

2-Bloodborne Pathogens Exposure Control Plan

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ANNUAL REVIEW:

REVIEWED	<u>Stanford N. Bailey, M.D</u>	<u>July 11-2025</u>
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SUPERSEDES: Procedure titled _____

Purpose:

The purpose of this Standard Operating Procedure (SOP) is to comply with the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens (BBP) Standard, 29 CFR 1910.1030, and to ensure the safety of employees in the clinical laboratory by minimizing or eliminating their occupational exposure to blood, certain other body fluids, or other potentially infectious materials (OPIM). By implementing this BBP control plan, the laboratory aims to protect its employees from the hazards of bloodborne pathogens and to maintain a safe and healthy work environment."

Scope:

This Bloodborne Pathogens Control Plan outlines the procedures and practices to be followed by all employees of the clinical laboratory who may be exposed to bloodborne pathogens. The plan applies to all areas of the laboratory where potentially infectious materials may be present, including but not limited to laboratory workstations, equipment, and storage areas. The plan also covers the use of personal protective equipment (PPE) and the handling and disposal of contaminated materials. The scope of this plan is to provide a safe and healthy work environment for all employees and to prevent the spread of bloodborne pathogens. This is part of the orientation provided by Meharry for all new employee and can be access at:

<https://home.mmc.edu/ehs/>

ENVIRONMENTAL HEALTH & SAFETY; SAFETY PROGARM

Includes all of the following:

Biosafety
Bloodborne Pathogens
Emergency Preparedness
Formaldehyde Safety
Hazard Communication
Hazardous Waste
Indoor Air Quality
Laboratory Safety
Laser Safety
Respiratory Protection
Radiation Safety Committe

Health and Safety:

Always be sure to wear proper PPE when handling hazardous waste.

Definitions and abbreviations

BBP- Bloodborne Pathogens
CSF - Cerebrospinal fluid
GS- General Supervisor
HBV - Hepatitis B virus
HIV - Immunodeficiency virus
LD- Lab Director
MMCCCL- Meharry Medical College Clinical Consolidated Laboratory
OPIM- Other potentially infectious materials
OSHA- Occupational Safety and Health Administration's
PPE-personal protective equipment

Definitions:

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

Bodily Fluids – means semen, vaginal secretions, cerebrospinal fluid (CSF) synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

Other Potentially Infectious Material – OPIM – means any unfixed tissue or organ (other than intact skin) from a human (living or dead) and human immunodeficiency virus (HIV)- containing cell or tissue cultures, organ cultures, and HIV- or hepatitis B virus (HBV) - containing medium or other solutions; and blood organs or other tissues from experimental animals infected with HIV or HBV.

Health and Safety:

The health and safety of laboratory personnel is of the utmost importance in the prevention of blood borne pathogens exposure. In addition to following the guidelines outlined in this SOP, all laboratory personnel must adhere to applicable laws and regulations related to health and safety in the workplace.

To prevent exposure to blood borne pathogens, laboratory personnel must wear appropriate personal protective equipment (PPE) at all times, including but not limited to a lab coat, gloves, eye protection, and face shields. All PPE must be properly removed and disposed of after use. All necessary PPE that staff need to safely perform their duties will be provided free of charge by the laboratory.

In addition to wearing PPE, all laboratory personnel must follow universal precautions. This means that all blood and other potentially infectious materials (OPIM) must be treated as if they are infectious and handled with extreme care. All instruments and equipment must be decontaminated after use according to the laboratory's decontamination procedures.

If an exposure incident occurs, laboratory personnel must immediately notify their supervisor and follow the laboratory's post-exposure management procedures.

Policy:

MMCCCL is committed to providing a safe and healthy work environment for all employees. In compliance with OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030, we have implemented this SOP to identify situations and job classifications in which employees may be exposed to blood or other potentially

infectious materials (OPIM), and to provide the necessary protection to mitigate the risk of occupational exposure. Through the implementation of engineering controls, Personal Protective Equipment (PPE), training, and risk reduction measures, we aim to safeguard our employees' health and well-being.

Procedure:

1. Assignment of Responsibilities

Program Administrator

The Safety/Compliance Officer shall be responsible for managing and overseeing the implementation of the BBP Exposure Control Plan. In the absence of a dedicated Safety/Compliance Officer, the Lab Manager/Supervisor will act as the Safety/Compliance Officer.

Management

Laboratory Management will provide the necessary controls and equipment to minimize or eliminate the risk of occupational exposure to blood or OPIM. These controls and equipment shall be provided at no cost to the employees. Laboratory Management will ensure compliance with this plan through regular audits.

