharps Disposal

Contaminated sharps will be discarded immediately or as soon as feasible into a reusable sharps container. During use, the sharps container will be easily accessible to laboratory members and located as close as is feasible to the immediate area where sharps are used. These containers should remain upright throughout use, be replaced routinely and not be overfilled.

When moving the sharps container from the area of use, the containers should be closed immediately prior to removal to prevent spills or protrusion of contents during handling, storage, transport, or shipping. Filled reusable sharps containers are replaced by laboratory personnel. Any filled sharps containers are closed and brought to central

pick up areas near freight elevators on each laboratory floor and placed on single-use sharp container racks. An empty sharps container on the same or an adjacent rack is then brought back to the lab. In some cases, and when deemed appropriate by the Biosafety Officer, smaller, single-use sharps containers may be used. When full, these may be placed into a red-bagged lined grey bin (see below).

### **Solid Biological Waste Disposal**

Solid waste materials (e.g. flasks, tubes, plates, serological pipets, petri dishes, and plastic transfer or aspiration pipets, etc.) generated within a BSC are to be placed in red bag-lined, stainless-steel cylindrical container. Once full, or when work in the BSC is complete, these red bags are to be twisted shut and zip-tied sealed. The sealed red bags are then placed red biohazard waste bag-lined, impermeable grey biohazard bins. In some cases, e.g. when using BL-1 materials, or if flasks and/or tubes are capped within the BSC, solid waste may be placed directly in bag-lined, solid-walled grey bins. Liquids are to be removed from every solid waste item before that item is discarded.

When the lined grey bin is nearly full, close up and seal as follows:

- Close and tape or zip-tie the inner bag.
- Leave the hinged cover flaps open – Janitronics personnel will close the covers if they see the red bag is secured properly and remove the entire bin and contents for shipment off-site by our biohazardous waste vendor.

Grey bins are removed daily. Call Janitronics at 617- 632-7243, Pager # 90598 to pick up a biological waste grey bin or deliver empty biological waste bins.

Animal and Human tissue in 10% formalin (3.75% formaldehyde) is treated as hazardous chemical waste. Label the hazardous waste tag: 10% formalin and non-infectious human or animal tissue. Contact Wyss EH&S for other biological/chemical waste,

### **Liquid Biological Waste Disposal**

Liquid biological waste from Biosafety Level 2 laboratories is disinfected with 10% bleach, and, after 20 minutes contact time, is carefully poured down a sink drain. Flush the drain with water after disposal.

Mixed liquid biological/chemical waste can be disinfected by using carefully selected chemical treatments only if compatible with other chemicals in the experiment. Handle resulting waste as hazardous chemical liquid waste. Mixing bleach with mixed liquid

chemical/biological waste may result in an unanticipated chemical reaction. Contact EH&S for advice on avoiding adverse chemical reactions.

### **Equipment and Working Surfaces**

Contaminated work surfaces and equipment should be cleaned with a U.S. Environmental Protection Agency approved germicidal disinfectant (<http://www.epa.gov/oppad001/chemregindex.htm>). Application and contact time with the surface being cleaned must be done in accordance with the manufacturer's recommendations,

Laboratory personnel must clean contaminated equipment and surfaces after contact with blood or other potentially infectious materials after the completion of procedures, immediately (or as soon as feasible) when surfaces are overtly contaminated, after any large spill of blood or infectious materials, or at the end of the work shift if the surface may have been contaminated during that shift.

### **Contaminated Laundry**

Personnel should replace laboratory gowns or coats regularly and when they become contaminated. Contaminated laundry that can be reused should be placed in leak-proof bags labeled with the biohazard symbol or color-coded red before transporting by a vendor laundry service for decontamination or cleaning.

### **Labels and Signs**

Regulated waste containers, refrigerators, freezers, centrifuges and incubators containing blood or OPIM; and other containers used to store, transport, or ship blood or OPIM must be labeled with the biohazard warning label. The label must incorporate the universal biohazard sign and a predominant florescent orange or orange-red background with contrasting letter and symbol.



Universal Biohazard Symbol

Labels should be affixed to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

At the entrance to laboratories where tenants are working with BBP or other infectious materials, the following sign shall be posted at the entrance:



(Special requirements, if any, for entering the area)  
(Name, telephone number of laboratory director or other responsible person)

These signs must be fluorescent orange-red with lettering and symbols in a contrasting color.

## Hepatitis B Vaccination, Post-Exposure Evaluation and Follow-Up

Staff members must contact the Occupational Health Department for their respective home institution to obtain information about the HBV vaccination program.

