Bloodborne Pathogens
Exposure Control Plan

UNIVERSITY OF MICHIGAN
Environment, Health & Safety
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SECTION 1: INTRODUCTION

The following University of Michigan (U-M) Exposure Control Plan (ECP) has been developed and implemented to meet the letter and intent of Michigan Occupational Safety and Health Administration’s (MIOSHA) Bloodborne Infectious Diseases Standard, codified as R325.70001 through R 325.700018. Compliance with the Bloodborne Infectious Disease Standard will reduce occupational exposure to blood and other potentially infectious materials, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and other bloodborne pathogens.

The following principles must be applied when employees are potentially exposed to bloodborne pathogens:

- Minimize all exposures to bloodborne pathogens
- Institute as many engineering and work practice controls as possible to eliminate or minimize employee exposure to bloodborne pathogens
- Routinely employ universal precautions when exposure to blood or potentially infectious materials is anticipated

The objectives of the U-M Exposure Control Plan are to:

- Provide information on procedures and regulations regarding bloodborne pathogens
- Protect employees from health hazards associated with bloodborne pathogens
- Provide information on appropriate treatment and counseling to employees exposed to bloodborne pathogens

SECTION 2: GENERAL

About the U-M Bloodborne Pathogens Exposure Control Plan

University of Michigan is an employer with various groups of employees who have a reasonably anticipated risk of exposure to human blood and other potentially infectious materials when performing their required job duties. As such, U-M must have an exposure control plan in accordance with MIOSHA’s Bloodborne Infectious Diseases standard. This plan is an administrative document that outlines how this occupational exposure risk will be controlled through the use of administrative controls, engineering controls, work practice controls, and personal protective equipment.

The following document has been prepared by U-M Environment, Health & Safety (EHS) in order to outline the institutional exposure control policies & procedures that will be followed by all affected U-M departments. The scope of this plan is the Ann Arbor campus and those areas outside of Ann Arbor that are affiliated with Ann Arbor departments. U-M Hospital is covered by its own ECP.

Due to the diversity of job tasks with associated bloodborne pathogens risk, it must be recognized that information related to task-specific and site-specific procedures may need to be prepared and maintained at the local level along with this institutional exposure control plan in order to fully address regulatory requirements. The EHS Document Binder will be used to store site-specific compliance information and records.
Areas of Responsibility

Four areas of responsibility are central to the implementation of the U-M Exposure Control Plan:

- Biological Safety Officer
- Supervisory Personnel (including Department Chairpersons, Directors, Principal Investigators, Managers and Supervisors)
- Education/Training Coordinators and Instructors
- Employees

**Biological Safety Officer**

The EHS Biological Safety Officer (BSO) is responsible for management and support of the Bloodborne Pathogens Compliance Program. U-M Occupational Health Services (OHS) will assist the BSO. Activities delegated to the BSO include:

- Overseeing implementation of the U-M Exposure Control Plan
- Developing any additional bloodborne pathogens related policies and practices needed to support the effective implementation of this plan
- Revising, updating and improving the U-M Exposure Control Plan when necessary, and on an annual basis
- Collecting and maintaining a suitable reference library related to bloodborne pathogens
- Understanding current legal requirements concerning bloodborne pathogens
- Conducting periodic organizational audits to maintain an up-to-date Exposure Control Plan

**Supervisory Personnel**

- Department Chairs, Directors, Principal Investigators, Managers and Supervisors are responsible for compliance in their areas. They shall work with the BSO, EHS, U-M OHS and their employees. Activities delegated to the supervisory personnel include:
  - Assuring that employees in their area who are at risk of exposure to bloodborne pathogens receive initial training and annual retraining (including site-specific training) in bloodborne pathogens as outlined in the "Information and Training" section of this document.
  - Evaluating the bloodborne pathogen risk associated with an employee's job classification. This must be done when a new employee is hired, or when an employee changes jobs. This evaluation must include:
    - Checking the employee's job classification and the tasks and procedures that he/she will perform to determine if there is a reasonably anticipated risk of exposure to blood or other potentially infectious material (OPIM)
    - Identifying the new job classifications and/or tasks and procedures which will potentially expose the employee to blood or other potentially infectious materials
    - Informing EHS of all changes so records can be updated
  - Assuring that proper exposure control procedures are followed as outlined in the “Methods of Compliance” section of this document
  - Assuring that appropriate personal protective equipment is available and in good working condition for all employees at risk of exposure to bloodborne pathogens
  - Assuring that any employee who experiences an occupational exposure incident to blood or other potentially infectious materials is provided with post-exposure medical services as outlined in the “Post-Exposure Evaluation and Follow-Up” section of this document
**Training Instructors**

EHS will provide information and training to all employees who have an anticipated risk of exposure to bloodborne pathogens. EHS will:

- Provide training records for the required initial training and annual retraining taken through My Linc
- Develop suitable training programs
- Periodically review the training programs to include appropriate new information

**Employees**

The employees are responsible for following procedures and practices as outlined in the U-M Exposure Control Plan. This includes but is not limited to:

- Taking the bloodborne pathogens initial training, annual retraining, and site specific training
- Demonstrating an understanding of which tasks have a potential occupational exposure to bloodborne pathogens
- Conducting all operations in accordance with established work practice controls
- Following universal precautions
- Developing and maintaining good personal hygiene habits
- Reporting all occupational exposure incidents and following post-exposure medical services as indicated by OHS

**Exposure Control Plan Availability and Review**

The U-M Exposure Control Plan **must** be readily available to all employees through their supervisor. The plan can be accessed online at [www.ehs.umich.edu](http://www.ehs.umich.edu) and/or a hard copy of the plan can be kept in areas where needed. Employees are to be advised of the availability of the plan as well as the site-specific information kept in the EHS Document Binder during their training sessions.

