WAYNE STATE UNIVERSITY

Bloodborne Infectious Diseases Exposure Control Plan

Pursuant to the requirements of the MIOSHA Bloodborne Infectious Diseases Standard
(R 325.70001 through R 325.700016)

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I. INTRODUCTION AND SCOPE

The WSU Exposure Control Plan has been developed and implemented to meet the requirements of the MIOSHA Bloodborne Infectious Diseases Standard (R 325.70001 through 325.700016).

Compliance with the Bloodborne Infectious Diseases Standard will reduce the risk of exposure to blood and other potentially infectious materials (OPIM) that may pose a risk of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and other bloodborne diseases.

OSHA has identified occupational settings where individuals are reasonably anticipated to come into contact with blood or other potentially infectious materials during the performance of their duties. These include in part, healthcare facilities, health clinics, research labs, linen services, law enforcement, fire and rescue, schools, lifesaving, and regulated biological waste removal services.

Wayne State University employs people in positions where they may be reasonably anticipated to come into contact with blood or other potentially infectious materials during the performance of their duties. Therefore, the University is required to comply with the MIOSHA Occupational Exposure to Bloodborne Infectious Diseases Standard.

The Office of Environmental Health and Safety (OEHS) is charged with the overall responsibility for the development and implementation of the University Exposure Control Plan. OEHS provides information and training to University employees on how to protect themselves from exposure to blood and other potentially infectious materials during the performance of their job. OEHS also provides technical assistance to individual University departments in their efforts to comply with the standard.

Individual departments and units of the University will be responsible for ensuring that the provisions of the University's Exposure Control Plan and the mandates of the MIOSHA standard are carried out.

Departments and units identified as having employees with occupational exposure include, but are not necessarily limited to:

- Athletics, Intramural and Recreation
- Biomedical Engineering
- College of Nursing
- College of Pharmacy and Health Sciences
- College of Liberal Arts and Sciences
- Division of Laboratory Animal Resources
- Division of Research
- Facilities Planning and Management
- Health, Physical Education, and Recreation
- Police Department

- Research and Graduate Programs
- School of Medicine
- Medical Examiner's Office

Employees incur risk each time they are exposed to blood or other potentially infectious materials (OPIM). Any exposure incident may result in infection and subsequent illness; therefore, exposures must be prevented whenever possible. The goal of the Bloodborne Pathogen Standard is to reduce the significant risk of infection by:

- Eliminating or limiting occupational exposure to blood or OPIM.
- Providing the hepatitis B vaccine.
- Providing post-exposure medical evaluation and follow-up.

All University employees who hold positions determined to have occupational exposure are entitled to the protection afforded by the standard.

II. DEFINITIONS

For purposes of this plan, the following definitions shall apply:

Blood: human blood, human blood components, products made from human blood

Bloodborne Pathogens: pathogenic microorganisms that are present in human blood and can cause disease in humans, including, but not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV)

Clinical Laboratory: workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials

Contaminated: the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface

Contaminated Laundry: laundry which has been soiled with blood or other potentially infectious materials or may contain sharps

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

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

Engineering Controls: controls such as sharps disposal containers, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems, that isolate or remove the bloodborne pathogens hazard from the workplace

Exposure Incident: a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties

Handwashing Facilities: facility providing an adequate supply of running potable water, soap and single use towels or hot air-drying machines

Licensed Healthcare Professional: a person whose legally permitted scope of practice allows him or her to independently perform the activities required by Section (VI) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up

HBV: hepatitis B virus

HCV: hepatitis C virus

HIV: human immunodeficiency virus.

Needless Systems: devices that provide an alternative to needles for various procedures to reduce the risk of injury involving contaminated sharps

Occupational Exposure: 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 duties

OPIM or Other Potentially Infectious Materials: 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; any unfixed tissue or organ (other than intact skin) from a human (living or dead); any HIV-containing cell or tissue cultures, organ cultures, and HIV, HBV, or HCV-containing culture medium or other solutions; any blood, organs, or other tissues from experimental animals infected with HIV, HBV, or HCV

Parenteral: piercing the skin or the mucous membranes through such events as needlesticks, human bites, cuts, and abrasions

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

Production Facility: a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV

Regulated Waste (Infectious Waste, Biohazardous Waste): 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 that 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

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

Source Individual: any individual, living, or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee

Supervisor: laboratory supervisor, principal investigator, foreman, course instructor, advisor, or any other individual who is responsible for supervising the activities of employees, students, or volunteers

Sharps with Engineered Sharps Injury Prevention: non-needle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury

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

Universal Precautions: an approach to infection control whereby all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens

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

III. EXPOSURE CONTROL PLAN

Based on the requirements established by the MIOSHA Bloodborne Infectious Diseases Standard, Wayne State University's Exposure Control Plan has been developed and designed to eliminate or limit employee occupational exposure to bloodborne pathogens during the performance of their duties.

