

University of Michigan

Department: _____

Principal Investigator: _____

Date of Last Update: _____

EXPOSURE CONTROL PLAN

Required for compliance with OSHA Standard 29 CFR 1910.1030 “Occupational Exposure to Bloodborne Pathogens” and MIOSHA Standard R 325.70001 – 325.70018 “Bloodborne Infectious Diseases”.

Electronic Version Saved in: _____

University of Michigan
Regulatory Compliance Document

REGULATION: OSHA Standard 29 CFR 1910.1030 “Occupational Exposure to Bloodborne Pathogens” and MIOSHA Standard R 325.70001 – 325.70018 “Bloodborne Infectious Diseases”.

2001 revisions to OSHA's Bloodborne Pathogens Standard mandated by The Needlestick Safety and Prevention Act (Pub. L. 106-430)

TABLE OF CONTENTS

Section 1.	General Policy
Section 2.	Exposure Determination
Section 3.	Methods of Compliance
Section 4.	HIV & HBV Research Labs and Production Facilities
Section 5.	Hepatitis B Immunization Program
Section 6.	Post-Exposure Evaluation and Follow-up
Section 7.	Communication of Hazards to Employees
Section 8.	Recordkeeping
Appendix A	Hepatitis B Vaccination Program
Appendix B	Biohazard Spill Response Standard Operating Procedure (SOP)

Section 1. General Policy

SCOPE:

This policy applies to all non-hospital University of Michigan departments whose employees may reasonably anticipate contact with blood or other potentially infectious materials (OPIM) during the performance of their duties.

POLICY:

In compliance with the Bloodborne Pathogens Standard, the University requires all departments that fall within the scope of this policy to minimize employee risk from exposure and infection by implementing Exposure Control Plans (ECP) in the form of departmental policy.

PROCEDURE:

EXPOSURE DETERMINATION – Laboratory supervisors will determine which employees are occupationally exposed (at-risk from occupational exposure) to bloodborne pathogens by reviewing job classifications and specific tasks and procedures according to procedures *described in Section 2* of this Exposure Control Plan. The determination results will be recorded and may be found in that same section. Employees classified as occupationally exposed will qualify for various provisions of this policy addressing exposure control.

METHODS OF COMPLIANCE - Exposure control methods concerning administrative controls, engineering controls, personal protective equipment, and housekeeping will be implemented as Standard operating procedures. Details of the standard procedures are *described in Section 3* of this Exposure Control Plan.

HIV AND HBV RESEARCH LABORATORIES AND PRODUCTION FACILITIES - Specialized control methods are required for areas that present an exceptional pathogen risk to employees. The specialized methods address standard and special microbiological practices, containment equipment, special lab practices and disposal methods. Additional training and skill requirements are also *described in Section 4* of this Exposure Control Plan.

HEPATITIS B IMMUNIZATION PROGRAM - The hepatitis immunization series will be provided, free-of-charge, to all employees determined to be at-risk from their regular handling of human body substances. The immunization program will be conducted through an approved occupational medical provider, as *described in Section 5* of this Exposure Control Plan.

POST-EXPOSURE EVALUATION AND FOLLOW-UP – In the event an employee sustains an occupational exposure to human blood or body substances, evaluation, follow-up, and counseling will be provided free-of-charge. The evaluation and follow-up program will be conducted as *described in Section 6* of this Exposure Control Plan.

COMMUNICATION OF HAZARDS TO EMPLOYEES – The workplace risks associated with human body substances will be effectively communicated to at-risk employees. Prudent practices and mandatory safety procedures in the ECP will be described in detail. The information will be communicated to the employees in a manner *described in Section 7* of this Exposure Control Plan.

RECORDKEEPING - Employee records concerning training, exposures, medical surveillance, etc. will be maintained according to specific methods *described in Section 8* of this Exposure Control Plan. Sharps injury and exposures are reported to Work Connections and the logs are maintained by UM Risk Management.

