Bloodborne Pathogen Exposure Control Plan

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ANNUAL REVIEW:

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SUPERSEDES: Procedure titled _____

PURPOSE:

Meharry Medical College Consolidated Clinical Laboratories are committed to providing a safe and healthful work and learning environment for our entire faculty, staff, and students, including part-time, temporary, contract, and per diem employees. In pursuit of this goal, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with **OSHA standard 29 CFR 1910.1030**, "Occupational Exposure to Bloodborne Pathogens."

POLICY STATEMENT:

The ECP is a key document to assist our organization in implementing and ensuring compliance with the standard, thereby protecting our employees, students, visitors etc. This ECP outlines the requirements concerning:

1) Exposure Determination
2) Methods of Compliance, including: universal precautions, engineering and work practice controls, personal protective equipment, and housekeeping
3) Communication of hazards to employees and training
4) Requirements for HIV Research Laboratories
5) Hepatitis B vaccination
6) Post-exposure evaluation and follow-up
7) Recordkeeping

Implementation methods for these elements of the standard are discussed in the subsequent pages of this ECP.

DEFINITIONS:

Bloodborne pathogens (BBP) — are pathogenic microorganisms that are present in blood or other body fluids and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). BBP are transmitted through contact with infected blood and other body fluids such as trauma fluids (synovial fluid, pleural fluid, cerebrospinal fluid, amniotic fluid, semen, etc.) and can also be transmitted through the mucous membranes of the eye, nose, or mouth, and through any damaged or broken skin (i.e. cuts, scrapes, rashes, acne).

Contaminated — means the presence, or the reasonably anticipated presence, of blood, or other potentially infectious materials on any item or surface.

Contaminated sharps - means 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.

Exposure Control Plan (ECP) — The ECP is required to contain the following elements: 1) an exposure determination; 2) the method of implementation for a) Methods of Compliance, b) HIV and HBV Research Laboratories, c) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, d) Communication of Hazards to Employees, and e) recordkeeping; and 3) the procedure for the evaluation of circumstances surrounding exposure incidents Exposure Determination — designates job classifications that have the potential to result in an occupational exposure. One set of job classifications includes ALL employees that have an occupational exposure (without regard to PPE) and the other set includes job classifications in

which SOME employees have occupational exposure (without regard to PPE). However, where SOME job classifications have occupational exposure, a list of all tasks and procedures that result in potential occupational exposure must accompany this designation.
Occupational exposure — the potential and/or actual contact with blood or other potentially infectious materials with skin, eye, mucous membrane, non-intact skin, or parenteral contact that may result from the performance of an employee's duties. Other potentially infectious materials (OPIM) — are materials, in addition to human blood, that may be capable of transmitting bloodborne pathogens. These include:

1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental settings, anybody 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).
3. HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture media or other solutions.
4. Human cell/tissue/organ cultures not shown to be free of bloodborne pathogens.
5. Blood, organs, or other tissues from experimental mammals infected with human bloodborne pathogens.

Personal protective equipment (PPE) — is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g. uniforms, pants, shirts, blouses) not intended to function as protection against a hazard are not considered personal protective equipment.
Regulated waste - means l) liquid or semi-liquid blood or other potentially infectious materials; 2) contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; 3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; 4) contaminated sharps; and 5) pathological and microbiological wastes containing blood or other potentially infectious materials.
Work practice controls — are 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

PROCEDURE:

PROGRAM ADMINISTRATION

- The Environmental Health and Safety Office under the guidance of the Office of General Counsel is responsible for implementation of this ECP. The EHS Officer will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. The EHS Officer and/or Biosafety Officer/Laboratory Supervisor will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives. **Contact the EHS Office at 615-327-6642**

- Laboratory Managers/Supervisor/Department Administrators/Laboratory Chairman will, for their respective area of responsibility, provide and maintain all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. They will also ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes.
- Employee and Student Health Services Director will be responsible for ensuring that all medical actions required by the standard are performed and that appropriate employee health and OSHA records are maintained. **Contact the clinic at 615-327-5757**
- The Meharry Medical Group (MMG), MMCCCLs Executive Director, or designee, are responsible for notifying the EHS Office of any new clinical facilities or activities,
- Those employees, students and visitors who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP. This includes part-time, temporary, contract and per diem employees.
- All Biological waste will be collected and disposed of offsite through an outside vendor.

1.0 EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at Meharry, MMCCCLs in which all employees have occupational exposure: Laboratory staff, Students, Nurses, Physicians, Dentists, Residents, Patient Service Representatives, Lab Techs, Respiratory Therapists, Phlebotomists, Medical Assistants, and Custodians.

