Laboratory Exposure Control Plan

1.0 Introduction

1.1 Purpose

Northwestern University is required to comply with the Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens Standard found in Title 29, Code of Federal Regulations, Part 1910.1030.

The Bloodborne Pathogens Standard requires a written Exposure Control Plan (ECP), which must be made available to each occupationally exposed employee. The ECP must be customized to meet the individual needs of each laboratory.

1.2 Date

Date this ECP was last updated: [ ]

1.3 Scope

This document is the written Exposure Control Plan for the [ ] Lab as required by the Bloodborne Pathogens Standard. This plan is required if any laboratory employee has duties with occupational exposure, meaning reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of those duties.

The Bloodborne Pathogens Standard applies to staff who have occupational exposure to the following:

- Blood, meaning human blood, human blood components and products made from human blood
- 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
  - All body fluids in situations where it is difficult or impossible to differentiate between body fluids
- Any fixed tissue or organ (other than intact skin) from a human, living or dead
- Human Immunodeficiency Virus (HIV)-containing cell or tissue cultures, organ cultures, and HIV- or hepatitis B Virus (HBV)-containing culture medium or other solutions; and blood, organs or other tissues from animals experimentally or incidentally infected with HIV or HBV.

1.4 Lab Overview

1.4.1 Potentially infectious material used

List all potentially infectious materials used in research in your laboratory.

1.4.2 Location(s) where research is conducted

List all locations where research involving potentially infectious materials is conducted. All locations where potentially infectious material is manipulated or used in research must be listed.

1.4.3 Personnel

List all laboratory workers (staff and students) who have duties with occupational exposure.

2.0 Universal Precautions

2.1 Definition

Universal precautions is an approach to infection control in which **all** human blood and other potentially infectious materials are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. When it is difficult or impossible to differentiate between fluid types, universal precautions shall be observed.

2.2 Schedule and Method of Implementation of Universal Precautions

Universal precautions shall be implemented immediately. The method of implementation shall be as follows.

a. Work practice controls for all work involving blood or other potentially infectious material are followed.
b. Training is provided as required by the Exposure Control Plan.
c. Engineering controls are provided as required by the Plan.

d. Appropriate personal protective equipment is provided as required by the Plan.
e. All of the above are followed and/or correctly used and maintained, and the principal investigator ensures compliance.

2.3 Laboratory-Specific Information on the use of Universal Precautions

Do you have any laboratory-specific universal precautions, which supplement or differ from the information presented in the *Bloodborne Pathogens Program*?

◯ Yes ◯ No

If yes, list lab- laboratory-specific universal precautions.

3.0 Engineering and Work Practice Controls

3.1 Definitions

Engineering controls are controls that isolate or remove the bloodborne pathogens hazard from the workplace. Examples are sharps containers and self-sheathing needles.

Work practice controls are controls that reduce the likelihood of exposure by altering the manner in which a task is performed. If there remains a likelihood of occupational exposure even when engineering and work practice controls are in place, then personal protective clothing shall also be used.

3.2 Controls to be Used

3.2.1 Handwashing

The laboratory shall provide readily accessible handwashing facilities, or, if this is not feasible, an appropriate antiseptic hand cleanser and clean cloth or paper towels. In any case, employees shall wash hands with soap and running water as soon as feasible after removal of gloves or other personal protective equipment.

The principal investigator shall ensure that employees wash hands immediately or as soon as feasible after removing gloves or other personal protective equipment and also shall ensure that employees wash hands and any other skin with soap and water or flush mucous membranes with water immediately, or as soon as feasible, following contact of such body areas with potentially infectious materials.

3.2.2 Needles and Sharps

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted below. Shearing or breaking of contaminated needles is prohibited.

Contaminated needles and sharps shall be recapped or removed only when no alternative is feasible or when it is required by a specific medical procedure. Any recapping or removal must be accomplished through the use of a mechanical device or a one-handed technique. The recapping or removal of contaminated sharps is actively discouraged under any circumstances because of the high potential risk of injection. For guidance regarding a one-handed technique for recapping needles, please contact Research Safety or the Center for Comparative Medicine (CCM) training staff.

Immediately after use, contaminated sharps shall be placed in sharps containers that are puncture-resistant, labeled or color-coded, and leak-proof.

3.2.3 Eating, Drinking, Smoking, Etc.

Eating, drinking, smoking, applying cosmetics (including hand/body lotion and lip balm), and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or benchtops where blood or other potentially infectious materials are present.