ANNUAL REVIEW AND UPDATE - This Exposure Control Plan will be carefully reviewed and updated annually by the laboratory manager. Engineering controls will be evaluated for effectiveness and new technology will be considered.

SCHEDULE AND METHOD OF IMPLEMENTATION – Compliance with the Bloodborne Pathogens Standard became mandatory in 1992, for research operations utilizing human body substances and OPIM.

Section 2. Exposure Determination

POLICY:

The Principal Investigator or designated Laboratory Supervisor shall determine the exposure risk of employees, both in terms of position descriptions and specific task categories, and classify the employees as “Occupationally-exposed” or “Non-exposed” for the purposes of training, recordkeeping, protective equipment, and Hepatitis B immunization. **Occupational Exposure** means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duty. **Other Potentially Infectious Materials** means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

PROCEDURE:

- Exposure determination will be made without regard to the use of personal protective equipment.
- The following forms will be completed to document the exposure determination of all occupationally exposed employees as described in the above definition:
 - FORM I - List all job/position descriptions/categories/titles in which ALL employees handle human body substances.
 - FORM II - List all job/position descriptions/categories/titles in which SOME employees handle human body substances.
 - FORM III - List all tasks and procedures (or groups of closely related tasks and procedures) in which human body substances are handled and are performed by employees in job classifications listed on FORM II.
- Employees whose job/position descriptions/ categories/titles are listed in Forms I or II are entitled to the protection of the Bloodborne Pathogens Standard and this Policy.
- Employees whose job/position descriptions/categories/titles do not have occupational exposure to bloodborne pathogens may be entitled to protection under other OSHA Standards including, but not limited to:
 - 29 CFR 1910.1200 “Hazard Communication”
 - 29 CFR 1910.1400 “Laboratory Safety Standard”

Section 3. Methods of Compliance

POLICY:

Research operations that use human body substances will minimize employee risk from bloodborne pathogens by selecting appropriate control measures from the list below, and implementing them as standard written procedures in the lab.

PROCEDURE:

General Administrative Controls

- Universal precautions will be observed to prevent contact with blood or other potentially infectious materials. Universal precautions are an approach by which all human blood and body fluids are treated as if they are potentially infectious for bloodborne pathogens.
- For clinical faculty/staff who have research appointments, 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 Bloodborne Pathogens 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.

Engineering and Work Practice Controls

- Engineering and work practice controls will be used to reduce or eliminate potential employee exposures to human blood and body fluids. Where occupational exposure remains, after institution of these controls, personal protective equipment will also be used.
- Engineering controls will be reviewed and updated on a yearly schedule to ensure their effectiveness.
- Readily accessible hand washing facilities will be provided to employees. When provision of hand washing facilities is not feasible in a work area, employees will be provided with either an appropriate antiseptic hand cleanser in conjunction with paper towels or antiseptic towelettes. Supervisors will ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.
- Supervisors will ensure that employees wash any exposed skin with soap and water and flush mucous membranes with water immediately following contact of such body areas with blood or other potentially infectious materials.
- Contaminated needles and other contaminated sharps will not be bent, recapped. Shearing or breaking of contaminated needles is prohibited. Under conditions where equipment does not allow single-handed needle disposal into a sharps container, such as dental syringe assemblies, contaminated needles may be recapped or removed through the use of a mechanical device or a one-handed technique.
- Immediately or as soon as possible after use, contaminated reusable sharps will be placed in appropriate containers until properly reprocessed. These containers will be:
 - Closable
 - Puncture resistant
 - Labeled or color-coded
 - Leak-proof on the sides and bottom
 - Stored or processed in a manner that does not require employees to reach by hand into the containers
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. Food and drink will not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or other potentially infectious materials are present. All procedures involving blood or other potentially infectious materials will be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances. Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.
- Specimens of blood or other potentially infectious materials will be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. When universal precautions are used for handling all specimens within a facility, and the specimens are not destined to leave the facility, the labeling or color-coding of specimen containers as biohazardous is not necessary, provided containers are recognizable as containing specimens. When such specimens and containers are destined to leave the facility, they will be labeled with the internationally recognized biohazard logo and the word "biohazard".