The U-M Exposure Control Plan will be reviewed annually. It will be updated:

- When new or modified tasks and procedures are implemented which affect occupational exposure of employees
- To reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens

Departments will be responsible for reviewing and updating site-specific content as necessary within their EHS Document Binder.
SECTION 3: EXPOSURE DETERMINATION

MIOSHA’s Bloodborne Infectious Diseases Standard requires an employer to evaluate routine and reasonably anticipated tasks and procedures to determine whether there is actual or reasonable anticipated employee exposure to blood or other potentially infectious materials. Occupations that require procedures or other occupational-related tasks that involve exposure or reasonably anticipated exposure to blood or other potentially infectious material or that involve a likelihood for spills or splashes of blood or other potentially infectious material are classified as Category A in the exposure control plan. This determination also includes procedures and tasks conducted in non-routine situations as a condition of employment. The determination shall be made without regard to the use of personal protective clothing and equipment.

Job classifications which may have a reasonably anticipated risk of exposure to bloodborne pathogens, either by the nature of the occupation or by specific tasks which an employee is required to perform as part of their job are classified as Category A and are listed in Appendix A. This list may not cover all job classifications where an employee may have a bloodborne pathogens risk. Some employees with a job classification on this list may not be at risk. Risk assessment will be performed by the supervisor and documented in the EHS Document Binder.

NOTE: If an employee job classification is not included in Appendix A, the supervisor should notify EHS to update information.

SECTION 4: METHODS OF COMPLIANCE

Universal Precautions

Employees at University of Michigan will observe universal precautions. All human blood and other potentially infectious materials (OPIM) are treated as if they are known to be infectious for HBV, HIV and other bloodborne pathogens.

OPIM are defined as:

- 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 in situations where it is difficult or impossible to differentiate between body fluids
- Any unixed tissue or organ (other than intact skin) from a human, living or dead
- HIV-containing cell or tissue cultures, organ cultures, and HIV, HBV or HCV-containing culture medium or other solutions; and blood, organs, or other tissue from experimental animals infected with HIV, HBV, HCV or any other human, bloodborne pathogen
- Blood, organs or other tissues from experimental animals infected with BBP
- Introduction of human-derived materials (i.e. tumor cells) into animals

For clinical faculty/staff, Body Substance Isolation (BSI) is a method of infection control in which all body fluids and substances are considered to be infectious. Since BSI incorporates not only the fluids and materials covered by the standard, but expands coverage to include all body fluids and substances, BSI is an acceptable alternative to universal precautions provided facilities utilizing BSI adheres to all other provisions of this standard.

The only exception to the use of universal precautions is in unexpected, extraordinary circumstances involving the provision of healthcare or public safety services. An example would be a medical emergency where an employee is unable to put on gloves, don a gown, or tie on a face-mask immediately. This DOES NOT
NOT mean that an employee can decide not to use personal protective equipment because he/she considers it impractical. It is only an option in rare situations where the employee decides that such equipment will prevent the proper delivery of medical care or emergency services, or it will create a greater hazard to his/her safety if such equipment is used.

**Engineering Controls**

Where engineering controls such as hand washing facilities, eye wash stations, sharps disposal containers, biological safety cabinets, ventilating laboratory hoods, autoclaves, and safer sharps devices will reduce employee exposure either by eliminating or isolating the hazard, they **must** be used.

EHS and departments will review tasks and procedures performed to determine where engineering controls can be implemented or updated. The Supervisor will ensure that employees are trained regarding the use of the engineering controls for their job classification and the tasks/procedures they perform.

The following engineering controls are to be used throughout the University:

- Safer sharps devices are to be used on human blood or other potentially infectious materials, where appropriate, in order to reduce the risk of injury from needlesticks and from other sharp devices. (Refer to section on the Sharps Injury Protection Program)

  **NOTE**: Needles that will not become contaminated by blood or OPIM during use (such as those used to draw medication or chemicals from vials) are not required to have engineering controls.

- Hand washing facilities are readily accessible to all employees who have a potential for exposure. Waterless antiseptic hand cleansers or antiseptic towelettes **must** be available to employees at risk of exposure if running water is not readily available. If waterless cleansers or towelettes **must** be used, the employee **must** follow-up with a soap and water wash as soon as feasible.

- Emergency eye wash stations are in close proximity to workstations where employees perform tasks that produce splashes of potentially infectious materials. Eyewash stations should meet ANSI requirements. The eye wash facility **must** be flushed on at least a monthly basis and documented. The equipment **must** be annually tested and documented.

- Autoclaves are available in many departments to decontaminate solid biohazardous waste. These departments will monitor this equipment to assure that proper sterilization occurs. Proper instrumentation will be used to verify that time, temperature, and steam are adequate.

- Sharps containers are used to properly store and dispose of sharps. Approved sharps containers are designed to isolate the cut or puncture hazard associated with handling contaminated sharp items. Approved sharps containers are:
  - puncture-resistant
  - red in color or labeled with a biohazard warning label
  - leak-proof on the sides and bottom
  - closable

  During use, sharps containers will be:
  - Easily accessible to personnel and located as close as is feasible to the area where sharps are used
  - Maintained in an upright position throughout use
  - Replaced routinely and not allowed to overfill
Containers for reusable sharps **must** meet the same requirements as containers for disposable sharps, with the exception that they are not required to be closable. Reusable sharps will not be stored or processed in a manner that requires reaching into containers of contaminated sharps.