### **Vaccination Program**

The hepatitis B vaccine is offered to all employees who have occupational exposure to bloodborne pathogens, and post-exposure follow-up is offered to employees who have had an exposure incident. All medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure follow up, including prophylaxis, are:

- Made available at no cost to the employee.
- Made available to the employee at a reasonable time and place.
- Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional.
- Provided according to the recommendations of the U.S. Public Health Service (PHS).

All records of Hepatitis B vaccinations and test results are kept on file in the Institution's Occupational Health Department. An accredited laboratory conducts all laboratory tests.

Hepatitis B vaccination is made available to all employees who have occupational exposure within 10 working days of their initial assignment.

Participation in a pre-screening program is **not** a prerequisite for receiving hepatitis B vaccination. If an employee initially declines the hepatitis B vaccination, but decides to accept the vaccination at a later date and is still covered under the standard, the vaccination will be made available. **All employees who decline the offered hepatitis B vaccination must sign the OSHA-required declination indicating their refusal.** If the PHS recommends a routine booster dose of hepatitis B vaccine at a future date, such booster doses will be made available, at no cost to the employee.

### **Post-Exposure Evaluation and Follow-up**

All exposure incidents are reported, investigated, and documented. When an employee is exposed to blood or other PIM, the incident is reported to the Wyss Institute EH&S Office, Harvard EH&S, and the corresponding Occupational Health Department.

#### What to do if exposed:

- Immediately, wash the exposed skin area, needle sticks, and/or cuts with soap and water. Flush eyes, and exposed mucous membranes with large amounts of clear water. Do not use caustic agents, such as bleach.
- Next, report the exposure to your supervisor and Wyss Institute EH&S immediately, so that post-exposure evaluation, counseling, and any necessary treatment can begin. Act quickly, because with some infections, treatment works best when started right away.

**When an employee is exposed, he or she will receive a confidential medical evaluation and follow-up, including at least the following elements:**

- Documentation of the route of exposure and the circumstances, under which the exposure occurred.
- Identification and documentation of the source individual, unless it can be established that identification is infeasible or prohibited by state or local law.
- The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV, HCV, and HIV infectivity. If consent is not obtained, the treating physician establishes that legally required consent cannot be obtained. When law does not require the source individual's consent, the source individual's blood, if available, will be tested and the results documented. When the source individual is already known to be infected with HBV, HCV, or HIV, testing for the source individual's known HBV, HCV, or HIV status need not be repeated.

- Results of the source individual's testing are made available to the exposed employee, and the employee is informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
- Collection and testing of blood for HBV, BCV, and HIV serological status will comply with the following:
  - The exposed employee's blood is collected as soon as possible and tested after consent is obtained.
  - The employee will be offered the option of having their blood collected for testing of the employee's HIV/HBV/HCV serological status. The blood sample will be preserved for **up to 90 days** to allow the employee to decide if the blood should be tested for HIV serological status.

**All employees who incur exposure will be offered post-exposure evaluation and follow-up according to the OSHA Standard.** The employee's primary care physician may provide all post-exposure follow-ups. In some instances, if the employee saw a physician at a hospital emergency room, that physician may provide the post-exposure follow-up.

The healthcare professional responsible for the employee's hepatitis B vaccination is provided with the following:

- A description of the exposed employee's duties as they relate to the exposure incident.
- A description of the route of exposure and circumstances under which exposure occurred.
- Results of the source individuals blood testing, if available.
- All medical records relevant to the appropriate treatment of the employee including vaccination status.

The healthcare professional' written opinion for HBV vaccination must be limited to whether HBV vaccination is indicated for an employee, and if the employee has received such vaccination. **The healthcare professional's written opinion for post-exposure follow-up is limited to the following information:**

- A statement that the employee has been informed of the results of the evaluation.
- A statement that the employee has been told about any medical conditions resulting from exposure to blood or OPIM, which require further evaluation or treatment.

**NOTE:** All other findings or diagnosis shall remain confidential and will not be included in the written report.

## Procedures for Evaluating the Circumstances Surrounding an Exposure Incident

The Wyss EH&S will review the circumstances of all exposure incidents to determine:

- engineering controls in use at the time
- work practices followed
- a description of the device being used (including type and brand)
- protective equipment or clothing that was used at the time of the exposure incident (*gloves, eye shields, etc.*)
- location of the incident (*specific location if relevant.*)
- procedure being performed when the incident occurred
- employee's training

If it is determined that revisions in procedures are required, the Biosafety Officer will ensure that appropriate changes are made to this ECP

## Training

The Wyss Institute ensures that persons who provide BBP training are knowledgeable in the required subject matter. Harvard EH&S provides on-line Biosafety and BBP Training through the Harvard Training Portal (HTP). We make sure that employees covered by the BBP standard are trained at the time of initial assignment to tasks where occupational exposure may occur, and every year thereafter, on or around the anniversary of their initial training.