The plan will be reviewed and updated annually and whenever necessary to reflect new or modified tasks and procedures which may affect exposure, new or revised employee positions with occupational exposure, or changes in the regulatory requirements.

University employees, employee representatives, and regulatory authorities have access to the Exposure Control Plan through the OEHS website at: http://research.wayne.edu/oehs/pdf/exposurecontrolplan.pdf.

Departments and laboratories are responsible for the development and implementation of task-specific standard operating procedures (SOPs) that address the following areas:

- Employee recognition of reasonably anticipated exposure to blood or OPIM.
- Appropriate selection, use, maintenance, and disposal of PPE.

- Contingency plans for foreseeable circumstances that prevent following the recommended SOPs.

A site-specific training checklist is available in Appendix B of this plan.

IV. EXPOSURE DETERMINATION

The provisions of WSU's Exposure Control Plan apply to all employees who have a reasonably anticipated risk of exposure to blood or other potentially infectious materials (OPIM) as the result of required occupational tasks. This exposure determination has been made without regard to the use of personal protective equipment.

All employees in the following job classifications have reasonably anticipated risk of exposure to bloodborne pathogens and are included in the Exposure Control Plan:

Athletic Trainer
Animal Transportation Technician
Athletic Coach
Athletic Director
Athletic Trainer
Autopsy Attendant
Bone Density Technician
Child Care Service Coordinator
Child Care Service Worker
Classroom Attendant
Custodian
Custodial Supervisor
Custodial Technician Embalmers
Environmental Health Specialist
Environmental Health Manager
Groundskeeper
Hazardous Materials Manager
Hazardous Materials Specialist
Hazardous Materials Technician
Health Physics Assistant
Health Physics Technician
Histotechnologist
Housekeeper
Impact Sled Technician
Laboratory Animal Aide
Laboratory Animal Leader
Laboratory Animal Supervisor
Laboratory Animal Technician
Lead Autopsy Attendant
Lifeguard
Medical Assistant
Medical Investigator I & II
Medical Technologist
Morgue Assistant
Morgue Supervisor
Nurse Practitioner
Pathologist Assistant
Pipefitter
Plumber
Police Captain
Police Director
Police Lieutenant
Police Officer
Police Sergeant
Registered Nurse
Student Intramural Official Student
Recreation Area Manager Student
Swimming Pool Supervisor
Substitute Teacher
Teacher
Veterinary Technician
Veterinary Technician Assistant
Veterinary Technician Sr. Vivarium Technician

Some employees in the following job classifications are required to perform duties that have a reasonably anticipated risk of exposure to bloodborne pathogens. Employees in these job classifications who work in a research or teaching laboratory are the employees who may be at risk of exposure. The tasks that may involve occupational exposure are listed below the job classifications.

Assistant Professor
Associate Professor
Clinical Assistant Professor
Clinical Associate Professor
Clinical Instructor
Clinical Professor
Graduate Research Assistant
Graduate Student Assistant
Graduate Teaching Assistant
Instructional Assistant
Laboratory Aide
Laboratory Manager
Laboratory Supervisor
Laboratory Technician
Laboratory Technician, Senior
Part-Time Faculty
Post-Doc Fellow
Professor
Research Assistant
Research Associate
Research Scientist
Research Technician
Research Technologist
Senior Research Scientist
Student Assistant
Student Laboratory Assistant
Student Research Assistant
Visiting Assistant Professor
Visiting Associate Professor
Visiting Instructor
Visiting Professor

A partial list of laboratory tasks that may involve a risk of exposure to blood or other potentially infectious materials for some employees in these job classifications includes:

- Processing, handling, and analyzing human blood, tissue, organs, cells or OPIM
- Transporting human samples
- Disposing of biohazardous waste
- Working with research animals that have been injected with human cell lines.

V. METHODS OF COMPLIANCE

A. Universal Precautions

All University employees will observe universal precautions to prevent contact with blood and other potentially infectious materials (OPIM).

OPIM are defined by MIOSHA 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 unfixed 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.

The underlying concept of universal precautions is that all blood and certain body fluids are considered to be infectious for bloodborne pathogens. Employees must treat all blood and OPIM as if they are known to be infected with a bloodborne pathogen. This can be accomplished through a combination of engineering and work practice controls, use of personal protective equipment, and good housekeeping.

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 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.

B. Engineering and Work Practice Controls

Engineering and work practice controls are the primary means of reducing employee exposure in the workplace, by either removing the hazard or isolating the worker from exposure. Engineering controls eliminate or reduce employee exposure by acting on the source of the hazard, and not relying on the employee to take self-protective action. These controls may include process or equipment redesign, (e.g. use of self-sheathing needles), process or equipment enclosure, (e.g. biosafety cabinets) and employee isolation.

Work practice controls reduce the likelihood of exposure by altering the way a task is performed. The protection they provide is based more upon the behavior of the employer and employee. Engineering and work practice controls should be used together to ensure the maximum protection for employees.