Approved sharps containers are available from EHS Hazardous Materials Management (HMM) at 763-4568 or complete the online [Waste and Supply Request](#) form. Food containers such as coffee cans should not be used to dispose of contaminated sharp objects.

- Storage containers are used to reduce the possibility for an environmental release of potentially infectious materials. Primary containers should be designed to be leak-proof, puncture-resistant, and capable of being closed. Single primary containers used for potentially infectious materials should be labeled with the biohazard symbol.

**Exceptions:**

- Containers of blood, blood components, or blood products which are labeled as to their contents and which have been released for transfusion or other clinical use are exempted from these labeling requirements.
- Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage are exempted from labeling requirements.

Examples of containers that **must** be labeled as biohazardous if storing blood or potentially infectious materials:

- Refrigerator
- Freezer
- Liquid nitrogen tank
- Incubator
- Transport containers

- Transport containers are secondary containers that are used to reduce the possibility for an environmental release of potentially infectious materials when transporting biological materials between campus facilities as well as over the roadways. (See Appendix B: Transporting Biological Materials)

**Work Practices**

Supervisors, working in conjunction with Deans, Directors, Chairs or designees will oversee the implementation of Work Practice Controls in cooperation with EHS. The Department Manager or Supervisor will ensure that employees are trained to use work practice controls for their job classification and the tasks/procedures they perform.

The following **Work Practice Controls** are to be implemented:

- Employees will wash their hands:
  - After removal of gloves or other personal protective equipment
  - When visible contamination with blood, body fluids, or other potentially infectious materials are present
  - When work is completed and before leaving the work area (i.e. laboratory, clinic)
  - Before eating, drinking, smoking, applying makeup, changing contact lenses, or using the bathroom
  - Before activities that entail hand contact with mucous membranes, eyes, or breaks in the skin
NOTE: Alcohol based hand rubs may be used by healthcare personnel for patient care. When healthcare personnel's hands are visibly soiled, they should wash with soap and water.

- Contaminated needles and other contaminated sharps must not be bent, recapped or removed unless:
  o It can be demonstrated that there is no feasible alternative or
  o The action is required by a specific medical procedure

When recapping or removal of needles is required because there are no alternatives, a mechanical device or a one handed method must be used.

- Use mechanical means (i.e. tongs) when handling contaminated sharps when possible and eliminate hand-to-hand passing of sharp instruments.
- Contaminated sharps must be placed in appropriate containers immediately, or as soon as possible after use.
- Eating, drinking, smoking, applying cosmetics or lip balm and handling contact lenses is prohibited in work areas where there is potential for exposure to bloodborne pathogens.
- Food and drink must not be kept in refrigerators, freezers, on countertops, or in other storage areas where blood or other potentially infectious materials are present.
- Mouth pipetting/suctioning of blood or other infectious materials is prohibited.
- Minimize splashing, spraying or other actions generating droplets of blood or other potentially infectious materials during all procedures. At a minimum, Biosafety Level 2 precautions are required for laboratories working with specimens of blood or body fluids. Contact EHS for further information and assistance regarding these requirements.
- Specimens of blood or other materials must be placed in designated leak-proof containers, appropriately labeled for handling and storage. If outside contamination of a primary specimen container is likely, that container must be placed within a second leak-proof container, appropriately labeled, for handling and storage. If the specimen can puncture the primary container, the secondary container must be puncture-resistant.
- Primary containers of potentially infectious materials must be placed in puncture-resistant, leak-proof, closable secondary containers for transportation outside of the work area (i.e. from lab to lab where a common hallway is used, etc.).
- Properly prepare and transport biological materials in a vehicle by following the Transporting Biological Materials procedure (Appendix B).
- Perform disinfection and housekeeping procedures as outlined in “Housekeeping” section of this Exposure Control Plan.

**Personal Protective Equipment (PPE)**

Personal protective equipment will be provided by the employer at no cost to the employee with an occupational exposure to blood or potentially infectious material. This equipment may include: gloves, gowns, laboratory coats, face shield/masks, splash goggles, resuscitation bags, pocket masks, hoods, and shoe covers.

Personal protective equipment is considered to be appropriate only if it does not permit blood or other potentially infectious material to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used.
The Department Manager or Supervisor will ensure:

- That all work areas have appropriate personal protective equipment available to employees. Employees **must** be trained regarding the use of the appropriate personal protective equipment for their job classification and the tasks/procedures they perform.
- That the personal protective equipment is available in appropriate sizes and accessible locations.
- The employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use PPE when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance the use of PPE would have prevented the delivery of health care or public safety services or posed an increased hazard to the safety of the worker or coworker.

When the employee makes this judgment, the circumstances shall be investigated and documented to determine if changes can be made to prevent future occurrences.

To ensure that personal protective equipment is not contaminated and is in the appropriate condition to protect employees from potential exposure, the following practices are to be utilized:

- All personal protective equipment **must** be inspected periodically by the department manager or supervisor and repaired or replaced as needed.
- Reusable personal protective equipment is cleaned, laundered and decontaminated as needed.
- Single-use personal protective equipment (or equipment that cannot, for whatever reason, be decontaminated) is disposed of through as Biological Waste through EHS-Hazmat.