- If outside contamination of the primary container occurs, the primary container will be placed within a second container that prevents leakage and is properly labeled as containing biohazardous materials. If the specimen could puncture the primary container, the container will be placed within a second container that is puncture-resistant in addition to the above characteristics.
- Equipment that may become contaminated with blood or other potentially infectious materials will be examined prior to servicing or shipping and will be decontaminated as necessary, unless it can be demonstrated that the decontamination of such equipment or portions of such equipment is not feasible. A readily observable label containing the internationally recognized biohazard logo and the work “biohazard” will be attached to the equipment stating which portion remains contaminated. The departmental management will ensure that information pertaining to the contamination status of a piece of equipment is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping, so that appropriate precautions will be taken.

Personal Protective Equipment

- When there is potential occupational exposure, employees will be provided, at no cost to the employee, with appropriate personal protective equipment such as, but not limited to gloves, gowns, laboratory coats, face shields or masks and eye protection. Personal protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials 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.
- The laboratory management will ensure that employees use appropriate personal protective equipment and that the equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Employees who demonstrate sensitivity to certain personal protective items, such as latex gloves, will be supplied with hypoallergenic versions of the equipment or protective liners or alternative equipment that allows the same level of performance of duties.
- Cleaning, laundering, and disposal of personal protective equipment will be provided by the laboratory at no cost to the employees. The department will repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employees. If blood or other potentially infectious materials penetrate a garment, the garment will be removed immediately or as soon as feasible.
- All personal protective equipment will be removed prior to leaving the work area. When personal protective equipment is removed it will be placed in an appropriately designated area or container for storage, washing, decontamination, or disposal. Gloves will be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, or non-intact skin; and when handling or touching contaminated items or surfaces. Disposable (single use) gloves, such as surgical or examination gloves, will be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.
- Disposable gloves will not be washed or decontaminated for re-use. Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured. Employees will wear gloves during all phlebotomies they may perform. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, will be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated.
- Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, will be worn whenever splashes, spray, spatter, or droplets of blood or OPIM are generated.
- Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments will be worn in occupational exposure situations. Surgical caps or hoods and/or shoe covers or boots will be worn in instances when gross contamination can reasonably be anticipated (e.g. autopsies, infectious animal dissection).

Housekeeping and Waste Disposal

- The laboratory management will ensure that the worksite is maintained in a clean and sanitary condition. Management will determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.
- All equipment and environmental and working surfaces will be cleaned and decontaminated after contact with blood or other potentially infectious materials. Contaminated work surfaces will be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are

overtly contaminated, 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.

- Protective coverings, such as plastic wrap, aluminum foil, or impervious-backed absorbent paper used to cover equipment and environmental surfaces, will be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.
- All bins, pails, cans, and similar receptacles intended for reuse that have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials will be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
- Broken glassware that may be contaminated will not be picked up directly with the hands. It will be cleaned up using mechanical means such as a brush and dustpan, tongs, or forceps. Reusable sharps that are contaminated with blood or other potentially infectious materials will not be stored or processed in a manner that requires employees to reach into the containers with their hands.
- Instructions on research biomedical waste disposal can be found in [OSEH Guideline – HM001 “Biohazardous \(Medical\) Waste Disposal”](#)
 - Contaminated sharps waste will be discarded immediately or as soon as feasible in containers that are:
 - closable
 - puncture-resistant
 - leak-proof on sides and bottom
 - labeled with the international biohazard logo and the word “biohazard”
 - During use, containers for contaminated sharps waste will be:
 - easily accessible
 - located at the point of generation
 - maintained upright throughout use
 - replaced routinely and not allowed to be overfilled
 - When moving containers of contaminated sharps waste from the area of use, the containers will be:
 - closed prior to removal
 - placed in a secondary container if leakage is possible
 - The secondary container will be:
 - closable
 - constructed to contain all contents and prevent leakage during handling
 - labeled as biohazardous
 - Reusable containers will not be opened, emptied, or cleaned manually or in any other manner that would expose employees to the risk of needle sticks or cuts.
 - Non-sharps contaminated waste will be placed in containers that are:
 - closable
 - constructed to contain all contents and prevent leakage of fluids during handling
 - labeled as biohazardous
 - closed prior to removal.