Where the risk of occupational exposure remains after the implementation of engineering and work place controls, University departments must provide and assure that employees use personal protective equipment to further protect themselves.

Engineering and work practice controls that should be in place include:

1. Handwashing Facilities

In all facilities where employees are reasonably anticipated to come into contact with blood or other potentially infectious materials, hand washing facilities should be readily accessible. Where hand washing facilities are not feasible, departments will provide other means (antiseptic hand cleanser with clean cloth/paper towels or antiseptic towelettes) by which employees can wash their hands. When these other methods are used, employees will be instructed to wash their hands as soon as feasible with soap and warm running water.

Employees are required to wash their hands or any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following exposure of those body areas to blood or other potentially infectious materials. Employees are also required to wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

2. Contaminated Sharps

Contaminated needles and other contaminated sharps will not be bent, recapped, or removed unless it can be demonstrated by the department that no alternative is feasible or that a specific medical or dental procedure requires such action. Under these circumstances, recapping or needle removal shall be accomplished through the use of a mechanical device or one-handed technique.

Immediately or as soon as feasible after use, contaminated sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

- puncture resistant
- appropriately labeled or color-coded
- leak proof on the sides and bottom
- not handled in a manner that requires employees to reach by hand into the sharps container.

3. Sharps Injury Prevention

Principal Investigators or designated laboratory supervisors shall consider and, where appropriate, use effective engineering controls including safer medical devices, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments.

All sharp devices that have available products with safer engineering features shall be identified, evaluated and, if appropriate, selected.

Safer medical devices must be implemented that are appropriate, commercially available, and effective. An appropriate safer medical device includes only

devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated.

Evaluation Process:

- Evaluation of safer sharps devices must be done annually and documented on the Safer Devices and Sharps Evaluation Form. (Appendix D)

- Principal Investigators, or designated laboratory managers, must choose members of the non-managerial employees who perform tasks with sharps exposure risk to assist in the evaluation of safer sharps devices.

- Once the evaluation process is complete, if a new device has been chosen, its use must be implemented as soon as possible.

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

4. Additional Work Practices

- Eating, drinking, smoking, applying cosmetics, and handling contact lenses are activities that are prohibited in work areas where there is a reasonably anticipated risk of occupational exposure.

- Food and drink will not be stored in refrigerators, freezers, shelves, cabinets, or on bench tops where blood or OPIM are present.

- All procedures involving blood or OPIM shall be performed in a manner that minimizes the risk of splashing, spraying, or the generation of aerosols of these substances.

- Mouth pipetting or suctioning of blood or OPIM is strictly prohibited.

- Specimens of blood or OPIM shall be placed in containers which prevent leakage during collection, handling, processing, storage, transport, and shipping. The container for storage, transport or shipping shall be labeled or appropriately color-coded and closed prior to being stored, transported, or shipped. When universal precautions are utilized in the handling of specimens, the labeling/color-coding of specimens is not necessary, provided the containers are recognizable as containing specimens. This exception only applies while such specimens/containers remain within the facility. Appropriate packing, labeling, and color-coding is required when such specimens or containers leave the facility.

- If the outside of the container becomes contaminated, the primary container will be placed inside a second container which prevents leakage during handling, processing, storage, transport, or shipping and will be appropriately labeled or color-coded. If the specimen could puncture the primary container, it will be placed inside a secondary container that is also puncture resistant.

- Equipment which may become contaminated with blood or other potentially infectious materials will be examined prior to servicing or shipping and will be decontaminated, unless it can be demonstrated that decontamination of the equipment or portions of the equipment is not feasible. This equipment will be appropriately labeled in a readily observable area stating what area on the equipment is still contaminated. The department is responsible for ensuring that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer as appropriate, before handling, servicing, or shipping, so that appropriate precautions will be taken.

C. Personal Protective Equipment (PPE)

- Where there is occupational exposure, each department will provide, at no cost to the employee, appropriate personal protective equipment (PPE) such as, but not limited to, gloves, gowns, lab coats, face shields, masks, or other ventilation devices.

- PPE should not permit blood or OPIM to pass through to or reach the employee's clothing, skin, eyes, or mouth under normal conditions of use and for the duration of time in which the protective equipment will be used.

- The PPE shall be available in the appropriate sizes for the employee and be readily accessible at the work site. Departments will repair or replace, clean, launder and dispose of PPE whenever necessary at no cost to the employee.

- Departments and supervisors will ensure that the employee uses PPE, unless it can be demonstrated that they temporarily and briefly declined to use it when, under rare circumstances, it was the employee's judgment that its use would have prevented delivery of health care or public safety services, or it would have posed an increased hazard to the safety of the worker or a co-worker.

- PPE will be removed prior to leaving the work area. If a piece of protective clothing is penetrated by blood or OPIM, it will be removed as soon as possible and placed into a designated container or area for storage, washing, decontamination and/or disposal.