Supervisors

Supervisors shall ensure that they and their employees follow proper work practices, universal precautions, and the use of PPE. They shall also ensure that employees are properly trained on cleanup and disposal techniques.

Employees

Employees, including Lab Techs and Lab Assistants, are responsible for employing proper work practices, using PPE, and following cleanup and disposal techniques. Employees are also responsible for reporting any exposure incidents to a General Supervisor immediately. If medical attention is required, employees must report the incident within 24 hours.

Contractors

Contractors shall comply with this plan and shall receive the necessary training from the General Supervisor to ensure they follow proper work practices, universal precautions, and the use of PPE.

2. Exposure Determination

The General Supervisor (GS) or Lab Director (LD) shall identify and evaluate all job classifications and locations in which employees may incur occupational exposure to blood or OPIM, based on the nature of the job or collateral duties, regardless of

frequency. This list shall be updated as job classifications or work situations change and shall be made without regard to the use of personal protective equipment (PPE).

Category 1

Job classifications in which employees are regularly exposed to blood or OPIM, and in which such exposures are considered a normal course of work, fall into Category 1. The GS or LD shall complete a form identifying the job classification and location and store it with the General Supervisor or Quality Manager.

Category 2

Job classifications in which employees may have occasional exposure to blood or OPIM, and which such exposures occur only during certain tasks or collateral to the normal job duties, fall into Category 2. The GS or LD shall complete a form identifying the job classification and location and store it with the General Supervisor or Quality Manager.

3. Safety Controls

1. Universal precautions

All employees shall use universal precautions to prevent contact with blood or OPIM. Universal precautions require treating all blood and OPIM as potentially infectious, regardless of the perceived status of the source individual.

2. Engineering Controls

The laboratory shall implement engineering and work practice controls to minimize or eliminate employee exposure. These controls include the following:

- Specified and labeled waste containers shall be used for disposal of specimen containers.
- Exhaust hoods, vented areas, and/or face shields shall be used when transferring untreated specimens.

The effectiveness of engineering controls shall be reviewed regularly according to the following schedule:

1. Daily review during lab operation
2. Weekly at Lab Meetings
3. Monthly review during quality management system audits
4. Upon acquisition or implementation of new equipment and technologies present at the workplace.

The Lab Director and General Supervisor shall be responsible for reviewing the effectiveness of each control.

If occupational exposure remains after implementing engineering controls, The plan should be reviewed, change policy and practice to completely resolved the issue and keep monitoring.

3. Needles

Except as noted below, contaminated needles and other sharps shall not be bent, recapped, removed, sheared, or purposefully broken. Contaminated sharps shall be placed immediately, or as soon as possible, after use into appropriate sharps containers. All disposable sharps containers shall be puncture resistant, labeled with a biohazard label, and leak-proof not to be filled not exceeding exceed 2/3 capacity.

4. Containers for Reusable sharps

Contaminated sharps that are reusable shall be placed immediately, or as soon as possible, after use into appropriate sharps containers. All disposable sharps containers shall be puncture resistant, labeled with a biohazard label, and leak-proof.

Reusable sharps containers will be placed throughout the lab at work stations. The general supervisor is ultimately responsible for the removal of these containers (usually a company is contacted to remove biohazard waste, and also removes the sharps containers.

E. Sharps Injury Log

A needlestick, or sharps injury log shall be maintained, and shall include the following information for each incident:

1. Period of the time the log covers
2. Date of the incident
3. Date the incident is logged
4. Type and brand of device
5. Department, or area of incident
6. Description of incident
7. Report to FDA or not

The log shall be retained for 5 years

6. Hand washing facilities

Hand washing facilities shall be made available and readily accessible to all employees who may be exposed to blood or OPIM. Where hand washing facilities are not feasible, the lab will provide antiseptic cleansers in conjunction with clean cloth/paper towels or antiseptic towelettes. When these alternatives are used, employees shall wash their hands with soap and running water as soon as feasible.

7. Work Area Restrictions

a. In work areas where there is a feasible risk of exposure to blood or OPIM, employees shall not eat, drink, apply cosmetics or lip balm, or handle contact lenses. Food and beverages shall not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or OPIM may be present.

b. Mouth Pipetting or suctioning of blood or OPIM is prohibited.

c. All processes and procedures shall be conducted in a manner that will minimize splashing, spraying, splattering, and generation of droplets or OPIM.

d. Centrifuges are operated with all covers in place and analyzers following the manufacturer instructions.

e. Pipetting is performed with an auto-pipettor, manual pipettor, or disposable pipettes only.