If outside contamination of the waste container occurs, it will be placed in a second container that meets the criteria listed in above.

Section 4. HIV & HBV Research Labs and Production Facilities

POLICY:

HIV and HBV research laboratories and production facilities present increased risk for occupational exposure to bloodborne pathogens. All laboratories engaged in bloodborne pathogens infectious disease research will reduce employee exposure risk by providing additional administrative controls, protective equipment, information and training beyond that required for research laboratories not involved in such work.

PROCEDURE:

- Employees working in HIV and HBV Research Laboratories and Production Facilities will adhere to standard microbiological safety practices as described in **the CDC/NIH Guidelines for Biosafety in Microbiological and Biomedical Research Laboratories** - Laboratories - Section III, Biosafety Level 2, part A (*available from OSEH*). These standard practices offer limited control of hazards associated with microbiological research.
- The following special practices will be followed in HIV and HBV Research Laboratories AND Production Facilities:
 - A biosafety manual will be prepared or adopted and periodically reviewed and updated at least annually. Personnel will be advised of the potential hazards, will be required to read instructions on practices and procedures, and will be required to follow them.
 - Access to the work area will be limited to authorized persons. Only persons who have been advised of the potential biohazard, who meet any specific entry requirement, and who comply with all entry and exit procedures will be allowed to enter the work areas.
 - A hazard warning sign incorporating the universal biohazard symbol and the word “biohazard” will be posted on all access doors.
 - Laboratory doors will be kept closed when work involving HIV or HBV is in progress.
 - Before disposal, all contaminated waste will either be incinerated or decontaminated by a method, such as autoclaving, known to effectively destroy bloodborne pathogens.
 - Contaminated materials that are to be decontaminated at a site away from the work area will be placed in a durable, leakproof, labeled or color-coded container that is closed before removal from the work area.
 - All activities involving potentially infectious materials will be conducted in biological safety cabinets or other physical containment devices within the laboratory.
 - Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing will be used in the work area and animal rooms. Protective clothing will not be worn outside the work area and will be decontaminated before being laundered.
 - Special care will be taken to avoid skin contact with potentially infectious materials. Gloves will be worn when handling infected animals and when making hand contact with potentially infectious materials is unavoidable.
 - A facility for hand washing and an emergency eyewash station will be readily available within the work area. An autoclave will be available within the work area for the decontamination of biohazardous waste.
 - Vacuum lines will be protected with liquid disinfectant traps and high efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and that are checked routinely and maintained or replaced as necessary.
 - Hypodermic needles and syringes will be used only for parenteral injection and aspiration of fluids from laboratory animals or diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units will be used for injection or aspiration of other potentially infectious materials. Extreme caution will be used when handling needles and syringes. Needles will not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe will be promptly placed in a puncture-resistant container and routed as waste to an incinerator.
 - All spills will be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials. A spill or accident that results in an exposure incident will be immediately reported to the laboratory director or other responsible person. See Appendix B Biohazard Spill Response SOP.
 - All activities or procedures with potentially infectious materials that pose a threat of exposure to droplets, splashes, spills or aerosols require a combination of personal protective equipment and primary containment such a respirator and biological safety cabinet, or special protective clothing and containment caging for animals. Biological safety cabinets will be certified by OSEH when installed, when moved, and at least annually.