3.2.4 Splashing, Spraying, Spattering

All procedures involving blood or other potentially infectious materials shall be performed so as to minimize splashing, spraying, spattering, and generation of droplets.

3.2.5 Mouth Pipetting

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

3.2.6 Specimen Containers

The Standard has detailed requirements for specimen containers. In general, specimens of blood or other potentially infectious materials shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. Secondary containers are used when the outside of the primary container may be contaminated and when puncture of the primary container is possible. Storage, transport, or shipping containers are closed and appropriately labeled. When appropriate, the label should include the biohazard symbol. Color-coded containers should be red or orange.

3.2.7 Potentially Contaminated Equipment

Any equipment to be serviced or shipped that may be contaminated shall be examined prior to servicing or shipping and shall be decontaminated as necessary. If decontamination is not feasible, then the equipment shall be clearly labeled as to which portions remain contaminated.

The laboratory is obligated to clearly communicate this information to employees, service personnel, and manufacturers as appropriate.

3.2.8 Other Engineering Controls

Other engineering controls include biological safety cabinets and chemical fume hoods. Engineering controls shall be examined and maintained on a regular schedule.

The principal investigator is required to ensure that biological safety cabinets used to protect workers from hazardous biological agents shall be tested and certified after installation, whenever they are moved, and annually. Certification shall be in accordance with National Sanitation Foundation Standard Number 49. The principal investigator is responsible for scheduling biological safety cabinet certification with CEPro. For more information regarding biological safety cabinet certification, contact Research Safety.

3.3 Schedule and Method of Implementation for Engineering and Work Practice Controls

Engineering and work practice controls shall be implemented immediately. The method of implementation shall be as follows:

1. The principal investigator or safety designate evaluates existing practices for compliance with the standard.
2. Equipment and procedures are modified as required to achieve compliance.

3.4 Laboratory-Specific Engineering and Work Practice Controls

3.4.1 Engineering Controls

Will controlled ventilation of any kind be used for these procedures?

◯ Yes ◯ No

Will you use any laboratory-specific ventilation devices which supplement or differ from information presented in the *Bloodborne Pathogens Program*?

◯ Yes ◯ No

If yes, describe laboratory-specific ventilation devices.

Will a respirator be used for these procedures?

◯ Yes ◯ No

3.4.2 Work Practices

Do you have any laboratory-specific work practices or procedures using bloodborne pathogens, which supplement or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific work practices or procedures.

4.0 Personal Protective Equipment

4.1 Responsibility

The principal investigator shall provide or ensure provision of appropriate personal protective equipment to each employee who is subject to occupational exposure to human blood or potentially infectious material. The equipment is provided at no cost to the employee. Examples of such equipment include gloves, gowns, laboratory coats, head and foot coverings, face shields, masks, eye protection, resuscitation bags, pocket masks, or other ventilation devices.

The principal investigator shall either directly or by delegation ensure that each employee uses personal protective equipment when warranted. If this responsibility is to be delegated, it may only be delegated to the laboratory Safety Designate who must be assigned such a role in Lumen.

4.2 Availability

Protective equipment in appropriate sizes shall be available in the work area or issued to employees. Hypoallergenic gloves or similar alternatives shall be readily available to those allergic to the normal gloves provided. Research Safety strongly recommends the use of nitrile disposable gloves.

4.3 Cleaning and Repair

The principal investigator shall ensure that personal protective equipment shall be cleaned, laundered, or disposed of at no cost to the employee. Personal protective equipment shall be repaired or replaced as needed to maintain its effectiveness.

4.4 Wear in Work Areas Only

All personal protective equipment shall be removed prior to leaving the work area.

4.5 Gloves

Gloves shall be worn when it is reasonably anticipated that employees may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin. Gloves shall be worn when performing vascular access procedures and when handling or touching contaminated items or surfaces.

Disposable gloves shall be replaced as soon as practical when contaminated, torn, punctured, or otherwise compromised in their ability to function as a barrier. Research Safety strongly recommends the use of nitrile disposable gloves.

Utility gloves (non-disposable gloves) may be decontaminated for reuse provided the integrity of the glove is not compromised. They must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration.