1. Gloves

Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, no-intact skin. Gloves shall be worn when performing vascular access procedures and when handling contaminated items or touching contaminated surfaces.

Disposable (single use) gloves such as surgical or examination gloves, shall 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 an effective barrier is compromised. Disposable gloves will not be washed or decontaminated for reuse.

Heavier utility gloves may be decontaminated for reuse if the integrity of the glove is not compromised. If the gloves are cracked, torn, punctured, or deteriorated and no longer work as an effective barrier, they must be discarded.

If an employee is allergic to the gloves provided, hypoallergenic gloves, glove liners, powderless gloves, or other alternatives will be provided at no cost to the employee.

2. Facial Protection

Masks and eye protection devices such as goggles or glasses with solid side shields, or chin-length face shields, will be worn whenever splashes, spray, or aerosols of blood or OPIM may be generated, and there is a potential for mucous membrane (eyes, nose, mouth) to be exposed to the material.

3. Protective Clothing

Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments will be worn in areas where there is a potential for occupational exposure.

The type of clothing selected will depend upon the tasks being carried out and the degree of exposure anticipated. In situations where gross contamination can be reasonably anticipated, (e.g. autopsies, orthopedic surgery), surgical caps or hoods, and shoe covers, or boots will be worn.

D. Housekeeping

Supervisors shall ensure that worksites are maintained in a clean and sanitary condition. Each affected department or area (such as a laboratory) will determine and implement an appropriate written schedule for cleaning and a method of

decontamination based upon the type of surface to be cleaned, type of material present, and the tasks or procedures being performed there.

All equipment, environmental surfaces, 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, such as a 1:10 solution of household bleach or an approved germicidal cleaner, 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 they have become contaminated since the last cleaning.

Protective coverings (e.g. plastic wrap, aluminum foil, or imperviously-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 work shift if they have become contaminated during the shift.

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood of 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 by hand. A mechanical means, such as a brush and dustpan, tongs or forceps will be used.

Reusable sharps containers that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires employees to reach by hand into the containers.

E. Regulated Waste

Regulated waste will be place in containers that are:

- Closable
- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping
- Appropriately labeled or color-coded
- Closed prior to removal to prevent spills of material during handling, storage, and transport

If outside contamination of the regulated waste container occurs, it will be placed in a second container that meets the same requirements as the primary container.

Collection and disposal of regulated waste will be coordinated in accordance will all applicable federal, state, and local regulations, by the WSU Office of Environmental Health and Safety.

Contaminated sharps will be discarded immediately, or as soon as feasible, into containers that are:

- Closable
- Puncture resistant
- Leak-proof on sides and bottom
- Appropriately labeled or color-coded

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

Sharps containers are provided free of charge by the Office of Environmental Health and Safety. To arrange for sharps disposal, or receive empty containers, submit requests at http://research.wayne.edu/oehs/forms/bio-waste.php.

When moving contaminated sharps containers from the area of use, the containers will be:

- Closed immediately prior to removal or replacement
- Placed in a secondary container that meets the same requirements as the primary container if leakage is possible

Sharps containers will not be reopened, emptied, or cleaned manually, or handled in any way that may expose an employee to the risk of a needlestick injury.

F. Contaminated Laundry

Contaminated laundry will be handled as little as possible, with a minimum of agitation. It will be bagged or put into containers at the location where it was used. Contaminated laundry will not be sorted or rinsed at the location where it was used. It will be placed in bags or containers appropriately labeled or color-coded. When a department utilizes universal precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient, if it permits all employees to recognize the containers as requiring compliance with universal precautions.
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.

When a department ships contaminated laundry off-site to a second facility that does not utilize universal precautions in the handling of all laundry, the department generating the contaminated laundry will place such laundry in bags or containers which are appropriately labeled or color-coded.

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.

VI. HIV AND HBV RESEARCH FACILITIES

- Research laboratories engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV are required to comply with the special provisions outlined in this section in addition to the other requirements contained in this plan. They also must follow any additional guidelines established by the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC).

- These special provisions do not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissue, or organs.

- The requirements are as follows:

- All regulated waste will be incinerated or decontaminated by a method, such as autoclaving, known to effectively destroy bloodborne pathogens.

- Laboratory doors will be kept closed when work involving HIV or HBV is in progress.

- Contaminated materials that are to be decontaminated at a site away from the work area will be placed in a durable, leak proof, labeled or color-coded container that is closed before being removed from the work area.

- Access to the work area will be limited to authorized persons. Written policies and procedures will be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures will be allowed to enter the work areas and animal rooms.
- When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol will be posted on all access doors. Hazard warning sign will comply with the signs and labels requirements contained in this plan.

- All activities involving potentially infectious materials will be conducted in biological safety cabinets or other physical containment devices within the

containment module. No work with this material will be conducted on an open bench.