- HIV and HBV Production Facilities, in particular, will meet the following criteria:
 - The work areas will be separated from areas in the building that are open to unrestricted traffic.
 - Passage through two sets of doors will be required for entry into the work area from access corridors or other contiguous areas.
 - Access doors to the work area will be self-closing.
 - The surfaces of doors, walls, floors, and ceilings will be water resistant to that they can be easily cleaned.
 - Penetrations in these surfaces will be sealed or capable of being sealed to facilitate decontamination.
 - The sink for hand washing will be foot, elbow, or automatically operated and will be located near the exit door of the work area.
 - The facility will be serviced by a ducted exhaust-air ventilation system. The system will create directional airflow that draws air into the work area through the entry area. The exhaust air will not be recirculated to any other area of the building, will be discharge to the outside, and will be dispersed away from occupied areas and air intakes. Qualified ventilation engineers will verify the proper direction of the airflow in the work area.
- Personnel who work in HIV and HBV Research Laboratories and Production Facilities will receive special training in addition to that required for employees who do not specifically handle known pathogenic agents. This extra training, detailed in Section VII of the Exposure Control Plan, will cover the following areas:
 - proficiency in standard & special microbiological practices
 - prior experience in handling human pathogens
 - training program for employees with no prior experience
 - initial activities do not involve pathogens
 - progression of activities as proficiency develops
 - infectious agents handled only after proficiency is shown

Section 5. Hepatitis B Immunization Program

POLICY:

One major bloodborne infectious disease, Hepatitis B, is entirely preventable through immunization. Employees must be offered immunization at the time they begin working with human blood and body substances. The research laboratory must cover the cost of the elective vaccination series, administered through an approved occupational medical provider.

PROCEDURE:

- Immunization against Hepatitis B virus (HBV) by means of a vaccination series will be made available, by the supervisor, to all employees who are determined to be “occupationally-exposed.”
- Employee participation in the Immunization Program will be on a completely voluntary basis and the Program will be provided at no cost to them.
 - Although the vaccine is recommended, there will be no negative consequences to any person who chooses not to participate in the immunization program, for any reason.
- The employee may choose to accept the vaccination series, decline, or have the opportunity to discuss participation with a clinician and then decide to accept/decline the vaccination.
- The Immunization Program consists of a series of three intramuscular vaccinations administered at times zero, one month and six months.
 - Vaccination will be made available by the supervisor within 10 working days of initial employee assignment; and after the employees have been given information on the HBV vaccine efficacy, safety, method of administration, the benefits of immunization, and that the vaccination series will be offered free of charge.
 - 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.
- If the employee consents to participate in the Immunization Program, the vaccinations will be offered at a time and place convenient to the employee.
- If the employee has previously received the complete HBV vaccination series and/or antibody testing has revealed that the employee is immune or the vaccine is contraindicated for medical reasons, the vaccination series will not be offered.
- If an occupationally exposed employee chooses not to participate in the immunization program, he/she is required to document the declination with a special form, included as **Appendix (A)** in this policy. *A copy of this form must be retained by the Primary Investigator.* Each year employee’s must be given the opportunity to accept/request the vaccination (if previously declined), or fill out a new declination form. Previous years declination forms may be discarded.
 - It is recommended that the immunization program and request/declination forms be discussed annually during the Blood Borne Pathogens training.
- If the employee initially declines to participate in the HBV immunization program, but at a later decides to become immunized, the vaccination series will be made available at that time.
- **HBV vaccinations** will be provided at the **UM Occupational Health Services** clinic (*ph. 998-8788*) in the Med Inn Building.

Section 6. Post-Exposure Evaluation and Follow-up

POLICY:

All occupational exposures to human blood and body substances will be regarded as serious, reported promptly, evaluated by a trained healthcare professional, and treated according to Public Health Service (PHS) Guidelines (Management of Health-Care Worker Exposure to HIV and Recommendations for Post-exposure Prophylaxis, MMWR No. RR-07, May 15, 1998).