Employees **must** adhere to the following practices when using personal protective equipment:

- Any garments, including personal clothing, penetrated by blood or other infectious materials, **must** be removed as soon as possible. Contaminated laundry will be handled as little as possible. Place in bags or containers that are appropriately labeled and if saturated, the bags or containers should prevent soak-through or leakage of fluids to the exterior.
- All personal protective equipment **must** be inspected prior to use to verify that it is in good working condition.
- All personal protective equipment **must** be removed prior to leaving the work area.
- Gloves **must** be worn when:
  - employees anticipate hand contact with potentially infectious materials
  - performing vascular access procedures
  - handling or touching contaminated items or surfaces

**NOTE:** “The US Food and Drug Administration has issued a ban on all powdered gloves. Exposure to starch powder from gloves can cause undesirable reactions, which vary from well-known allergy symptoms and upper respiratory-tract disorders to surgical adhesions and infections. The presence of glove powder can also result in many other undesirable effects, such as interference in laboratory testing causing false results (i.e. PCR – Polymerase Chain Reaction, enzyme immunoassay or some HIV tests).”

- Disposable gloves **must** be replaced as soon as possible after contamination or immediately when torn, punctured, or are otherwise rendered unable to function as an exposure barrier. Disposable gloves will not be washed or decontaminated for reuse.
- Non-latex gloves **must** be provided to employees who are allergic to the gloves normally provided.
- Utility gloves must be decontaminated for reuse; if utility gloves are cracked, peeling, torn or exhibit other signs of deterioration, they must be disposed.
- Masks/eye protection, or chin-length face shield must be worn as appropriate whenever there is a chance that a splash or spray may generate droplets of infectious materials.
- Protective clothing must be worn whenever potential exposure to the body is anticipated.
- Surgical caps/hoods and shoe covers/boots must be used in any instances where gross contamination is anticipated.

**Sharps Injury Protection Program**

Supervisors of all departments who have employees with occupational exposure to bloodborne pathogens involving the use of sharps must:

- Use effective engineering controls, including safer sharps devices, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments
  
  **NOTE:** An appropriate safer sharps device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated.

- Establish a program for evaluating safer sharps devices designed to eliminate or minimize occupational exposure. This program should include an identification process, an evaluation process and a selection process
- Review the sharps that are being used on an annual basis

**Identification Process**

Supervisors shall identify all sharp devices that have available products with safer engineering features and determine which products are to be evaluated.

**Evaluation Process**

Evaluation of the safer sharps devices must be documented on the “Safer Sharps Device Evaluation Form” (Appendix D).

Supervisors in departments with direct patient care cannot evaluate and select the safer sharps devices alone; supervisors must choose non-managerial employees who perform tasks with sharps exposure risks to be involved in this process. Supervisors will:

- Provide test samples of each product being evaluated to each individual evaluating the product
- Provide visual instructions and a demonstration of the proper use of each device to all evaluators
- Encourage each evaluator to provide comments.
- Keep all records of completed evaluation forms in the EHS Document Binder or in departmental records

**NOTE:** If safer sharps devices are currently in use, the evaluation process must still be completed.

**NOTE:** If there is no safer option for a particular sharps device used where there is exposure to blood or OPIM, you are not required to use something other than the device that is normally used. This information must be documented. During your annual review of devices, you must inquire about new or prospective safer options.
**Selection Process**

Once the evaluation process is complete and the safer sharp device has been chosen, supervisors **must** implement use of the safer sharps devices as soon as possible.

**NOTE:** The selection and implementation process cannot be postponed in order to use up supplies of non-safer sharps. Additionally, when the safer sharps are in place, supplies of the non-safer sharps may not be used. Contact EHS for disposal assistance if needed. Do not put unused supplies in the trash or send to salvage. If the safety device is not available (due to supply shortages, back orders, shipping delays, etc.), this **must** be documented.

**Annual Review**

All sharps that are being used where there is exposure to human blood or OPIM **must** be reviewed on an annual basis. This will be accomplished by completing a “Safer Sharps Devices Annual Review Form” (Appendix D). This form should be completed annually and kept with departmental records.

The purpose of this review form is to document annual consideration and implementation of appropriate commercially available and effective safer sharps devices designed to eliminate or minimize exposure.

The review and update **must** reflect innovations in procedure and technological developments that eliminate or reduce exposure to bloodborne pathogens. This includes, but is not limited to, newly available sharps devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens.

**Housekeeping**

Work locations that involve blood or other potentially infectious material **must** be maintained in a clean and sanitary condition. Departments and Units or other assigned employees **must** do the following:

- Clean and decontaminate all equipment and surfaces with an appropriate disinfectant:
  - After contact with blood or other potentially infectious materials. (Gross contamination **must** be removed before decontaminating to ensure the disinfectant is completely effective)
  - At the end of the work shift if the surface may have become contaminated since the last cleaning
  - Prior to servicing or shipping equipment, decontamination **must** be completed. An **Equipment Decontamination Form** **must** be attached. If it can be demonstrated that decontamination is not possible, then the following steps need to be taken:
    - Attach a biohazard label is to any contaminated equipment, identifying the contaminated portions
    - Inform all affected employees, the equipment manufacturer and the equipment service representative of remaining contamination prior to handling, servicing or shipping
- Immediately when blood or other potentially infectious material is spilled. The following considerations should be made when treating and removing a spill of infectious material:
  - Wear appropriate personal protective equipment when cleaning up spills
  - Spills should be covered with an absorbent material, wiped up and disposed of in a biohazard bag

**NOTE:** Any department that has a potential for a spill of potentially infectious materials shall have a spill kit and a spill response procedure. An example of a general response procedure and items for assembling a departmental spill kit are included in Appendix E, Biohazardous Spill Response.
NOTE: Decontamination must be performed with a disinfectant product that is EPA-registered for the destruction of Hepatitis B, or is a tuberculocidal. The disinfectant must be applied to contaminated surfaces for the amount of time prescribed by the manufacturer to assure effective decontamination.