- Laboratory coats, gowns, smocks, uniforms, or other appropriate personal protective clothing will be used in the work areas and animal rooms.

- Personal protective clothing will not be worn outside of 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.

- Before disposal, all waste from work areas and animal rooms will either be incinerated or decontaminated by a method, such as autoclaving, known to effectively destroy bloodborne pathogens.

- Vacuum lines will be protected with liquid disinfectant traps and high efficiency particulate air (HEPA) filters, or filters of equivalent or superior efficiency and which 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 and diaphragm bottles. Only needle-locking syringes or disposable syringe units (where the needle is integral to the syringe) will be used for the injection or aspiration of other potentially infectious materials. Extreme caution will be used when handling needles and syringes. A needle 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 autoclaved or decontaminated before reuse or disposal.

- All spills will be immediately contained and cleaned up by appropriate professional staff or others trained and equipped to work with potentially infectious, concentrated materials.

- A spill or accident that results in an exposure incident will be immediately reported to the principal investigator, laboratory manager, or other responsible person.

- A biosafety manual will be prepared or adopted and reviewed and updated if necessary, at least annually, or more often if necessary. Personnel will be advised of potential hazards and required to read and follow the standard operating procedures set forth in the lab’s biosafety manual.

- Certified biological safety cabinets or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing,

respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals will be used for all activities with potentially infectious materials that pose a threat of exposure to splashes, spills, or aerosols.

- Biological safety cabinets will be certified by OEHS when installed, whenever they are moved, and at least annually.

HIV and HBV research facilities will contain the following:

- A facility for hand washing
- An eye wash facility which is readily available within the work area
- An autoclave which is readily available for decontamination of regulated waste

Additional training requirements for employees in HIV and HBV research facilities are covered in the training section of this plan.

VII. HEPATITIS B VACCINATION

The University will make the hepatitis B vaccination series available to all employees who are determined to have occupational exposure. Vaccination will be:

- Made available at no cost to the employee within ten working days of initial assignment and after the employee has received training

- Made available at a reasonable time and place

- Performed by or under the supervision of a licensed health care professional

- Provided according to the recommendations of the U.S. Public Health Service current at the time of vaccination

- Recorded and filed in the employee's medical records

HBV vaccinations will be provided at the Henry Ford Harbortown, Occupational Health Clinic, for employees at risk of occupational exposure. HBV antibody testing will be provided if an employee desires such testing before deciding whether or not to receive the HBV vaccination.

If the employee declines vaccination, he/she will sign a declination form (see Appendix A). A copy of this form will be retained by the employee, his/her department, and OEHS, for the duration of the employee's tenure. If the employee has declined but changes his/her mind at a later date, the vaccination will be made available at that time.

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.

VIII. POST-EXPOSURE EVALUATION AND FOLLOW-UP

All occupational exposures to human blood or other potentially infectious materials will be reported promptly, evaluated by a trained healthcare professional, and treated according to the U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis, Follow-up treatment will be available at no cost to the employee.

In the event of an exposure, employees should:

- Carry out any immediate first aid, if necessary, washing with soap and water any exposed area.
- Report the incident to his/her immediate supervisor as soon as possible following the incident.
- Discuss the circumstances and the nature of the exposure with his/her supervisor, and determine if the incident constitutes an occupational exposure.
- Receive medical follow-up at the Henry Ford Harbortown, Occupational Health Clinic as soon as possible. 3300 E. Jefferson, 313-656-1618 (M-F, 8 am to 4 pm)
- In the event of an emergency, or an after-hours exposure incident, the employee should go to either the Henry Ford Hospital - ER (2799 W. Grand Blvd.) or Detroit Receiving Hospital ER (3201 St. Antoine) for medical follow-up.
- Complete a WSU Report of Injury Form through the Office of Enterprise Risk Management,
  313-577-3110 or at http://idrm.wayne.edu/risk/compensation-forms.php.

The medical evaluation and follow-up will include the following elements:

- Documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred.
- Identification and documentation of the source individual or material, unless it has been established that the identification is infeasible or prohibited by law.
- Testing of the source individual's blood as soon as feasible after consent is obtained in order to determine HIV, HBV, or HCV infectivity. If consent is not obtained, the department will establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source, if available, will be tested and the results documented.

- Results will be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of identity and infectious status of the source individual.

- Baseline collection and testing of employee's blood after consent is obtained, if desired by the employee. If the employee does not give consent at the time for serologic testing, the sample will be preserved for at least 90 days, and testing will be done within if the employee elects to have the baseline sample tested.

- Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service.

- Counseling, and evaluation of reported illness.

Employee acceptance of any tests and/or treatments will be on a voluntary basis.

Information provided to the healthcare professional will include:

- A copy of the MIOSHA Bloodborne Infectious Diseases Standard and the WSU Exposure Control Plan.

- A description of the employee's duties as they relate to the exposure incident, and a description of any PPE used or to be used.