4.6 Masks, Eye Protection, and Face Shields

Masks in combination with eye protection devices (such as goggles or glasses with solid side shields) or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

4.7 Gowns, Aprons, and Other Protective Body Clothing

Appropriate protective body clothing shall be worn in occupational exposure situations. Appropriate clothing includes long pants that cover the legs (dresses or skirts which cover the legs but do not touch the floor are acceptable) and durable, closed-toed shoes. Loose-fitting clothing is not recommended. Where appropriate, loose-fitting garments may be pinned in place while working with potentially infectious material. Consult Research Safety for additional guidance.

When gross contamination can be anticipated, surgical caps or hoods and shoe covers should be worn.

4.8 Schedule and Method of implementation for Personal Protective Clothing and Equipment

The principal investigator shall initiate the procurement and use of personal protective equipment immediately. The method of implementation shall be as follows.

1. Such equipment is made available
2. Its use is ensured through periodic checks by supervisors or other laboratory personnel
3. Equipment is cleaned regularly or disposed of properly
4. Equipment is repaired or replaced as needed.

4.9 Laboratory-Specific Information Regarding Personal Protective Clothing and Equipment

Do you have any laboratory-specific personal protective equipment (PPE) which supplements or differs from information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific PPE.

5.0 Housekeeping

5.1 Responsibility

The principal investigator is responsible for ensuring that the work area shall be maintained in a clean and sanitary condition. A written schedule for cleaning and method of decontamination is required.

5.2 Cleaning

All equipment and environmental and working surfaces shall be cleaned and decontaminated with an appropriate disinfectant after contact with blood or other potentially infectious material. Contaminated work surfaces shall be decontaminated after completion of procedures, immediately or as soon as feasible after any contamination of surfaces or after any spill of blood or other potentially infectious materials, and at the end of the work shift if the surface may have become contaminated since the last cleaning.

Chemical disinfectants with their usage parameters, applications and the organisms for which they are effective are summarized in the Biological Safety section of the Research Safety website. In general, a 10% dilution of household bleach in water, made fresh daily is appropriate for decontamination. Additionally, cleaning products that are tuberculocidal are appropriate. Purchased disinfectants are recommended if their parameters meet those described.

Protective coverings such as plastic-backed absorbent paper shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

All bins, pails, cans, and similar receptacles intended for reuse that have a reasonable likelihood of becoming contaminated shall be inspected and decontaminated on a regularly scheduled basis. They shall be cleaned or decontaminated immediately or as soon as feasible if there is visible contamination.

5.3 Broken Glassware

Broken glassware that may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush or dustpan, tongs, or forceps.

5.4 Schedule and Method of Implementation for Housekeeping

Housekeeping measures required in this section are to be implemented immediately.

Environmental surfaces (e.g., floors) are routinely cleaned either by Facilities personnel or by an outside contractor under the direction of Facilities. Inquire with Facilities as to the schedule and method of implementation. NOTE: Facilities or Housekeeping do not clean contaminated floors. If floors are overtly contaminated or suspected of being contaminated, laboratory personnel shall clean and decontaminate the floors using appropriate procedures.

The principal investigator shall ensure routine cleaning of work surfaces and equipment as well as cleaning and disinfection of equipment, environmental surfaces, and work surfaces that have been in contact with human blood or other infectious materials.

6.0 Waste Disposal

6.1 Contaminated Sharps

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are closable, puncture-resistant, leak-proof, and labeled or color-coded. Sharps containers shall be easily accessible to employees and located close to the immediate area where sharps will be used. Sharps containers shall be kept upright throughout use, be replaced routinely, and not be allowed to be overfilled.

Before sharps containers are removed from the work area, they shall be closed securely. If leakage is possible, a closable, sturdy, leak-proof, and labeled or color-coded secondary container shall be used.

6.2 Other Biohazardous Wastes

Other waste containers that contain blood or other potentially infectious material shall be closable, able to contain all contents, leak-proof, labeled and/or color-coded, and closed securely prior to removal. If the primary waste container is contaminated on the outside, a closable, sturdy, leak-proof, and labeled or color-coded secondary container shall be used, and it shall also be closed prior to removal.

6.3 Schedule and Method of Implementation for Waste Disposal

Waste disposal requirements are to be implemented immediately. Principal investigators are responsible for ensuring that appropriate sharps containers and other biohazardous waste containers are made available in the laboratory and are used.

6.4 Laboratory-Specific Waste Disposal Information

Do you have any laboratory-specific waste disposal procedures which supplement or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific waste disposal procedures.