The following is a list of job classifications in which some employees at Meharry and MMCCCLs have occupational exposure: Laboratory Director, Principal Investigators, Post-doctoral Fellows, Graduate Students, and Research Technicians. All research projects that have any potential for biosafety hazards is reviewed by the Institutional Biosafety Committee (IBC) to ensure proper understanding and minimization of hazards as well as compliance with this ECP. These projects may begin or end at any point in the year, and the tasks and procedures for each one may vary. Therefore, the IBC serves a vital role in ensuring compliance and safety with regard to research projects.

2.0 METHODS OF COMPLIANCE

2.1 Universal Precautions

All covered personnel will utilize universal precautions, which is an approach to infection control that treats all bodily fluids as if known to be infectious for blood borne pathogens.

2.2 Engineering Controls and Work Practices

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Personal protective equipment (PPE) shall be used when occupational exposure may occur even though engineering and work practice controls are in place.

Engineering controls shall be examined and maintained or replaced on a regular schedule. At Meharry, MMCCCLs engineering controls must be evaluated at least annually, and more frequent where appropriate.

1. Hand washing facilities shall be provided and maintained with adequate supplies.
2. Contaminated sharps and needles shall be disposed of in puncture resistant, color-coded or labeled, leak-proof containers.
3. Resuscitation devices including mouthpieces or resuscitation bags shall be available for use in areas where the need for resuscitation is predictable.
4. All specimens of blood or OPIM shall be placed in closable, labeled or color-coded, leakproof containers prior to transport. If contamination of the outside of the primary container occurs, the primary container should be placed in a secondary container which prevents leakage during handling, processing, storage, or shipping.
5. Eye wash stations shall be easily accessible and functional.
6. Syringes, safety syringes and needle-less systems used for direct patient care: Safety devices such as self-sheathing needles and needle-less systems will be used for staff protection whenever possible. These devices will be reviewed by non-managerial staff representatives and chosen by consensus for ease of use and engineering controls.

Work practice controls shall be determined for each work area and consistently utilized. At Meharry, MMCCCLs signs must be posted and readily visible to workers to assist in consistent application of appropriate work practice controls. Example work practice controls include:

- Hand washing after removal of gloves and after contact with blood or OPIM.
- Employees with exudative lesions or weeping dermatitis refrain from handling blood or OPIM until the condition resolves.
- Contaminated sharps and needles shall not be bent, recapped, or sheared.
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics are prohibited in work areas where there is a potential for blood or OPIM exposure.
- Food and drink are prohibited in work areas where there is a potential for blood or OPIM exposure.
- All procedures involving blood and OPIM shall be performed in such a manner to minimize splashing, spraying, spattering, generation of droplets, or aerosolization of these substances.
- Mouth pipetting and suctioning are not allowed. Mechanical pipetting devices are required.

2.3 Personal Protective Equipment (PPE)

Personal protective equipment (PPE), including gloves, gowns, laboratory coats, face shields, face masks, eye protection, foot coverings, and other items shall be provided to employees, as appropriate, to prevent exposure to blood or OPIM. Appropriate PPE shall be determined for

each work area, by competent persons in that work area and consistently utilized. PPE shall be considered "appropriate" if it does not permit the passage of blood or OPIM through to an employee's skin, mucous membranes, or street clothes.

Gloves

- Disposable gloves shall be worn when it is reasonably anticipated that the employee will have hand contact with blood or OPIM. The gloves shall be replaced when worn, tom, or contaminated. They shall not be washed or decontaminated for re-use.
- Utility gloves may be decontaminated and re-used if not punctured.
- Latex-free gloves will be provided as necessary.

Masks, eye protection, face shields

Masks in combination with eye protection devices (with side shields) or a chin-length face shield with a mask shall be worn when there is a reasonably anticipated chance of exposure to blood or OPIM through splashes, sprays, spatters or droplets.

Gowns, coats, aprons and other protective coverings

Protective coverings shall be worn depending upon the task and the degree of exposure anticipated. This apparel shall not be taken home for laundering.

Surgical caps, hoods or boots

Head and foot covers shall be worn when gross contamination is reasonably anticipated. There shall be a designated area in each work setting for the dispensing, storage, cleaning and disposal of PPE. Contaminated PPE that is not immediately decontaminated shall be clearly designated and treated as biohazardous material. All PPE must be removed before leaving the work area.

Closed-toe shoes must be worn at all times in laboratory/clinical areas at Meharry/MMCCCLs.