- Documentation of the route(s) of exposure and circumstances under which exposure occurred.

- Results of the source individual's blood testing, if available.

- All medical records relevant to the appropriate treatment of the employee, including vaccination status.

Healthcare Professionals Written Opinion

The employee will be provided with a copy of the evaluating healthcare professional's written opinion within 15 days of completion of the evaluation. The written opinion for post-exposure evaluation and follow-up will summarize that the employee has been informed of:

- the results of the evaluation and told about any medical conditions resulting from the exposure which require further evaluation or treatment

- whether post-exposure prophylactic treatment is indicated

- recommended limitations upon use of personal protective clothing or equipment

All other findings and diagnosis will remain confidential and will not be included in the written report.

IX. LABELS AND SIGNS

Warning labels will be affixed to containers and bags of regulated waste, refrigerators and freezers containing blood or OPIM, and other containers used to store, transport, or ship blood or OPIM.

Contaminated equipment scheduled for maintenance or repair will be labeled in accordance with the provisions in this section. The label will also state which portions of the equipment remain contaminated.

Labels will be affixed as close as feasible to the container by string, wire, adhesive, or another method that prevents their loss or unintentional removal.

The label will be fluorescent orange-red, with letters and symbols in a contrasting color, and will contain the word “biohazard” with the internationally recognized biohazard symbol.

Signs will be posted at the entrance to HIV or HBV research laboratories. They will be fluorescent orange in color, and contain the word “biohazard” with the internationally recognized biohazard symbol.

Exemptions to the labeling requirement include:

- Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use.

- Individual containers of blood or OPIM that are placed in a secondary labeled container during storage, transport, shipping, or disposal.

Departments are responsible for providing their own labels, signs, bags, or containers. OEHS is available to provide technical assistance in the purchasing of these materials.

X. INFORMATION AND TRAINING

Information and training will be provided for all University employees with occupational exposure, at the time of initial assignment, and at least annually thereafter. Training will be provided at a convenient time during the employee’s regular working hours, at no cost to the employee.

The employee’s supervisor, manager, or principal investigator is responsible for ensuring that the employee is informed of and participates in the training program.

Informational material and training sessions will be appropriate in content and vocabulary to the educational level, literacy, and language of the participating employees.

Training must be provided by individuals who are knowledgeable in the subject matter as it relates to the specific workplace being addressed.

OEHS periodically provides training in the general provisions of the Exposure Control Plan. This training consists of the following elements:

- Bloodborne Pathogens Standard: access to the regulatory text
- Modes of transmission, epidemiology, and symptoms of bloodborne diseases
- Exposure Control Plan: means by which an employee may obtain a copy
- Tasks and activities that may include a risk of exposure
- Methods that will prevent or reduce the risk of exposure, including engineering and work practice controls
- Personal protective equipment: types, proper use, limitations, locations, removal, decontamination, and disposal
- The rationale for selecting prospective PPE
- Hepatitis B Vaccination Program: availability, efficacy, safety, administration, and benefits of vaccination, including that the vaccine is offered free of charge to affected employees
- Actions to take and persons to contact in the event of an emergency
- Procedures to follow if an exposure occurs, including method of reporting and information on post-exposure medical evaluation and follow-up
- How to recognize task and other activities that may involve exposure to blood and OPIM
- Labels and signs: explanation of wording, color-coding, locations
- Questions and answers: opportunity for interactive questions with person conducting the training

The employee's supervisor, manager, or principal investigator must provide further information on site-specific risks and specific safety policies and procedures.

HIV or HBV Research Facility Training

The principal investigator must provide specialized additional training for employees working in HIV or HBV research facilities before work with HIV or HBV begins. This training shall include:

- Employee's demonstration of proficiency in standard microbiological techniques and in the practices and procedures specific to the facility.

- Verification that employee has prior experience in the handling of human pathogens or tissue cultures

- Training for employees who have no prior experience in handling human pathogens. Initial work activities shall not include handling infectious agents, and the employee shall only be assigned work as techniques are learned and proficiency has been demonstrated.

XI. RECORDKEEPING

A. Training Records

Training records for basic training provided by OEHS will be maintained by OEHS. Employees trained by OEHS will receive a certificate of training for their records.

Training records for site-specific training on laboratory policies and procedures must be maintained by the principal investigator or laboratory manager.

Training records will include the following information:

- Date(s) of training session
- Summary of contents of training program
- Names of persons conducting the training
- Names and job titles of all persons attending the training

Training records will be maintained for a minimum of three years from the date on which the training occurred and will be provided upon request to: the employee, employee's representative, director of NIOSH, Assistant Secretary of Labor, and/or the MIOSHA.