- Remove and replace protective coverings as soon as possible when contaminated, and at the end of the work shift after use
- Routinely inspect all pails, bins, cans and other receptacles for contamination. Clean these items on a routine basis and decontaminate whenever visibly contaminated
- Pick up potentially contaminated broken glassware using mechanical means (such as dustpan and brush) and dispose of in an appropriate sharps container
- Inspect laundry to verify that it is free of sharps and other hazardous materials prior to placement in bags or containers appropriately labeled for transport to the laundry. Handle contaminated laundry as little as possible. Whenever contaminated laundry is wet and may be reasonably expected to soak or leak through a normal container, the laundry will be placed and transported in bags or containers that prevent soak-through and/or leakage of fluids to the exterior
- The department will provide employees who may have contact with contaminated laundry with the appropriate personal protective equipment including gloves and protective clothing. The department shall ensure that all contaminated laundry is cleaned and laundered in such a way that any bloodborne pathogens present are inactivated or destroyed
- When disposing of biohazardous waste follow the SOPs according to waste type:
  
  Solids:
  
  - Autoclaving Solid Biohazardous Waste that Will Not Puncture the Skin
  - Autoclaving Solid Biohazardous Waste that May Puncture the Skin
  - Chemically Treating Solid Biohazardous Waste that May Puncture the Skin
  - Preparing Solid Biohazardous Waste that Will Not Puncture the Skin for Collection
  
  Liquids:
  
  - Preparing Liquid Biohazardous Waste for Collection
  - Disposing Liquid Biohazardous Waste Using the Sanitary Sewer Drain
  
  Sharps:
  
  - Preparing Biohazardous Sharps Waste for Collection
  
  Pathological waste:
  
  - Preparing Pathological Waste for Collection
  
  Uncontaminated Waste
  
  - Disposal of Uncontaminated Waste

NOTE: Biohazardous wastes are not to be held in the work area for more than 60 days. All biohazardous waste will be disposed of according to the procedures outlined on EHS website under Hazardous Waste-Biological Waste.
SECTION 5: HIV AND HBV RESEARCH LABORATORIES AND PRODUCTION FACILITIES

HIV and HBV research laboratories and production facilities present increased risk for occupational exposure to bloodborne pathogens.

HIV or HBV Research Laboratories:

All laboratories engaged in the culture, production, concentration, experimentation, and manipulation of HIV or HBV will reduce employee risk by providing additional administrative controls, protective equipment, information and training beyond that required for research laboratories not involved in such work. Refer to Appendix F HIV and HBV Research Laboratories for these additional requirements.

SECTION 6: HEPATITIS B VACCINATION, POST-EXPOSURE EVALUATION AND FOLLOW-UP

A “Hepatitis B Vaccination Program” has been established through the U-M Occupational Health Services. OHS is also the location for the follow-up evaluation and treatment for any occupational exposure to bloodborne pathogens.

Hepatitis B Vaccination Program

U-M has a vaccination program through the U-M Occupational Health Services. This program is offered to all employees who have occupational exposure to bloodborne pathogens. The cost, as required by statute, is assumed by the employer, U-M.

The MIOSHA Bloodborne Infectious Diseases standard requires that Hepatitis B vaccine be made available to the employee within ten days of initial assignment and after the employee has completed bloodborne pathogens initial training.

The vaccination program consists of a series of three vaccinations over a four to six-month period. Although, follow-up serology testing is not necessary after immunization- lifetime immunity has been documented, the employee may choose to confirm immunity through an antibody titer at OHS.

Employees will receive information regarding the vaccination program following the completion of the bloodborne pathogens training. They will also receive the required Hepatitis B Vaccination form to be completed as indicated. The vaccination series is completely voluntary; The employee may choose to accept the vaccination series, decline, or indicate that they previously completed the series. Employees also have the opportunity to discuss this further in person at the clinic before deciding to accept or decline the series.

This form must be maintained by the department or kept in the EHS document binder.

Any employee that initially declines to participate in the HBV immunization program, but at a later date decides to become immunized, can obtain the series at that time.

U-M Occupational Health Services, under the supervision of a licensed physician, is responsible for the vaccination program and will maintain records for those employees that obtain the series as part of their medical record for the duration of their tenure. The series will be provided according to the recommendations of the U.S. Public Health Service current at the time of the vaccination.
Post-Exposure Evaluation and Follow-Up

If an employee is involved in an incident where exposure to bloodborne pathogens may have occurred, the employee should seek medical consultation and treatment expeditiously. In these instances, actions should include the following:

- If contact with blood or other potentially infectious material occurs on non-intact skin (i.e. cuts, rashes, acne, dermatitis), wash the area for 15 minutes with soap and water.
- If blood or other potentially infectious material splashes in the eyes or on mucus membranes, flush the area for 15 minutes with water or normal saline.
- Follow EHS SOP “Responding to a Needlestick or Biological Exposure” which contains the following steps:
  1. Report the incident to a supervisor or person in charge.
  2. If the incident involved puncture of the skin or contact with non-intact skin, eyes or mucous membranes, the incident must be reported through the following system to ensure regulatory compliance and appropriate follow-up care for the individual.
     a. Call OHS at 734-936-6266
     b. Enter Pager ID # 5356
     c. Enter a phone number for a return call.
     d. Wait for a return call from an OHS nurse who will document the incident and further instruct the individual.