2.4 Housekeeping

Cleaning, Disinfection, and Sterilization Practices

- All environmental and work surfaces shall be properly cleaned and disinfected on a regular schedule and immediately or as soon as feasible after contamination with blood or OPIM.
- Appropriate personal protective equipment (e.g. gloves) shall be worn to clean and disinfect blood and OPIM spills.
- Cleaning, disinfection, and sterilization of equipment shall be performed, as appropriate, after contamination with blood and OPIM.
- Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

- 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 these sharps have been placed.
- Disinfectants must be EPA listed "tuberculocidal."

Regulated Waste

Contaminated Sharps Discarding and Containment.

Contaminated sharps shall be discarded immediately, or as soon as feasible, in containers that are: closable; puncture resistant; leak-proof on sides and bottom; and labeled or color-coded in accordance with this policy.

During use, containers for contaminated sharps shall be:

- Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found;
- Maintained upright throughout use; and
- Replaced routinely and to prevent overfilling

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

- Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
- Placed in a secondary container if leakage is possible, and the second container shall be: closable; constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
- Labeled or color-coded according to this policy.

Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

Other Regulated Waste Containment

Regulated waste shall be placed in containers which are: closable; constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; labeled or color-coded in accordance with this policy; and closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall meet all the same specifications as the first container.

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States and the State of Tennessee.

Labels

Warning labels shall be affixed to containers of regulated waste, refrigerators, and freezers containing blood or other potentially infectious material and other containers used to store, transport or ship blood or other potentially infectious materials, with the following exceptions:

- Red bags or red containers may be substituted for labels
- 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 other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal
- Regulated waste that has been decontaminated need not be labeled or color-coded.

Labels required by this section shall include the following legend:

- These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.
- Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
- Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

Signs

Signs shall be posted at the entrance to Laboratories covered by this policy (BSL2 and above), which shall bear the same appearance as specified for Labels, with the addition of the following information:

- Name of the Infectious Agent
- Special requirements for entering the area
- Name and telephone number of the laboratory director or other responsible person

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

All investigators must post the Biohazard Signs. These signs will be supplied by the EHS Office.

3.0 TRAINING

Each employee with occupational exposure shall receive training at the time of initial assignment (usually through Health streams online training) to tasks where occupational exposure may take lace and at least annually thereafter. Employees shall receive additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. Contact the EHS Office to coordinate additional training. The additional training may be limited to addressing the new exposures created.

The training program shall contain at a minimum the following elements:

- An accessible copy of the regulatory text of the OSHA Bloodborne Pathogen standard and an explanation of its contents;
- A general explanation of the epidemiology and symptoms of blood borne diseases;
- An explanation of the modes of transmission of bloodborne pathogens;
- An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;
- An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;
- An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;
- Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;
- An explanation of the basis for selection of personal protective equipment;
- Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;
- An explanation of the 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; Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;
- An explanation of the signs and labels and/or color coding required; and
- An opportunity for interactive questions and answers with the person conducting the training session.

Employees in bloodborne pathogen laboratories shall receive the following initial training in addition to the above training requirements:

- Employees shall demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with blood borne pathogens.
- Employee shall have prior experience in the handling of human pathogens or tissue cultures before working with blood borne pathogens.
- Employees who have no prior experience in handling human pathogens shall not be assigned initial work activities that include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. Employees shall participate in work activities involving infectious agents only after proficiency has been demonstrated.

4.0 HEPATITIS B VACCINATION

The Hepatitis B vaccine has been available since 1982 and is thought to confer lifetime immunity. 20-year immunity has been documented. The hepatitis B vaccination series is available through Employee and Student Health at no cost after initial employee training and within 10 days of initial assignment to all employees identified in the exposure determination section of this plan. Vaccination is encouraged unless:

- documentation exists that the employee has previously received the series;
- antibody testing reveals that the employee is immune; or
- medical evaluation shows that vaccination is contraindicated

Individuals with occupational exposure to bloodborne pathogens should receive a 3-dose series of hepatitis B vaccine at 0-, 1-, and 6-month intervals. The CDC does not recommend a booster.

Vaccine refusal shall be documented by the employee signing the Hepatitis B Vaccine Declination statement on the training and vaccination form. The statement shall be maintained in the employee's medical record, in Employee and Student Health. Refusal of the vaccine is not final and the employee may request vaccination at any future time.