B. Medical Records

The Henry Ford Harbortown, Occupational Health Clinic will maintain an accurate record for each employee with occupational exposure. These records include:

- Name of employee
- Copy of employee's hepatitis B immunization status, including dates of vaccinations and any medical records relative to the employee's ability to receive vaccination.
- Copy of the results of examinations, medical testing, and any follow-up procedures
- Copy of the healthcare professional's written opinion concerning hepatitis B vaccination and post-exposure evaluation and follow-up

The WSU Office of Enterprise Risk Management (ERM) maintains all employee injury reports, including needle-stick and sharps injuries. The ERM maintains the OSHA 300 Log and determines if injuries are recordable and the recording classifications.

Injuries involving exposure to sharp, contaminated objects will also be documented on the ***Needlestick & Sharp Object Injury Report Form*** (Appendix C).

Employees' medical records are maintained in accordance with OSHA standards at the Henry Ford Harbortown, Occupational Health Clinic, or at other Occupational Health Clinics used by Wayne State University.

APPENDIX A

WAYNE STATE UNIVERSITY
HEPATITIS B VACCINE DECLINATION

29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself, however, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials, and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signature _____

Name (print) _____

Department _____

Date _____

Note: If you are declining vaccination because you have previously received vaccinated elsewhere, complete the following information:

Facility where you were vaccinated: _____

Date you completed vaccination series: Month _____ Year _____

Copies of this form must be distributed to:

Employee

Employee's department

WSU Office of Environmental Health & Safety
5425 Woodward, Suite 300
Detroit, MI 48202

APPENDIX B

Bloodborne Pathogen Site-Specific Training Checklist

In addition to the training provided by the Office of Environmental Health and Safety, employees should be instructed by their supervisor or Principal Investigator on the specific policies and procedures in their work area. Check (or write "N/A" if not applicable) next to each topic to be covered. The employee and the supervisor or Principal Investigator should sign and date the bottom of the form. Keep this form with your Exposure Control Plan (ECP) and other safety documentation.

Location of Written Policies/Plans

- ❑ Information on the location of written safety policies, including ECP

Specific Work Practices

- ❑ Discussion of the tasks that involve potentially infectious materials, and methods to reduce the risk of an exposure.

Personal Protective Equipment (PPE): gloves, eye/face protection, lab coat, etc.

- ❑ Explanation of the type and proper use of PPE required for specific tasks
- ❑ Location and availability of PPE
- ❑ Maintenance and disposal of PPE (cleaning, storage, inspection, etc.)

Engineering Controls

- ❑ Location and operation of eyewash and safety shower
- ❑ Explanation of equipment specific to work area (e.g.; sharps containers, mechanical pipettors)
- ❑ Explanation of biological safety cabinet and its proper use

Biohazardous Waste Handling and Disposal

- ❑ Review of specific disposal of sharps and non-sharp contaminated items (in accordance with the University's biohazardous waste disposal policies.

Emergency Response

- ❑ Review of procedures to follow in event of a spill (including appropriate disinfectant available)
- ❑ Review of procedure to follow in event of an exposure to potentially infectious material

Verification of Training

The site-specific training items listed above have been reviewed and understood as required by Wayne State University's Exposure Control Plan.

Supervisor / P.I. / Trainer Signature and Date

Employee Signature and Date

APPENDIX C

SHARPS Safety Device Evaluation Record and Form

SHARPS Safety Device Evaluation Record	
Evaluation Performed Due To: ❑ Follow-up to an injury/exposure involving a contaminated sharp ❑ Proactive review of sharps use with human / other potentially infectious materials (e.g. human/animal pathogens)	
Evaluation Date:	Principal Investigator:
Department:	Building/Room Number:
Contact Employee:	Fax Number:
Phone Number:	E-mail:
Procedure involving a contaminated sharp:	
Type/Brand of sharp currently in use:	
Recommendation: ❑ Elimination of sharp from procedure ❑ Use of engineering controls ❑ Personal Protective Equipment	❑ Substitution with a safe sharp device ❑ Implementation of safe work practices ❑ No recommendation, effective device(s) currently in use
Results of training and evaluation of new device:	
Type/Brand of sharp(s) evaluated:	
List employees involved in formal evaluation of safe sharps device(s):	
Training date for work with new safe sharps device(s):	
Device(s) formally in use following evaluation (selection/use date):	
Additional Comments:	

Safety Device Evaluation Form						
Device:			Number of Times Used:			
Product Name/Supplier:						
Applications:						
Reviewer:	Department:		Date:			
Circle the most appropriate answer for each question:						
1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree, N/A = not applicable						