7.0 Laundry

7.1 Instructions

Contaminated laundry shall be handled as little as possible with a minimum of agitation. It shall be placed into bags or containers at the point of use. It shall not be sorted or rinsed in the location of use. The bags or containers shall be labeled with the biohazard symbol or color-coded (red/ orange). The bag or container shall be constructed to prevent soak-through or leakage.

The principal investigator shall ensure that employees who handle contaminated laundry shall wear protective gloves and other appropriate personal protective equipment.

Current University policy on the handling of contaminated laundry requires that it be autoclaved or disinfected prior to laundering. This enhances the protection of those individuals who have to handle the laundry after it leaves the laboratory and simplifies the laundry handling procedures in the facility that cleans it.

Contaminated sharps shall never be included with laundry. Contaminated laundry is never washed with an individual's personal belongings or sent to a laundry service not aware of the hazards.

7.2 Schedule and Method of Implementation for Laundry

The requirements for handling laundry contaminated with blood or other potentially infectious materials shall be implemented immediately.

7.3 Laboratory-Specific Laundry Information

Do you have any laboratory-specific laundry procedures which supplement or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific laundry procedures.

8.0 Hepatitis B Vaccination and Post Exposure Follow-up

8.1 Responsibility

The principal investigator is responsible for making the hepatitis B vaccine and vaccination series available to all employees who have occupational exposure. Post exposure evaluation and follow-up shall be made available to all employees who have sustained an exposure incident. An accredited laboratory shall conduct all laboratory tests at no cost to the employee.

Vaccine, vaccination, and all medical evaluations and procedures:

- Shall be made available at no cost to the employee
- Shall be made available at a reasonable time and place
- Shall be performed by or under the supervision of a licensed physician or other licensed healthcare professional
- Shall be provided according to the recommendations of the U.S. Public Health Service at the time the evaluations and procedures take place, except as noted below

8.2 Hepatitis B Vaccination

Hepatitis B vaccination shall be made available after the employee has received the training required in Section 10 of this document, and within 10 working days of initial assignment to any employee who has occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons. Participation by the employee in a prescreening program shall not be a prerequisite for receiving hepatitis B vaccination.

An employee who accepts vaccination shall complete and sign the Hepatitis B Vaccination Certification found in myHR Learn.

An employee may decline vaccination but decide to accept it at a later date in accordance with Section 8.1 above. If an employee declines vaccination, the employee shall sign the statement also found in the Hepatitis B Vaccination Certification found in myHR Learn.

Any booster doses that may be recommended by the U.S. Public Health Service at a later date shall be made available in accordance with the vaccination requirements of this section.

The healthcare professional responsible for the employee's hepatitis B vaccination shall be provided with a copy of the OSHA Occupational Exposure to Bloodborne Pathogens Standard. The written opinion for hepatitis B vaccination shall depend on whether hepatitis B vaccination is indicated and if the employee has received the vaccination.

8.3 Schedule and Method of Implementation for Hepatitis B Vaccination

The requirements for making available hepatitis B vaccination shall be implemented immediately. Acceptable methods of compliance with the vaccination requirement include in-house vaccination for laboratories having healthcare professionals on the staff and at the University Health Service. Employees should contact their laboratory for vaccination information. Contact Research Safety for information on health care providers with whom the University contracts to provide such services.

8.4 Laboratory-Specific Information for Hepatitis B Vaccination

Do you have any laboratory-specific vaccination requirements which supplement the hepatitis B vaccination or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific vaccination requirements.

8.5 Post Exposure Evaluation and Follow-up

8.5.1 Required Elements

Following a report of an exposure incident, the principal investigator shall ensure that a confidential medical evaluation and follow-up are made available to the exposed employee. The evaluation shall include:

- Documentation of the route of exposure and the circumstances under which the exposure incident occurred
- Identification and documentation of the source individual unless it is not feasible or prohibited by law
- Collection and testing of the exposed employee's blood for HBV and HIV serological status
- Collection of an exposed employee's blood as soon as feasible and testing after consent is obtained: Testing may take place at a later date if the employee chooses, provided it is within 90 days of the exposure incident.
- Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service

- Counseling
- Evaluation of reported illnesses

See Appendix 3 for procedures, or contact Research Safety for more information on where to obtain post-exposure exams and follow-up care.