PROCEDURE:

- Upon injury from a suspected exposure source, the employee will attempt to determine the nature of the exposure and any biohazardous material associated with it.
- The employee will also attempt to carefully retain the exposure source and any biohazardous materials that may have constituted an exposure.
- If necessary, first-aid should be administered immediately for any cuts or punctures and any exposed skin should be washed with soap and water. The employee should report the injury to their supervisor within one hour.
- The supervisor will assess the situation and determine if the incident constitutes an occupational exposure to a biohazardous material. The supervisor will then locate and complete any necessary accident forms and refer the employee to the **UM Occupational Health Services** clinic (*ph. 998-8788*).
- If the injury is received during normal work hours, the employee will present at the **UM Occupational Health Services** clinic (*ph. 998-8788*) as soon as possible and report that they have received an occupational injury of a potentially infectious nature. If the supervisor has completed the "Employee Referral Form" it should be sent with the employee or faxed to the **UM Occupational Health Services** clinic when completed. If the employee arrives before the referral form, **Occupational Health Services** will contact the employee's supervisor for a verbal referral. If there is a problem getting the referral, **Occupational Health Services** will treat the employee first and then work to obtain the referral.
- Persons with exposure injuries after the **Occupational Health Services** clinic closes at 5 pm, on weekends or holidays must report immediately to UMHS Emergency for medical evaluation and treatment. Employees will report that they are UM staff and have received an occupational injury of a potentially infectious nature.
- The employee will provide details on their injury to the occupational medical physician:
 - the type of injury the employee received
 - the type and samples of any biohazardous material the employee was exposed to
 - circumstances under which the exposure occurred
 - the hepatitis immunization status of the employee
- The physician will provide the employee with a confidential medical evaluation and follow-up of the incident:
 - evaluation of the exposure risk of the incident based on the exposure source
 - providing the employee with a written list of recommended options for testing and preventative treatment
 - explaining to the employee the rationale and benefits of these tests and treatments.
- **Testing options** include Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human immunodeficiency virus (HIV) antibody testing of any samples of biohazardous material to which the employee was exposed, and base-line testing of an employee blood sample for Hepatitis B & C and HIV Ab for determination of pre-exposure status.
- **Preventative treatment options** include Hepatitis B immunoglobulin (H-BIG) - protective antibody product) for short-term protection and HBV immunization for long-term protection against HBV. For the preventative treatments to be most effective the H-BIG must be given within 72 hours of exposure and HBV immunization must begin within seven days of exposure. Depending on the circumstances of exposure, oral anti-viral medication may be given per CDC guidelines.
- Employee acceptance of these tests/treatments will be on a completely voluntary basis and services will be provided at no cost to them.
- The medical provider will provide the University with a written opinion (physician's determination), within 7 days of the exposure incident. 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 exposure to blood or other biohazardous materials that require further evaluation and treatment

- whether HBIG or HBV vaccine was indicated for the employee, and if the employee has received such treatment
- all other findings or diagnoses will remain confidential and will not be included in the report.
- The University will provide the employee a copy of the physician's determination within 15 days of the exposure incident. A copy of the report will be included in the employee's permanent medical records with the University.
- If the employee eventually becomes ill or seroconverts (develops antibodies to the virus) as a direct result of occupational exposure to a bloodborne pathogen, the medical provider will file a complete report with the University Office of Risk Management (ORM), which handles Worker's Compensation.
- The report will be confidential and will be sent to no other organization within the University.
- If the exposure source sample is positive or not available and the employee is negative for HBV, HCV, and HIV, follow up testing will be made available to them at 3 months and 6 months.
- If occupational exposure of the employee to a bloodborne pathogen is confirmed, the University shall provide, through the healthcare service, confidential counseling and evaluation of any consequent illness that the employee reports for a period of up to 6 months.