8. Specimens

a. Each specimen of blood or OPIM shall be placed in a container that will prevent leakage during the collection, handling, processing, storage and transport of the specimen.

b. Specimen containers shall be labeled or color coded in accordance with the requirements of the OSHA standard.

c. Any specimen that could puncture in the primary container shall be placed within a secondary, puncture-resistant, container. If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container that will prevent leakage during handling, processing, storage, transport, or shipping of the specimen.

9. Contaminated equipment

The General Supervisor shall ensure that equipment that has become contaminated with blood or OPIM is examined prior to servicing or shipping. Contaminated equipment shall be decontaminated, unless decontamination is not feasible. Contaminated equipment shall be tagged and labeled as such.

10. Personal Protective Equipment (PPE)

- a. The General supervisor shall ensure the provisions regarding personal protective equipment described in this plan are met and maintained.
- b. PPE shall be chosen based on the anticipated exposure to blood or OPIM. PPE shall be considered appropriate only if it does not permit blood or OPIM to pass through or to reach an employee's clothing, skin, eyes, mouth, or other mucous membranes under normal and proper conditions of use and for the duration of time that the equipment will be used.
- c. The following is a list of PPE associated specific jobs and duties.

Job Classification	Task/Procedure	PPE to be used
Tech/General Supervisor	Sample Preparation	Safety Glasses or Face Shield Gloves Lab Coat
Specimen Collector/ Processor	Collection/ Demographic Data Entry	Safety Glasses or Face Shield Gloves Lab Coat
Any	Just being in the lab	Lab Coat

- d. The General supervisor shall ensure that employees use appropriate PPE. In cases where an employee temporarily and briefly declines to use PPE because, this act may prevent delivery of quality healthcare or pose an increased hazard to the safety of the worker or co-worker, then the supervisor shall investigate and document the situation to determine whether changes can be instituted to prevent such occurrences in the future.
- e. The General Supervisor shall ensure that appropriate PPE in the necessary sizes is readily accessible at the work site or is issued at no cost to employees. Hypoallergenic gloves, Glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

11. PPE Cleaning, Laundering, and Disposal

- a. All PPE shall be provided, cleaned, laundered, and/or disposed of by the laboratory at no cost to the employees. The laboratory will also make all necessary repairs and replacements at no cost to employees
- b. All garments penetrated by blood or OPIM shall be removed immediately or as soon as feasible. All PPE shall be removed before leaving the work area.
- c. When PPE is removed it shall be placed in appropriately designated areas or containers for storage, washing, decontamination, or disposal.

12. Types of PPE

- a. Gloves - Disposable gloves are not to be washed or decontaminated for re-use, and are to be replaced as soon as possible when they become contaminated. Gloves that become torn or punctured (or their ability to function as a barrier is otherwise compromised) shall be replaced immediately or as soon as feasible.
- b. Utility gloves may be decontaminated for re-use if the integrity of the glove is uncompromised. Dispose of utility gloves that are cracked, peeling, torn, punctured, or they exhibit other signs of deterioration or inability to function as a barrier without compromise.

13. Situations where hand protection is needed

- a. Sample receiving, including opening of packages of specimens.
- b. Opening of specimen containers transfer of untreated specimens to analytical containers
- c. Transfer of chemicals

14. Eye and Face Protection

Masks worn in combination with eye protection devices (such as goggles or glasses with solid side shield, or chin length face shields) are required when the occurrence of splashes, splatters, or droplet or blood or OPIM can reasonably be anticipated to contaminate an employee's eyes, nose, or mouth.

Situations where and face protection is required:

- a. Sample receiving, including opening of packages of specimens.
- b. Opening of specimen containers transfer of untreated specimens to analytical containers
- c. Transfer of chemicals
- d. Eye protection is required in analytical areas during the transfer of treated specimens.

15. Other PPE

Additional Protective clothing (such as lab coats, gowns, aprons, clinic jackets, or similar outer garments) shall be worn in instances when gross contamination can reasonably be expected.

Lab coats are to be worn during sample receiving, including opening of packages of specimens, opening specimen containers, transfer of treated and untreated specimens to analytical containers, during sample analysis.

16. Housekeeping

a. This facility shall be cleaned and decontaminated regularly and as needed in the event of a gross contamination follow cleaning schedule and required cleaning materials. All contaminated work surfaces, bins, pails, cans, and similar receptacles shall be inspected and decontaminated regularly.

b. Any potentially contaminated glassware shall not be picked up directly with the hands. Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where sharps are placed.