8.5.2 Notification Requirement

When an exposure incident occurs, notify the claims manager at Risk Management regarding workers' compensation if the exposed individual is an employee. The contact number for the claims manager is (846) 491-5582. All incidents shall be reported to Research Safety for review by the Chemical and Biological Safety Committee. In keeping with the confidentiality requirement of the University AIDS policy, the names of persons involved in the incident and other identifying information may be omitted from the incident report.

8.5.3 Information Provided to the Healthcare Professional

The principal investigator shall ensure that the following information is supplied to the evaluating healthcare professional:

- A copy of the OSHA Occupational Exposure to Bloodborne Pathogens Standard
- A description of the exposed employee's duties as they relate to the exposure incident
- Documentation of the route of exposure and circumstances under which the exposure occurred
- Results of the source individual's blood testing, if available
- All medical records relevant to the appropriate treatment of the employee including vaccination status that the principal investigator is responsible for maintaining

8.5.4 Written Opinion Requirement

The principal investigator is required to obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

The healthcare professional's written opinion shall be limited to whether hepatitis B vaccination is indicated for the employee and, if the individual has received such vaccination, a statement that the individual has been informed of the results of the evaluation and that the individual has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment. All other findings or diagnoses shall remain confidential and shall not be included in the written report.

An accredited laboratory shall conduct all laboratory tests. The employer must be able to document (e.g., by certificate) that the laboratory is accredited by a national accrediting body (such as CDC or College of American Pathologists) or equivalent state agency that participates in a recognized quality assurance program.

8.6 Medical Records

The principal investigator shall ensure that an accurate record for each employee with occupational exposure is maintained. The record shall include:

- Name and Social Security number of the employee
- A copy of the employee's hepatitis B vaccination status, including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination
- A copy of all results of examinations, medical testing, and follow-up procedures
- The principal investigator's copy of the healthcare professional's written opinion
- A copy of the information provided to the healthcare professional

Employee medical records shall be kept confidential and shall not be disclosed or reported without the employee's express written consent to any person except as required by the OSHA standard and by law. If the employer has contracted with a clinic or other healthcare facility to provide the follow-up programs, the confidentiality requirements must be part of the contract.

The standard does not authorize the employer to be informed of the results of source-individual or exposed-employee testing. When an exposure incident occurs, the results of the source individual's testing become a part of the confidential medical record and must be made available to the employee. Employees must be afforded unrestricted access to their medical records.

Medical records do not have to be maintained by the employer, although the employer is responsible for record keeping. Records may be maintained by the physician or other licensed healthcare provider with whom the employer contracts to provide healthcare. The healthcare provider may be the preferred repository for medical records, at least as long as the employee is employed. It may be desirable to move selected records to a central, confidential archive after employment is terminated.

Employee medical records shall be maintained for at least the duration of employment plus 30 years.

9.0 Communication of Hazard to Employees: Labels

9.1 Labels

Warning labels are required on containers of biohazardous waste (unless the waste is placed into red/orange bags), refrigerators and freezers containing blood or other potentially infectious material, and other containers used to store, transport, or ship blood or other potentially infectious materials. The labels shall include the biohazard symbol and the word "biohazard."

9.2 Schedule and Method of Implementation for Labels

The labeling requirements are to be implemented immediately. The principal investigator shall ensure, either through inspection or delegation to supervisory staff that appropriate labels are in place. Labels may be obtained from Research Safety.

9.3 Laboratory-Specific Signage and Labeling Information

Do you have any laboratory-specific labeling requirements which supplement or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific labeling requirements.

10.0 Communication of Hazard to Employees: Information and Training

10.1 Responsibility

Principal investigators are responsible for ensuring that all employees with occupational exposure participate in a training program, which must be provided during working hours at no cost to the employee. Principal investigators shall provide laboratory-specific training on bloodborne pathogens to all employees with occupational exposure.

10.2 Training Program Available

Research Safety maintains the Bloodborne Pathogens training in myHR Learn that, when supplemented by site-specific information and presented in accordance with the criteria detailed below, can satisfy the training requirement of the standard. For further information on the training program please contact Research Safety.

10.3 Schedule

Training shall be provided at the time of initial assignment to tasks where occupational exposure may take place and at least annually thereafter. Annual training shall be provided within one year of previous training.

10.4 Additional Training

Principal investigators shall ensure that employees receive additional training when changes, such as modifications of tasks and procedures or institution of new tasks or procedures, affect the employee's occupational exposure.