Healthcare Worker Safety	**1**	**2**	**3**	**4**	**5**	**N/A**
1. The device prevents needlesticks during use (i.e., before disposal).						
2. After use, the safety mechanism remains activated throughout disposal.						
3. The device provides protection one of the following ways: either intrinsically or automatically (N/A if a specific action by the user is required to activate the safety mechanism).						
4. If "N/A", the mechanism activated in one of the following ways: either by one-handed technique or by a two-handed technique accomplished as part of the usual procedure.						
5. During the use of the device, the user's hands remain behind the needle until activation of the safety mechanism is complete.						
6. The safety mechanism is reliable when activated properly.						
7. The device minimizes the risk of user exposure to blood or OPIM*.						
Patient Safety and Comfort						
1. The device minimizes the risk of infection to the patient (e.g., through cross-contamination).						
2. The device can be used without causing more patient discomfort than a conventional device.						
3. *For IV devices*: The device is attached comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing).						
Ease of Use and Training						
1. The device operation is obvious. That is, it can be used properly without extensive training.						
2. The device can be used by a left-handed person as easily as by a right-handed person.						
3. The technique required for using the device is the same as that for using a conventional device.						
4. It is easy to identify the type and size of the product from the packaging.						
5. *For IV catheters & blood collection needle sets*: The device can provide a visible blood flashback during initial insertion.						
6. The device is easy to use.						
Compatibility						
1. The device is compatible with devices (e.g., blood collection tubes) from a variety of suppliers.						
2. *For IV devices*: A. The device is compatible with intralipid solutions.						
B. The device is attached securely at the catheter port						
C. The device is attached securely or locked at a Y-site (e.g. for piggybacking).						
3. The device is easy to dispose of in SHARPS containers of all sizes.						

Comments (describe problems, incompatibilities, your recommendations, etc.):
*OPIM = Other Potentially Infectious Materials

APPENDIX D

Application of the Exposure Control Plan to Human Cell Cultures

The provisions of the WSU Exposure Control Plan provide protection to employees who have occupational exposure to human blood or other potentially infectious materials (OPIM). Established human cell lines[1] which are characterized[2] as free of contamination from human hepatitis viruses, human immunodeficiency viruses, and other recognized bloodborne pathogens, are not to be considered as OPIM and are not covered by the bloodborne pathogens standard and the Exposure Control Plan.

Established human or animal cell lines that are potentially infected or contaminated with bloodborne pathogens are covered by the provisions of the Exposure Control Plan.

The final judgment for making the determination if human or animal cell lines in culture are free of bloodborne pathogens will be made by the Biological Safety Officer and/or the Institutional Biosafety Committee (IBC) in consultation with the Principal Investigator (PI), in accordance with the requirements of the Bloodborne Pathogen Standard. Documentation that such cell lines are not OPIM should be on file with the PI for MIOSHA review. All primary human cell explants and in vitro passages of human tissue explant cultures (human cell strains[3]) must be regarded as containing bloodborne pathogens and are subject to Universal Precautions and the requirements of the ECP. Non-transformed, human cell strains characterized by documented, reasonable laboratory testing, to be free of HIV, hepatitis viruses, or other bloodborne pathogens may be exempted from the ECP requirements. However, tissue explants or subsequent cultures derived from human subjects known to carry bloodborne pathogens (e.g., HIV, HBV), or deliberately infected with bloodborne pathogens, must be handled in accordance with the bloodborne pathogens standard and the WSU ECP. The same applies for animal tissues and explants or cell lines contaminated by deliberate infection with bloodborne pathogens.

Definitions

[1] Human cell lines are defined as in vitro or animal passage (e.g., nude mouse) cultures or human cells that fulfill traditional requirements of a cell line designation. That is:

immortalized cells;
cultures transformed by spontaneous mutation;
cultures transformed by natural or laboratory infection with an
immortalizing agent (e.g., Epstein-Barr Virus (EBV)).

Human cell lines may be adulterated with laboratory pathogens introduced by cultivation with other cell cultures, or cells may be physically contaminated by other cultures handled in the same lab. Cells should be documented to be pure cells and shown to be free of bloodborne pathogens in order to be exempted from the ECP requirements.

[2] Characterization of human cells, for exclusion from compliance with the bloodborne pathogen standard, must include (1) screening of the cell lines or strains for viruses characterized as bloodborne pathogens (e.g., HIV, HBV, EBV), and (2) determining that the cells are not capable of propagating such viruses. Most cell lines are screened only for human mycoplasmas and are determined to be free of bacterial and mycotic contaminants. Testing to identify latent viruses capable of infecting humans such as Herpesvirus (e.g., EBV), or papilloma members of the Papovirus group, etc. may include:
antigenic screening for viral or agent markers;
co-cultivation with various indicator cells that allow contaminants to grow;
using molecular techniques (polymerase chain reaction or nucleic acid hybridization).

Cell lines obtained from commercial vendors or other sources documented as free of human bloodborne pathogens and protected by the employer from environmental contamination may be excluded from the bloodborne pathogens standard.

[3] Human cell strains are cells propagated in vitro from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue cultures for 20-70 passages. Human cell strains must be handled as potential biohazards unless characterized by documented testing to be free of bloodborne pathogens.

Source: June 21, 1994 OSHA Standards Interpretation and Compliance Letters entitled "Applicability of 1910.1030 to established human cell lines.