Section 7. Communication of Hazards to Employees

POLICY:

Employees must be informed of the risks associated with the human blood and body substances they use, and required precautions they must follow to protect themselves and fellow workers. Labels, signs, and other written information assure that employees are aware of the hazardous materials in their workplace. Use of this information and precautions will reduce the risk of employee exposure to bloodborne pathogens.

PROCEDURE:

Labels and Signs

- Warning labels must be affixed to or printed on containers and bags of biohazardous waste, refrigerators, freezers, and other containers used to contain, store, or transport blood or other potentially infectious materials (OPIM).
- Labels must include the internationally recognized biohazard logo and the word “biohazard.”
- The labels must be printed on stickers as **black-on-orange** and on bags as **red-on-clear**.
- Labels must be affixed at a conspicuous location on the container by direct print or adhesive.
- Contaminated equipment must be labeled as biohazardous and indicate which parts are contaminated.
- Biohazardous waste that has been decontaminated by steam sterilization must have a positive indication of safety. Printed-on sterilization indicator on the autoclave bag accomplishes this. (e.g., Fisher brand #01-826A-E series autoclave bags).
- Signs that include the internationally recognized biohazard logo and the word “biohazard” will be posted at the entrance of HIV and HBV research laboratories and production facilities.

Information and Training

- The laboratory manager will ensure that all employees with occupational exposure, including themselves, participate in a training program that must be provided during working hours.
- The training will be provided at the time of initial assignment and at least annually thereafter.
- The laboratory manager will ensure that additional training is provided when changes such as modification of tasks or institution of new procedures affect employees’ occupational exposure.
- The bloodborne pathogens training program is provided by UM-OSEH twice monthly and covers basic risks and prudent practices to avoid occupational exposure:
 - **Bloodborne Pathogens Standard** purpose, policy and responsibilities
 - **Modes of transmission, epidemiology, and symptomatology** of bloodborne diseases
 - **Exposure Control Plan** - means by which the employee may obtain a copy of the document
 - **tasks and other activities** that may involve exposure to blood and other potentially infectious materials
 - **methods that will prevent or reduce exposure** - including appropriate engineering controls, work practices, and personal protective equipment
 - **personal protective equipment** - types, selection, proper use, storage location, removal, handling, decontamination and disposal.
 - **hepatitis B immunization program** - including information on the efficacy, safety, administration, and benefits of the vaccine and that the vaccine will be offered at no cost to the employees
 - **appropriate actions to take and persons to contact in an emergency**
 - **procedure to follow if an exposure incident occurs** - including the method of reporting the incident and the medical follow-up that will be made available
 - **post-exposure evaluation and follow-up** that the department is required to provide for the employee following an exposure incident
 - **labels, signs and color-coding pertaining to biohazards** required by departmental policy
 - **opportunity for interactive questions and answers**
- The laboratory manager must also instruct employees on the site-specific risks and safety procedures for their assigned research tasks.

Section 8. Recordkeeping

POLICY:

Accurate records of required safety services must be carefully maintained for the Bloodborne Pathogens Standard to be effective.

PROCEDURE:

Medical Records

- **UM Occupational Health Services** maintains accurate records for each employee with occupational exposure. These records include:
 - the name and employee number
 - a copy of the employee's hepatitis B immunization 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 exposure incident follow-up procedures
 - a copy of the physician's written opinion concerning hepatitis B vaccination and post-exposure evaluation and follow-up
- The University will ensure that the employee medical records are kept confidential and are not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by availability provisions the Michigan Occupational Safety and Health Act (MIOSHA).
- The University, through **Occupational Health Services**, will maintain the employee medical records for at least the duration of employment plus 30 years.

Training Records

- Training records for basic training in Bloodborne Pathogens given by OSEH will be maintained at OSEH.
- Training records for site-specific training on laboratory procedures must be maintained by the laboratory manager, and must include:
 - the dates of the training
 - the contents or a summary of the training
 - the names of persons conducting the training
 - the names and job titles of all persons attending the training sessions
- The University will maintain all training records for a period of 3 years after the training occurred.