17. Regulated Waste Disposal

a. Disposal of all regulated waste shall be in accordance with applicable federal, state, and local regulations.

i. Sharps: Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled or color-coded. Sharps disposal containers are available at point of use.

ii. Other Regulated Waste: Regulated waste containers are closable, leak proof, and identified with the biohazard label. These containers are removed from the premises periodically by a registered biohazard waste disposal service.

b. Laundry contaminated with blood or other potentially infectious materials shall be handled as little as possible. Such laundry shall be placed in appropriately marked bags.

18. Hepatitis B Vaccines and Post-Exposure Evaluation and Follow Up

a. The laboratory will make the Hepatitis B vaccine and vaccination series available to all employees who have the potential for occupational exposure, as well as post exposure follow up to employees who have experienced an exposure incident.

b. The Safety/Compliance Officer (or general supervisor) shall ensure that all medical evaluations and procedures involved in the Hepatitis B vaccine and vaccination series and post exposure follow up, including prophylaxis are:

i. made available at no cost to the employee

ii. made available to the employee at a reasonable time and place

iii. performed by or under the supervision of a licensed physician or other licensed healthcare professional

iv. and provided in accordance with the recommendations of the United States Public Health Service

c. An accredited laboratory shall conduct all laboratory tests at no cost to the employee. B. Hepatitis B Vaccination

d. The Safety/Compliance Officer (or general supervisor) shall manage the Hepatitis B vaccination program. The laboratory has contracted with a designated local urgent care facility to provide this service.

e. Category I Employees

i. The Hepatitis B vaccination shall be made available to an affected Category I employee after he or she has received training in occupational exposure and within 10 working days of initial assignment to job duties that involve exposure. Exceptions to the administration of the Hepatitis B vaccination include situations where an employee has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

ii. Participation in a re-screening program shall not be a prerequisite for an affected employee to receive the Hepatitis B vaccination. If an employee initially declines the Hepatitis B vaccination, but later decides to accept the vaccination and is still covered under the OSHA standard, the vaccination shall then be made available.

iii. All employees who decline the Hepatitis B vaccination shall sign a waiver indicating their refusal, as required by OSHA. If the United States Public Health Service recommends a routine booster dose of Hepatitis B vaccine, this shall also be made available free of charge to affected employees.

f. Category II Employees

i. The Hepatitis B vaccination series shall be made available and administered to Category II employees no later than 24 hours after an exposure incident (as per OSHA Letter of Interpretation, November 1, 2000). All employees who decline the Hepatitis B vaccination shall sign a waiver indicating their refusal

g. Post-Exposure Evaluation and Follow Up

i. All employees must report all exposure incidents to the General Supervisor immediately or within 24 hours. The Safety/Compliance Officer/GS shall investigate and document each exposure incident. Following a report of an exposure incident, the exposed employee shall immediately receive a confidential

post-exposure evaluation and follow up, to be provided by the designated local urgent care facility. The post exposure evaluation and follow up shall include the following elements, at a minimum:

1. Documentation of the route of exposure and the circumstances under which the exposure occurred.
2. Identification and documentation of the source individual, unless it can be established that identification is not feasible or prohibited by state or local law.
3. The source individual's blood shall be tested and documented as soon as feasible and after consent is obtained (if consent is required) to determine HBV and HIV infectivity. If consent cannot be obtained, the Chief Compliance Officer shall establish and document that legally required consent cannot be obtained.
4. When the source individual is already known to be infected with the hepatitis B virus (HBV) or human immunodeficiency virus (HIV), testing for the source individual's known HBV or HIV status need not be repeated.
5. Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulation concerning disclosure of the identity and infectious status of the source individual.
6. The exposed employee shall be offered the option of having their blood tested for HBV and HIV serological status. The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained. The blood sample shall be preserved for up to 90 days to allow the employee to decide if their blood should be tested for HBV and HIV serological status.
7. Names of employees that contract HIV or Hepatitis shall be recorded on the OSHA 300 log.
8. After an exposure incident occurs, the Safety/Compliance Officer/GS shall ensure that the healthcare professional responsible for the exposed employee's Hepatitis B vaccination, as well as the healthcare provider providing the post-exposure evaluation, if different, is provided with the following:
 - a. a copy of 29 CFR 191 0.1030, OSHA's Bloodborne Pathogen Standard, with emphasis on the confidentiality requirements contained therein;
 - b. a written description of the exposed employee's duties as they relate to the exposure incident;
 - c. written documentation of the route of exposure and circumstances under which the exposure occurred; results of the source individual's blood testing, if available; and all medical records relevant to the appropriate treatment of the employee, including vaccination status.