Per CDC recommendations, for individuals with a high risk of exposure (e.g. health care workers with risk of exposure to blood or OPIM, HBV research laboratory workers) the 3-dose vaccination series should be followed by testing for hepatitis B surface antibody (anti-HBs) to document immunity 1—2 months after dose #3. Anti-HBs testing (e.g. 'tittering") is not recommended routinely for previously vaccinated persons who were not tested 1—2 months after their original vaccine series. These individuals should be tested for anti-HBs when they have an exposure to blood or body fluids. If found to be anti-HBs negative, the individual should be treated as if susceptible.

5.0 POST-EXPOSURE EVALUATION AND FOLLOW-UP

Following a report of an exposure incident, a confidential medical evaluation and follow-up shall be immediately conducted by Employee and Student Health Service Director for the

exposed employee. If the exposure occurs after-hours, the evaluation must begin in the Emergency Department. The post-exposure evaluation must include at least 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, unless the employer can establish that identification is infeasible or prohibited by state or local law.

1. The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.
2. men the source individual is already known to be infected with, testing for the source individual's known status need not be repeated.

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 regulations concerning disclosure of the identity and infectious status of the source individual.

- Collection and testing of blood for serological status.

1. The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.
2. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

- Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;
- Counseling; and
- Evaluation of reported illnesses.

5.1 ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

Employee and Student Health ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard. Employee and Student Health will also ensure that the health care professional evaluating an employee after an exposure incident receives the following:

- a description of the employee's job duties relevant to the exposure incident
- route(s) of exposure
- circumstances of exposure
- if possible, results of the source individual's blood test

- relevant employee medical records, including vaccination status

The employee will be provided with a copy of the evaluating health care professional 's written opinion within 15 days after completion of the evaluation.

5.2 PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

The EHS Officer in conjunction with the Medical Director will review the circumstances of all exposure incidents to determine:

- engineering controls in use at the time
- work practices followed
- a description of the device being used (including type and brand)
- protective equipment or clothing that was used at the time of the exposure incident
- (gloves, eye shields, etc.)
- location of the incident (O.R., E.R.,patient room, etc.)
- procedure being performed when the incident occurred
- employee's training

Employee and Student Health will record all percutaneous injuries from contaminated sharps in a Sharps Injury Log.
If revisions to this ECP are necessary the EHS Officer will ensure that appropriate changes are made. (Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)

6.0 RECORDKEEPING

Medical Records.

Employee and Student Health will establish and maintain an accurate record for each employee with occupational exposure, which will include:

- The name and social security number of the employee
- A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination
- A copy of all results of examinations, medical testing, and follow-up procedures
- The employer's copy of the healthcare professional's written opinion, and
- A copy of the information provided to the healthcare professional, which will include a description of the exposed employee's duties as they relate to an exposure incident; the documentation of the route(s) of exposure and circumstances under which exposure occurred; and the results of the source individual's blood testing, if available.

Confidentiality: All employee medical records will be kept confidential; and will not be disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by law. Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days.

The employer shall maintain the medical records for at least the duration of employment plus 30 years.

Training Records.
Training records shall be maintained for 3 years from the date on which the training occurred. Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days.

Training records shall include the following information:

- The dates of the training sessions;
- The contents or a summary of the training sessions;
- The names and qualifications of persons conducting the training; and
- The names and job titles of all persons attending the training sessions.

Sharps injury log

A sharps injury log shall be developed and maintained for the recording of percutaneous injuries from contaminated sharps. The information in the sharp's injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

- The date of the injury
- The type and brand of device involved in the incident,
- The department or work area where the exposure incident occurred, and
- An explanation of how the incident occurred.

This log is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered. If a copy is requested by anyone, it must have any personal identifiers removed from the report

EXHIBITS:

Attachment A: Hepatitis B Vaccine Declination (Mandatory)

Consolidated Clinical Laboratories

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.

- Furthermore, I understand that the hepatitis B immune globulin will protect me from getting the hepatitis B virus (HBV).
- I understand that when a person gets hepatitis B virus, their risk for chronic (lifelong) infection varies according to the age when the person becomes infected.
- I understand that up to 15% of those who become chronically infected with the hepatitis B virus after childhood die prematurely from cirrhosis of the liver or liver cancer; and that most of these people do not show any symptoms until much later in life, when they develop cirrhosis or end liver disease.
- I understand the benefits of being vaccinated to prevent hepatitis B virus. The potential danger of not having myself vaccinated has been explained to me. My decision to refuse the hepatitis B immune globulin was made freely and without force or encouragement by my doctor or nurse practitioner, or Meharry staff.
- I accept all responsibility, legal, and otherwise for all consequences for this decision.

_____ _____

Printed Name Signature

_____

Date