   This service is available 24 hours per day, 7 days a week, 365 days per year.

3. The employee may be instructed to visit OHS or U-M emergency room if after hours. If outside of the Ann Arbor campus area, employee should go to nearest urgent care or emergency room per instructions. Locations outside of Ann Arbor should be documenting and training staff on the appropriate location for follow-up treatment as part of site-specific training.

- All evaluations, procedures, vaccinations and post-exposure prophylaxes are provided without cost to the employee and according to current recommendations of the United State Public Health Service.
- The physician will provide the employee with a confidential medical evaluation and follow-up of the incident to include:
  o Evaluation of the exposure risk of the incident based on the exposure source
  o Identification and documentation of the source individual (if applicable) and testing for HBV and HIV. Results of this testing will be provided to the employee
  o Recommended options for testing and preventative treatment
  o Rationale and benefits of the tests and treatment options
  o Testing will be completed as soon as feasible after the employee consents. Employee acceptance of these tests/treatments will be on a completely voluntary basis.
  o Additional testing as required
- The medical provider will provide the employee a written opinion (physician’s determination) within 15 days of the completion of the evaluation. The report will summarize that the employee has been informed of the results of the evaluation and has been told about any medical conditions resulting from their exposure that may require further treatment and evaluation. They will also indicate if HBV vaccine was indicated and if it was received.
- The supervisor should fill out the Work Connections Injury or Illness Report Form.
Incidents relating to research must then also be reported to EHS. Complete the Incident and Near Miss Report Form for both Laboratories and Shops/Studios or incidents at all other locations involving: near misses, fires/explosions, property damage, injuries, or illnesses.

- OHS will evaluate all bloodborne pathogens exposure incidents and record the following information:
  - Date/time of Incident
  - Name of employee, job title, department, supervisor
  - Incident description (including route of exposure, device in use, use of engineering/work practices/PPE)
- OHS will complete and maintain a Sharps Injury Log for all bloodborne pathogens exposure incidents involving sharps.
- The information in the Work Connections injury reporting system and the Sharps Injury Log will be recorded and maintained in such a manner as to protect the confidentiality of the employee.
- All costs associated with employees treatment involving an occupational exposure or injury at OHS will be covered by the university. Employees that present to U-M Hospital should indicate that they are U-M employees seeking treatment for a work-related incident. Those outside of the Ann Arbor area will need to work with Risk Management to seek reimbursement for costs incurred from their treatment of a work-related incident.

**Medical Record Keeping**

U-M Occupational Health Services must establish and maintain employee medical records. All information is confidential. Information will not be disclosed without the employee's written consent, except as required or permitted by law.

**SECTION 7: LABELS AND SIGNS**

Biohazards must be labeled according to the following procedures. Required labels consist of a red or fluorescent orange colored background with the traditional biohazard symbol in a contrasting color. Labels can be an integral part of the container or affixed by a method that prevents the loss of labels or the unintentional removal of labels.

The following items must be labeled:

- Containers of regulated waste
- Refrigerators, freezers, incubators, or other equipment containing blood or other potentially infectious materials
- Sharps disposal containers
- Containers used to store, transport or ship blood and other potentially infectious materials (When a secondary container holds a number of smaller items containing the same potentially infectious substance, only the secondary container needs to be labeled)
- Laundry bags/containers holding contaminated items
- Contaminated equipment

Biohazard signs must be posted at entrances to any Biosafety Level 2 (or higher) laboratory. For more information on signs and labels contact EHS at 647-6585.

Biohazardous waste that has been decontaminated by steam sterilization must have a positive indication of safety. A printed-on sterilization indicator on the autoclave bag meets this requirement.
Information and Training

All employees who have the potential for exposure to bloodborne pathogens must complete a comprehensive training program provided at no cost and during working hours. This includes:

- Bloodborne pathogens initial training
- Bloodborne pathogens annual refresher training

EHS will maintain documentation for all employees who have potential exposure to bloodborne pathogens and have received training through EHS. Departments will maintain documentation of all site-specific training within their EHS Document Binder.

Go to the EHS website at http://ehs.umich.edu/education/ehs-training-login/ to sign up for classes and view the training course catalog.

All new employees, as well as employees changing jobs or job functions, will be given any additional training their position requires by their new supervisor prior to beginning their new job assignments.

Training Methods

- Several training techniques may be used including:
  - Personal instruction
  - Video
  - Computer aided training
  - Training manuals/employee handouts
  - Employee review sessions
- Opportunities for employees to ask questions will be provided.
- Departments requesting training to be conducted at their site must provide a designated person to be available during the training session to answer site-specific questions
- The participant must complete site-specific training with their supervisor or a designated trainer for their area after completion of initial training, after new tasks have been assigned and annually. (See below for details)

Bloodborne Pathogen Initial Training

- Taken by all employees who have a potential risk of exposure to human blood or other potentially infectious human materials.
- Completed before the employee performs any tasks that have a bloodborne pathogens exposure risk.
- Available as an online course and in-person training as needed.  View course catalog and sign up for training at http://ehs.umich.edu/education/ehs-training-login/

Training Topics

Bloodborne pathogens initial training for new employees who will have occupational exposure to bloodborne pathogens will include the following mandatory topics:

- MIOSHA’s Bloodborne Infectious Diseases Standard
- Epidemiology, symptoms and modes of transmission of bloodborne diseases including HIV, HBV, and HCV
- Existence of other bloodborne diseases
- U-M’s Exposure Control Plan including how to access it
• Appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials
• A review of the use and limitations of methods that will prevent or reduce exposure, including:
  o Engineering controls
  o Work practice controls
  o Personal protective equipment
• Selection and use of personal protective equipment including: types, proper use, limitations, location, removal, handling, decontamination, and disposal
• Visual warning of biohazards including labels, signs, and color-coded containers
• Proper procedures and materials involved in the cleanup of spills of potentially infectious materials
• Information on the Hepatitis B Vaccine, including: availability, efficacy, safety, method of administration, benefits of vaccination, cost (no cost to employees), and U-M’s vaccination program
• Actions to take and persons to contact in an emergency involving blood or other potentially infectious materials
• Procedures to follow if an exposure incident occurs, including incident reporting
• Post-exposure evaluation and follow-up including medical consultation
• Recommendations specific to a particular department and unique threats posed by potentially infectious materials in that department

Annual Refresher Training

U-M employees who have previously completed initial bloodborne pathogens training through EHS must take annual refresher training that will be due one year from the last date of training. If overdue, the employee will be required to take the initial bloodborne pathogens training.

The participant must also complete site-specific training annually with their supervisor or a designated trainer for their area and maintain the documentation in the EHS Document Binder.

Site-Specific Training

Site-specific training must be completed. It must be administered by the employee’s supervisor or the supervisor’s designated trainer. Either of the following documents are available for use to meet the requirement:

• Bloodborne Pathogens Site-Specific Training Checklist (Appendix G) (best for non-laboratory settings)
• EHS Biohazard SOP template modified for specific tasks or procedures (best for laboratory settings)

**Bloodborne Pathogens Site-Specific Training Checklist (Appendix G)**

Completion of a site-specific training checklist is required in order to complete the training requirements of MIOSHA’s “Bloodborne Infectious Diseases” standard.

• The department supervisor or designated trainer must review site-specific information with the employee. A suggested training checklist (Appendix G) is available for use.
• A Supervisor’s Guidelines for Site-Specific Training form (Appendix H) is a tool to help assist the supervisor (or designated trainer) in completing the checklist with the employee.
• Bloodborne Pathogens Task Procedure forms or department procedures (involving tasks that may involve handling human blood or other potentially infectious materials) must be reviewed as part of the site-specific training checklist.
• When complete, the supervisor (or designated trainer) and the employee **must** sign and date the checklist.

• Checklists **must** be completed within 30 days of initial training, after a procedural change, when new tasks are assigned, and annually. They **must** be kept in the EHS Document Binder and may be subject to periodic checks by EHS. These records **must** be kept for three years.

**NOTE**: If the participant performs duties involving a bloodborne pathogen exposure risk at a location that is off-campus, such as clinical or research work at a local healthcare facility, the participant should complete the checklist with that facility’s supervisor/trainer. In these situations, the site-specific information to be reviewed **must** include the off-campus facility’s policies and procedures related to their exposure control plan and medical waste management plan.

**Bloodborne Pathogens Standard Operating Procedures/Departmental Procedures**

Written procedures are required for all tasks that have a reasonably anticipated risk of exposure to bloodborne pathogens. This can be accomplished through the use any of the following:

• Standard Operating Procedures
• Policies
• Directives

The **SOP Template** can be modified for specific tasks or procedures. The procedures **must** be reviewed as part of the Site-Specific Training Checklist:

• After completion of bloodborne pathogens initial training
• Whenever a procedure changes or new tasks are assigned
• Annually

Completed forms should be maintained in EHS Document Binder or departmental records and be readily available for review.

**U-M Standard Operating Procedures for Biological Work**

These SOPs can be modified or used as part of your site-specific task documentation:

• **U- M Biological Safety Designated Standards**
• **Adenovirus/Adenoviral Vectors: Standard Operating Procedure**
• **Retrovirus/Retroviral Vectors: Standard Operating Procedure**
• **Biological Safety Level 2 Inspection Checklist**
• **Biological Toxins Standard Operation Procedure**
• **Needle Recapping & Handling**
• **Responding to a Needlestick or Biological Exposure**
Training Record Keeping/Retention

- All bloodborne pathogens training that is conducted by EHS or by an EHS designated trainer **must** be documented and contain the following information:
  - Dates of training sessions
  - Names and job title of employees attending the training sessions
  - Contents/summary of the training sessions
  - Names of the instructors
- All EHS designated trainers **must** send a copy of the sign-in form to EHS for computerized record keeping purposes.
- Training records **must** be retained for three (3) years.
## SECTION 8: GLOSSARY OF TERMS

The following is a list of common terms and their definitions as they are used in the Exposure Control Plan.