Vaccination/Declination Records

- Vaccination records will be maintained by **Occupational Health Services** or Employee Health Services.
- Declination forms will be maintained by the Primary Investigator and will be accessible for review by OSEH or State of Michigan Dept. of Consumer and Industry Services (MDCIS).

Availability

- The University will ensure that all medical records are made available upon request to the MDCIS for examination and copying.
- The University will ensure that all medical records will be provided upon request for examination and copying to the subject employee and to anyone having written consent of the subject employee.
- The Primary Investigator or Laboratory Manager will ensure that all training records are provided upon request for examination and copying to employees and to employee representatives.

Sharps Injury Log

- The log is required for percutaneous injuries from contaminated sharps and it must be confidential to protect the privacy of the injured person. Alternative identifiers other than name will be used.
- Will be maintained by Risk Management.
- The information to be maintained in the log is the type and brand of the device, location of the incident, and a description of how the injury happened.

APPENDIX (B) - Biohazard Spill Response Standard Operating Procedure (SOP)

This SOP pertains to decontaminating biohazardous material spills. Biohazards include human blood and other potentially infectious materials (OPIM). OPIM means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

STEP 1: REQUIRED PERSONAL PROTECTIVE EQUIPMENT

Prior to entering the area of contamination wear the proper personal protective equipment.

- Gloves: Nitrile, neoprene, PVC or latex can provide effective skin protection. Two pairs Nitrile is recommended. If cleaning a large area place a large pair of vinyl or rubber gloves over the Nitrile gloves.
- Eyewear: Wear goggles for eye protection and face shield to prevent potential exposure to nose, and mouth.
- Clothing: Wear a labcoat for small spills or Tyvek suit for larger spills to protect clothing from contamination.
- Boots: Wear disposable Tyvek shoe covers.
- Respirator: Not required. Although a paper dust mask can also be worn in conjunction with goggles to protect from splashes to the nose and mouth.

STEP 2: SPILL DECONTAMINATION PROCEDURES

Cover the spill area with freshly mixed 10% bleach and water solution. Allow solution to soak into the biohazardous material for 20 minutes prior to cleaning up contaminated areas. Work from the outside edges of the spill inward when applying the bleach solution.

Any glass, needles, or other sharp objects that may puncture the skin will not be picked up by hand. Only mechanical means such as a brush and dustpan, tongs, or forceps are allowed.

Wipe up decontaminated material with paper towels or absorbent pads. It may be necessary to use a scrub brush to remove the material if it impacted a hard porous surface such as concrete.

Decontaminate with the bleach solution all potentially contaminated non-disposable tools or protective equipment used in the cleanup. This includes goggles, face shields, dustpans and brooms. Anything that cannot be effectively cleaned (disinfectant must be able to make contact with all surfaces) must be disposed as waste. After the contaminated area has been cleaned, use fresh water to remove bleach residue from all surfaces.

Place neutralized material, Tyvek suit and other potentially contaminated cleanup materials into autoclave bags for proper steam sterilization or place plastic bags into either a 5-gallon pail or biohazard disposal box. Ensure lids are firmly sealed on all waste containers when spill clean up is complete and call OSEH Hazmat for a pickup (3-4568).

WASH YOUR HANDS. If hand-washing facilities are not available at the job site use disinfectant wipes.

BIOHAZARD EXPOSURE

If you believe you were exposed to biohazard material that had not been decontaminated with the bleach solution follow these recommended steps:

- Skin exposure: Thoroughly wash affected skin with plenty of soap and water while removing contaminated clothing and shoes.
- Eye exposure: Wash eyes for at least 15 minutes with copious amounts of water, lifting the upper and lower eyelids occasionally.
- Seek follow-up medical attention. **UM Occupational Health Services (998-8788)**