The following training methods may be employed:

- Training sessions conducted by a knowledgeable trainer.
- Online training with an opportunity to reach a knowledgeable trainer.
- Access to additional materials and consultation provided by the Wyss Institute EH&S Office or their designees.

Initial BBP training is tailored to the education and language level of the employee, and offered during the normal work shift. The initial training covers the following:

- The BBP Standard and its contents, and a method for obtaining a copy.
- The epidemiology and symptoms of bloodborne diseases.
- The modes of transmission of bloodborne pathogens: HIV, HBV, and HCV.
- The ECP and a method for obtaining a copy.

- The recognition of tasks that may involve exposure.
- The use and limitations of methods to reduce exposure, for example engineering controls, safety devices (such as self-sheathing needles), work practices and PPE.
- The types, use, location, removal, handling, decontamination, and disposal of PPE.
- The basis of selection of PPE.
- The hepatitis B vaccination, including efficacy, safety, method of administration, benefits, and that it will be offered free of charge.
- The appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.
- The procedures to follow if an exposure incident occur, including the method of reporting and medical follow-up.
- The evaluation and follow-up required after an employee exposure incident.
- The signs, labels, and color-coding systems.

Additional training is provided to employees when there are any changes of tasks or procedures affecting the employee's occupational exposure. Employees who have received training on BBP in the 12 months preceding the effective date of this plan will only receive training in provisions of the plan that were not covered.

## Recordkeeping

### **Medical Records**

Medical records shall be maintained in accordance with OSHA Standard Title 29 Code of Federal Regulations Part 1910.20 (29 CFR 1910.20). These records shall be kept confidential, and must be maintained by the individual's home institution for at least the duration of employment plus 30 years.

The records generally include the following:

- The name and social security number of the employee.
- A copy of the employee's HBV vaccination status, including the dates of vaccination.
- A copy of all results of examinations, medical testing, and follow-up procedures.
- A copy of the information provided to the healthcare professional, including a description of the employee's duties as they relate to the exposure incident, and documentation of the routes of exposure and circumstances of the exposure.

Medical records are confidential and will be kept in the institution's occupational health department.

### **Training Records**

Training records shall be maintained for a minimum of three years from the date of training. Training via the Harvard Training Portal are saved electronically and Wyss EH&S holds records for BL2 specific training.

The following information shall be documented:

- The dates of the training sessions.
- An outline describing the material presented.
- The names and qualifications of persons conducting the training.
- The names of all persons attending the training sessions.

### **Availability**

All employee medical records shall be made available to the employee in accordance with 29 CFR 1910.20 by their home institution's Occupational Health Department. All employee training records shall be made available to the employee in accordance with 29 CFR 1910.1030.

### **Transfer of Records**

If this facility is closed or there is no successor employer to receive and retain the records for the prescribed period, the Director of the National Institute for Occupational Safety and Health shall be contacted for final disposition.

## Definitions

**Blood** means human blood, human blood components and products made from human blood.

**Bloodborne Pathogens** means microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), Hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

**Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials (PIM) on an item or surface.

**Contaminated Laundry** means laundry which has been soiled with blood, other PIM or may contain sharps.

**Contaminated Sharps** means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

**Decontamination** means the use of physical or chemical means to remove, inactivate or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Engineering Controls** means controls (e.g. sharps disposal containers, self-sheathing needles, safer medical devices such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

**Exposure Incident** means a specific instance of contact with blood or other PIM, via eye, mouth, other mucous membrane, non-intact skin, or parenteral contact, during the course of the performance of an employee's duties.

**Handwashing Facilities** means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

**Needleless Systems** means a device that does not use needles for: 1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;

2) The administration of medication or fluids; or 3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

**Non-intact skin** includes skin with dermatitis, hangnails, cuts, abrasions, chafing, and acne.

**Occupational Exposure** means reasonably anticipated contact with blood or other PIM, via eye, mouth, other mucous membrane, non-intact skin, or parenteral contact, during the course of the performance of an employee's duties.

**Other Potentially Infectious Materials (OPIM)** means: 1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; 2) Any

unfixed tissue or organ (other than intact skin) from a human (living or dead); and 3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

***Parenteral*** means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

***Personal Protective Equipment*** is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard is not considered to be personal protective equipment.

***Regulated Waste*** means liquid or semi-liquid blood or OPIM; contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other PIM.

***Research Laboratory*** means a laboratory producing or using research-laboratory-scale amounts of HIV, HBV, or HCV. Research laboratories may produce high concentrations of HIV, HBV, or HCV but not in the volume found in production facilities.

***Sharps with engineered sharps injury protections*** means a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids that has a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

***Sterilize*** means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

***Universal Precautions*** is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

***Work Practice Controls*** means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).