10.5 Language, Literacy, and Educational Level

Training shall consist of material appropriate in content and vocabulary to the educational level, literacy, and language of employees. If an employee is proficient in a foreign language only, the trainer or an interpreter must convey the information in that language.

10.6 Content

As a minimum, the training program shall contain:

- An accessible copy of the standard and an explanation of its contents
- A general explanation of the epidemiology and symptoms of bloodborne diseases
- An explanation of the modes of transmission of bloodborne pathogens
- An explanation of the laboratory's Exposure Control Plan and how to obtain a copy of the laboratory's written plan
- An explanation of how to recognize tasks and activities that may involve exposure to blood and other potentially infectious materials
- An explanation of the use and limitations of methods that will prevent or reduce exposure, including appropriate engineering controls, work practices, and personal protective equipment
- Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment
- An explanation of the basis for the selection of personal protective equipment
- Information on the hepatitis B vaccine
- Information on appropriate actions to take and persons to contact in an emergency
- An explanation of the procedure to follow if an exposure incident occurs
- Information on post exposure evaluation and follow-up
- An explanation of the signs and labels and/or color coding
- An opportunity for interactive questions and answers

10.7 Records

Laboratory-specific training records shall be maintained by the principal investigator and shall include:

- Dates of training sessions
- Contents or summary of the training sessions
- Names and qualifications of persons conducting the training
- Names and job titles of all persons attending the training sessions

Training records shall be maintained in the laboratory for three years from the date on which the training occurred. Training records shall be provided on request for examination and copying to employees and to employee representatives. See Appendix 4 for a sample training documentation form.

10.8 Schedule and Method of Implementation for Training

The principal investigator shall ensure that all employees who are occupationally exposed receive training according to the requirements of the OSHA standard.

Training may be provided through the use of a combination of videos, handouts, pre- and post-tests, and personal presentations. Each training session shall include an opportunity for employees to ask questions. Training employees solely by means of a film or video is not permitted unless the required site-specific information is presented and a trainer is available to answer questions.

The person conducting the training is required to be knowledgeable on the subject matter covered by the training program, including site-specific information. Possible trainers include a variety of healthcare professionals such as infection control practitioners, nurse practitioners, registered nurses, physician's assistants, or emergency medical technicians.

Non–healthcare professionals such as industrial hygienists, epidemiologists, or professional trainers may conduct the training provided they can demonstrate evidence of specialized training in the area of bloodborne pathogens however employees must have access to an identified occupational health professional to answer health related questions.

10.9 Laboratory-Specific Training Information

Do you have any laboratory-specific training or health records which supplement or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific training or health records.

11.0 First Aid Provision

First aid providers whose primary job is not first aid administration do not have to be offered pre-exposure hepatitis B vaccination, according to OSHA. If the so-called secondary first aid providers are exposed to human blood or other potentially infectious materials on the job, the vaccine must then be offered within 24 hours of the incident. In addition, appropriate post-exposure evaluation, prophylaxis, and follow-up must be provided to employees who have an exposure incident.

If you have secondary first aid providers in your laboratory, your written Exposure Control Plan must address this issue. It must include:

- A reporting procedure for incidents
- A list (a log) of first aid incidents
- Documentation of employee training in the specifics of the reporting procedure. Exposure incidents must be reported before the end of the same shift during which the exposure incident occurred.

Your Exposure Control Plan's exposure determination—the list of employee classifications having exposure to human blood or other potentially infectious materials—must include the secondary first aid providers.

Technically, the failure to offer pre-exposure hepatitis B vaccination is still a violation. As a matter of policy, OSHA considers it a de minimis violation and citations will not be issued.

11.1 Laboratory-Specific First Aid Procedures

Do you have any laboratory-specific first aid requirements which supplement or differ from the information presented in the *Bloodborne Pathogens Program* document?

◯ Yes ◯ No

If yes, describe laboratory-specific first aid requirements.

12.0 Information about Hepatitis B and Hepatitis B Vaccine for University Employees

The Disease

Hepatitis B is a viral infection caused by hepatitis B virus (HBV), which causes death in 1% to 2% of patients. Most people with HBV recover completely, but approximately 5 to 10% become chronic carriers of the virus. Most of these people have no symptoms but can continue to transmit the disease to others. Some may develop chronic active hepatitis and cirrhosis. HBV also appears to be a causative factor in the development of liver cancer. Hepatitis B may be transmitted from a pregnant woman to the fetus. Thus, immunization against HBV can prevent acute hepatitis and also reduce the sickness and death from chronic active hepatitis, cirrhosis, and liver cancer. Hepatitis B vaccine will not prevent hepatitis caused by other agents, such as other viruses known to infect the liver.