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologically Hazardous Conditions</td>
<td>Equipment, containers, rooms, materials, experimental animals, and animals infected with HBV or HIV virus, or combinations thereof that contain, or are contaminated with, blood or other potentially infectious material.</td>
</tr>
<tr>
<td>Blood</td>
<td>Human blood, human blood components, and products made from human blood.</td>
</tr>
<tr>
<td>Bloodborne Pathogens (BBPs)</td>
<td>Pathogenic microorganisms that are present in human blood or OPIM and can infect and cause disease in persons who are exposed to blood containing the pathogen. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).</td>
</tr>
<tr>
<td>Clinical Laboratory</td>
<td>A workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious material.</td>
</tr>
<tr>
<td>Contaminated</td>
<td>The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.</td>
</tr>
<tr>
<td>Contaminated Laundry</td>
<td>Laundry that has been soiled with blood or other potential infectious materials (OPIM) or that may contain sharps.</td>
</tr>
<tr>
<td>Contaminated Sharps</td>
<td>Any contaminated object that can penetrate the skin (i.e. needles, scalpels, broken glass).</td>
</tr>
<tr>
<td>Decontamination</td>
<td>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.</td>
</tr>
<tr>
<td>Disinfect</td>
<td>To inactivate virtually all recognized pathogenic microorganisms, but not necessarily all microbial forms, on inanimate objects.</td>
</tr>
<tr>
<td>Engineering Controls</td>
<td>Controls designed to isolate or remove the bloodborne pathogen hazard from the workplace (e.g. sharps disposal containers, biosafety cabinets, and safer medical devices such as sharps with engineered sharps injury protections, needleless systems, blunt suture needles, plastic capillary tubes and mylar-wrapped glass capillary tubes).</td>
</tr>
<tr>
<td>Exposure Incident</td>
<td>A specific eye, mouth, other mucous membrane, non-intact skin (includes skin with dermatitis, hangnails, cuts, abrasions, chafing, acne, etc.), or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee’s duties.</td>
</tr>
<tr>
<td>TERM</td>
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<tr>
<td>Handwashing Facilities</td>
<td>Facilities that provide an adequate supply of running, potable water, soap, and single-use towels or an air drying machine.</td>
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</tbody>
</table>
| Needleless Systems          | A device that does not use needles for:  
  - The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established  
  - The administration of medication or fluid  
  - Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps |
| Occupational Exposure       | Reasonably anticipated skin, eye, mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties.                                                                                                                                         |
| Other Potentially Infectious Materials (OPIM) | Materials in addition to human blood that may be capable of transmitting bloodborne pathogens. These include:  
  - The following human body fluids:  
    - Semen  
    - Vaginal secretions  
    - Cerebrospinal fluid  
    - Cynovial fluid  
    - Pleural fluid  
    - Pericardial fluid  
    - Peritoneal fluid  
    - Amniotic fluid  
    - Saliva in dental settings  
    - 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  
  - Any unfixed tissue or organ (other than intact skin) from a human (living or dead);  
  - HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture media or other solutions as well as human cell cultures (see note);  
  - Blood, organs, or other tissues from experimental animals infected with HIV or HBV.  
  **NOTE:** Human cell lines are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis viruses, HIV, Epstein-Barr virus, human papilloma viruses and other recognized bloodborne pathogens. |
<p>| Parenteral                  | Piercing mucous membrane or the skin barrier through such events as, needlesticks, human bites, cuts, and abrasions.                                                                                                                                                                                                                 |</p>
<table>
<thead>
<tr>
<th>TERM</th>
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<tbody>
<tr>
<td>Personal Protective Equipment (PPE)</td>
<td>Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g. uniforms, pants, shirts, blouses) not intended to function as protection against a hazard are not considered personal protective equipment.</td>
</tr>
<tr>
<td>Post-Exposure Follow-Up</td>
<td>In the case of an exposure incident, the mandatory course of action taken by the employer to provide medical services (i.e. medical assessment, vaccination, source testing, baseline testing, and counseling) to the exposed worker in order to reduce the risk of infection.</td>
</tr>
<tr>
<td>Production Facility</td>
<td>Facility engaged in industrial scale, large volume or high concentration production HIV or HBV.</td>
</tr>
<tr>
<td>Regulated Waste</td>
<td>Any of the following: liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items which are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.</td>
</tr>
<tr>
<td>Research Laboratory</td>
<td>A laboratory producing or using research-laboratory-scale amounts of HIV or HBV, but not in the volume found in production facilities.</td>
</tr>
<tr>
<td>Sharps</td>
<td>Needles, syringes, scalpels, and intravenous tubing with needles attached, as well as any contaminated object that can penetrate the skin such as: Pasteur pipettes, razor blades, capillary tubes, etc.</td>
</tr>
<tr>
<td>Sharps with Engineered Sharps Injury Protections (Safer Sharps Devices)</td>
<td>A non-needle sharp or a needle device with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.</td>
</tr>
<tr>
<td>Source Individual</td>
<td>Any individual, living or dead, whose blood or other potentially infectious material may be a source of occupational exposure to an employee.</td>
</tr>
<tr>
<td>Sterilize</td>
<td>The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.</td>
</tr>
<tr>
<td>Supervisor</td>
<td>Individual responsible for supervising the activities of an employee, student or volunteer.</td>
</tr>
<tr>
<td>Universal Precautions</td>
<td>A method of infection control that treats all human blood and other potentially infectious material as capable of transmitting HIV, HBV, HCV, and other bloodborne pathogens.</td>
</tr>
<tr>
<td>Work Practice Controls</td>
<td>Controls that reduce the likelihood of exposure to bloodborne pathogens by altering the manner in which a task is performed.</td>
</tr>
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SECTION 9: APPENDICES

Appendix A: Exposure Determination
Appendix B: Transporting Biological Materials
Appendix C: Safer Sharps Device Evaluation Guidance
Appendix D: Safer Sharps Device Evaluation Form
Appendix E: Biohazardous Spill Response
Appendix F: HIV and HBV Research Laboratories
Appendix G: Bloodborne Pathogens Site-Specific Training Checklist
Appendix H: Supervisor’s Guidelines for Site-Specific Training form