9. Healthcare Professional's Written Opinion

a. The Safety/Compliance Officer/GS shall obtain and provide to the exposed employee a copy of the evaluating healthcare professional's written opinion within 15 days of completion of the evaluation.

b. The healthcare professional's written opinion for HBV vaccination shall be limited to whether HBV vaccination is indicated for the employees, and if the employee has received said vaccination.

c. The healthcare professional's written opinion for post-exposure follow up shall be limited to ONLY the following information:

i. A statement that the employee has been informed of the results of the evaluation, and a statement that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment.

ii. Other findings or diagnosis resulting from the post-exposure follow up shall remain confidential and shall not be included in the written report.

h. Labels and Signs

i. The General Supervisor shall ensure that biohazard labels are affixed to containers of regulated waste, refrigerators, and freezers containing blood or other potentially infectious materials. Labels shall also be affixed to any other containers used to store, transport, or ship blood or other potentially infectious materials.

ii. The labels shall be fluorescent orange or orange-red and shall include the universal biohazard symbol. Red bags or containers with the universal biohazard symbol may be substituted for labels. However, regulated wastes must be handled in accordance with the rules and regulations of the entity with jurisdiction. Blood products that have been released for transfusion or other clinical use are exempted from these labeling requirements.

19. Training

The Laboratory Director shall ensure that training is provided at the time of initial assignment to tasks where infectious materials may occur. Training shall be repeated every 12 months, or when there are any changes to tasks or procedures affecting an employee's occupational exposure. Training shall be tailored to the education level and language of the affected employees and offered during the normal work shift. Training shall be interactive and shall include:

i. a copy of 29 CFR 1910.1030, OSHA's Bloodborne Pathogen Standard;

ii. a discussion of the epidemiology and symptoms of bloodborne diseases;

- iii. an explanation of the modes of transmission of bloodborne pathogens;
- iv. an explanation of the laboratory's Bloodborne Pathogen Exposure Control Plan, and how employees can obtain a copy of the plan;
- v. a description and recognition of tasks that may involve exposure;
- vi. an explanation of the use and limitations of the methods employed to reduce
- vii. exposure (such as engineering controls, work practices, and personal protective equipment);
- viii. information about the types, use, location, removal, handling, decontamination, and disposal of personal protective equipment;
- ix. an explanation of the based-on selection of personal protective equipment;
- x. information about the Hepatitis B vaccination (including efficacy, safety, method of administration, and benefits), as well as an explanation that the vaccination will be provided at no charge to the employee
- xi. instruction on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;
- xii. an explanation of the procedures to follow if an exposure incident occurs, including the method of reporting and medical follow up;
- xiii. information on the post-incident evaluation and follow up required for all exposure
- xiv. incidents;
- xv. an explanation of signs, labels, and color-coding systems.
- xvi. The person conducting the training shall be knowledgeable in the subject matter.

20. Recordkeeping

a. Medical Records

The Safety/Compliance Officer (Or GS) shall maintain medical records as required by 29 CFR 1910.1020 in the Personnel Files. All records shall be kept confidential and shall be retained for at least the duration of employment plus 30 years with exception of records specified within 29 CFR 1910.1020. The Safety/Compliance Officer shall also ensure that all contracts with the

designated local urgent care facility for Hepatitis B vaccinations and post-exposure evaluations and follow ups stipulate any OSHA recordkeeping and retention requirements.

b. Medical Records shall include:

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

c. Training Records

The Laboratory Director shall ensure maintenance of training records for three years from the date of training. Record shall be kept in the electronic files and shall include:

1. the dates of the training sessions;
2. an outline describing the material presented;
3. the names of persons conducting the training; and
4. the names and signatures of all persons attending the training sessions.

d. Availability of Records

Whenever an employee (or designated representative) requests access to a record, the laboratory shall provide access to said employee's records in a reasonable time, place, and manner in accordance with 29 CE I 10.1020(e). An employee (or designated representative) will only be given access to his or her own records.

e. Transfer of Records

If the laboratory ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the management of the laboratory shall contact the Director of the National Institute for Occupational Safety and Health (NIOSH) three months prior to cessation of business for instruction on final disposition of the records.

Evaluation and Review The Laboratory Director shall review this Bloodborne Exposure Control Plan for effectiveness at least annually and as needed to incorporate changes to the standard or changes in the workplace

References

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Zaidi, A. A., & Calderwood, M. S. (2018). Bloodborne pathogens in the clinical laboratory: A review of risks and guidelines for prevention. *Archives of Pathology & Laboratory Medicine*, 142(11), 1321-1327.

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