The Vaccine

The recombinant hepatitis B vaccine is a noninfectious viral vaccine derived from HBV surface antigen (the viral coating material) produced in yeast cells. A portion of the hepatitis B virus

gene is cloned into yeast, and the vaccine is produced from cultures of this recombinant yeast strain. This vaccine is not produced from human blood or blood products. The safety and effectiveness are similar to the previously available vaccine derived from human plasma. The vaccine itself cannot cause hepatitis B.

Immunization requires three doses of vaccine over a six-month period, although some people may not develop immunity even after three doses. The second and third doses are given one month and six months after the first dose and must be taken on time or the series will be discontinued. If in the future you want to receive the hepatitis vaccine, you must start over again with the first dose. Clinical studies have shown that the vaccine produces protective levels of immunity in greater than 90% of healthy individuals when the three-dose regimen is administered. The duration of the protective effect is unknown at present. The need for booster doses is not yet defined.

Possible Vaccine Side Effects

The literature indicates that hepatitis B vaccine is generally well tolerated. No serious reactions have been reported. Some injection site soreness has been reported. Less common local reactions have included redness, swelling, warmth, or induration. These are generally well tolerated and usually subside within two days of vaccination. Low-grade fever occurs occasionally and is usually confined to a 48-hour period following vaccination. Other complaints such as malaise, headache, dizziness, and muscle and joint aches are infrequent and have been limited to the first few days.

You may wish to consult with your personal physician about the potential risk/benefits of this vaccine and to consult current medical literature.

13.0 Information Provided to the Healthcare Professional

The healthcare professional evaluating an employee after an exposure incident shall be provided with a copy of the OSHA Occupational Exposure to Bloodborne Pathogens standard as well as the following information:

- Date
- Name of exposed employee
- Laboratory
- The exposed individual’s duties as they relate to the exposure incident.
- Documentation of the route(s) of exposure and circumstances under which exposure occurred.
- Results of the source individual’s blood testing, if available.
- All medical records relevant to the appropriate treatment of the employee, including vaccination status. These are the principal investigator’s responsibility to maintain (attach copies).

14.0 Healthcare Professional's Post-exposure Evaluation

The post-exposure evaluation of an exposure incident involving an employee includes a written opinion from a healthcare professional. The principal investigator shall obtain and provide the employee with a copy of this opinion within 15 days of the completion of the evaluation.

This opinion shall be limited to the following:

- Employee Name
- Laboratory
- Statement:

1. The above-named individual has been informed of the results of the post-exposure evaluation.
2. The above-named individual has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment.

All other findings or diagnoses shall remain confidential.

Appendix 1: Aerosols, Respiratory Protection and Biological Safety Cabinets

The OSHA standard requires that all procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of those substances. This requirement decreases the chances of direct employee exposure and reduces contamination of surfaces.

OSHA has also reviewed whether aerosols require control measures. Aerosols are solid or liquid particles, ranging in size from submicrometer to multi-micrometer, that are suspended in a gas (the gas could be air). The suspension can last from a few seconds to a day or more. Aerosols of blood can be generated by a number of processes in healthcare and research settings. Sources are surgical power tools, removal of rubber tops from evacuated blood collection tubes, blood spills, and automatic pipetting instruments. Concerns have been raised about the generation of aerosols during centrifugation.

There is disagreement over whether respiratory protection should be used to protect against aerosol inhalation, and collateral questions about critical concentration values and monitoring. Some investigators have suggested that airborne transmission may exist, while CDC and NIOSH have stated that there are no cases traceable to airborne transmission. OSHA recognizes that the matter requires further study and has referred the matter to NIOSH. In the absence of sufficient information, OSHA has not required employers to control exposures to aerosols.

There is a hierarchy of controls to prevent exposure that must be implemented, beginning with universal precautions and including engineering controls and work practices. These should be implemented before relying on personal protective equipment such as respirators.

University policy states that human blood, blood products, and other potentially infectious materials are to be handled at Biosafety Level 2 (BL2) as defined in the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories. Under BL2, biological safety cabinets or other appropriate personal protective or physical containment devices are to be used whenever procedures with a high potential for creating infectious aerosols are conducted. These procedures may include, but are not limited to, centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, and opening containers of infectious materials whose internal pressures may be different from ambient pressures.

Materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used and if these rotors or safety cups are opened only in a biological safety cabinet.

Other physical containment devices could include chemical fume hoods. Care should always be taken to ensure that centrifugation or other procedures inside a hood or safety cabinet do not interfere with the airflow characteristics of the device, thereby increasing the potential for material to be carried out of the device.

Bench-top shields may be effective in protecting against splashing, spraying, spattering, and generation of droplets. Working in a chemical fume hood may also be effective provided the protective windows are manipulated both to maintain proper airflow and provide a physical barrier.

Appendix 2: Authorized Healthcare Providers

The Bloodborne Pathogens Standard is a performance standard; employers are informed of the requirements, and it is their responsibility to develop the methods of compliance. University laboratories are likewise given latitude in developing their programs and are free to obtain independently the services of healthcare providers. This supplement provides guidance on the qualifications of healthcare providers hired to perform services required by the standard.

The OSHA standard requires that all medical evaluations and procedures, including the hepatitis B vaccine and vaccination series and post exposure evaluation and follow-up, including prophylaxis, are provided by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional.

Licensed healthcare professional is defined as "a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f)." Paragraph (f) is the previous paragraph.

The legal scope of practice for this professional must allow the independent performance of all the procedures related to vaccination and post exposure evaluation and follow-up. A variety of healthcare professionals may perform these functions. For example, in addition to licensed physicians, the majority of states have laws that enable advanced nurse practitioners to provide medical services independently. Nurse practitioners and clinical nurse specialists are registered nurses prepared through a formal, organized education program and certified for an advanced practical role. This group of registered nurses provides primary healthcare that includes traditional medical services as well as nursing care.

Vaccination protocols require oversight by the licensed healthcare professional. The hepatitis B vaccination must be given in the standard dose and through the standard route of administration as recommended in the USPHS/CDC guidelines. The results of any pre-vaccination antibody testing must be reviewed to determine if the employee is immune. Any contraindications must be fully characterized before vaccination is provided.

Appendix 3: Post-exposure Evaluation and Follow-up Procedure

In the rare occurrence of an employee or student being exposed to blood or other potentially infectious material, follow the procedures described below. In the event of an exposure incident, it is the principal investigator's responsibility to ensure that a confidential medical evaluation and follow-up is made available to the exposed person.

STUDENTS

Evanston Campus

Students should notify their supervisor and call the University's Health Service at 491-8100 (available 24 hours), and consult with a physician. The physician will determine what course of treatment is appropriate for the exposure incident.

Chicago Campus

Students should notify their supervisor and call Northwestern Memorial Hospital Corporate Health at 6-8282. The health care professional on call will evaluate the exposure. Do not go to the emergency laboratory unless instructed by the healthcare professional answering the call.

If the exposure is coupled with life threatening circumstances, call the University Police at 911 immediately.

EMPLOYEES

Evanston Campus

Employees should notify their supervisor who will call the claims manager of Risk Management at 1-5582. The claims manager will call Occupational Medicine Evanston/Glenbrook Association (OMEGA) to arrange an appointment. The employee should proceed to OMEGA and secure treatment as scheduled. After normal working hours, employees should seek medical attention at Evanston Hospital's emergency room. It is important that injured employees taken to Evanston Hospital should themselves as Northwestern University OMEGA patients.

Chicago Campus

Employees should notify their supervisor and call Northwestern Memorial Corporate Health at 6-8282. The health care on answering the call will evaluate the exposure. Do not go to the emergency laboratory unless instructed by the healthcare professional answering the call.

Again, if the exposure incident is coupled with life threatening circumstances, call the University Police immediately at 911. UP will contact fire laboratory paramedics and direct them to the injured person for treatment and transportation to the hospital emergency room.

For incidents occurring on either campus, notify the claims manager of Risk Management at 1-5582, regarding workers' compensation if the exposed individual is an employee. All incidents shall be reported to Research Safety for review by the Chemical and Biological Safety Committee.

Appendix 4: Laboratory-Specific Training Documentation

Dates of training session:

Contents or summary of the training sessions:

Names and qualifications of person(s) conducting the training:

Names and job titles of all persons attending the training sessions:

Name	Job Title