

<b>UT Health Science Center: RS002 - Exposure Control Plan</b>	
<b>Version 1</b>	<b>Publication Date: 06/14/2022</b>

<b>No./Title:</b> RS002 – EXPOSURE CONTROL PLAN	<b>Resp. Office:</b> Research Safety Affairs	<b>Effective Date:</b> 11/1/2020
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<b>Related Policies:</b> <a href="#">RS102 Incident Reporting</a>		

### **PURPOSE/SCOPE/APPLICABILITY**

Purpose: The Exposure Control Plan (ECP) is designed to eliminate or minimize employee exposure to bloodborne pathogens. This ECP has been developed and implemented to meet the requirements of the [U.S. Department of Labor Occupational Safety and Health Administration’s \(OSHA\) Bloodborne Pathogen Standard \(29 CFR 1910.1030\)](#).

This federal standard has been adopted by the State of Tennessee with minor additional provisions. This standard was originally promulgated and continues to address occupational exposure risk to human body fluids that may contain bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). It is common for human-derived materials to be used in a variety of life science-related research applications. This policy applies to students, visitors, staff and faculty performing research with human blood or other potentially infectious materials (OPIM).

Scope and Applicability: This procedure shall apply to students, visitors, staff and faculty involved in research at the University of Tennessee Health Science Center (UTHSC) or on university property. It shall also apply to students, visitors, staff and faculty engaged in off-site, university-sponsored research activities.

### **DEFINITIONS**

**Amniotic fluid:** Fluid from the uterus.

**Blood:** Human blood, human blood components, and products derived from human blood (i.e. serum, plasma, albumin, immune globulins, factors 8 & 9).

**Bloodborne pathogens (BBPs):** Pathogenic microorganisms present in human blood and other body fluids that 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).

**Cerebrospinal fluid:** Fluid from the spine.

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**Contamination:** The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

**Contaminated Sharps:** Any (biologically) contaminated object that can penetrate the skin including, but not limited to: needles, scalpels, broken glass, glass slides, Pasteur pipettes, razor blades, and capillary tubes.

**Decontamination:** 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 causing disease. Thus, the surface or item is rendered safe for handling, use or disposal.

**Employee:** An individual who receives monetary compensation from the employer for performing work.

**Engineering controls:** Equipment that is designed to isolate or remove the bloodborne pathogen hazard from the workplace (i.e. sharps disposal containers, self-sheathing needles, blunt needles, plastic capillary tubes, biosafety cabinets, and autoclaves).

**Exposure incident:** A specific eye, mouth, other mucous membrane, non-intact skin (includes skin with dermatitis, hangnails, cuts, abrasions, chafing, acne, etc.), or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

**HBV:** Hepatitis B virus; causes inflammation of the liver and may lead to long-term liver damage including cirrhosis and cancer.

**HCV:** Hepatitis C virus; causes inflammation of the liver and can lead to long-term liver damage including cirrhosis and cancer.

**HIV:** Human immunodeficiency virus; attacks critical cells of the immune system, which leads to acquired immunodeficiency syndrome (AIDS), a life-threatening condition.

**Needleless systems:** A device that does not use needles for (1) collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or fluids; or (3) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

**Occupational exposure:** Reasonably anticipated (includes the potential for contact as well as actual contact with blood or OPIM) skin, eye, mucous membrane, non-intact skin, or parenteral

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contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

**Other potentially infectious materials (OPIM):** Materials in addition to human blood that may be capable of transmitting bloodborne pathogens. These include:

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental settings, all body fluids that is visibly contaminated with blood or body fluids in situations where it is difficult or impossible to differentiate between body fluids.
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
- HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture media or other solutions.
- Human cell/tissue/organ cultures not shown to be free of bloodborne pathogens.
- Blood, organs, or other tissues from experimental animals infected with human bloodborne pathogens.

**Parenteral exposure:** Exposure occurring due to piercing of the mucous membranes or skin barrier via a needle stick, human bite, cut or abrasion, or other mechanical means.

**Pericardial fluid:** Fluid surrounding the heart.

**Peritoneal fluid:** Fluid from the abdominal cavity that surrounds the major organs.

**Personal protective equipment (PPE):** 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 to be personal protective equipment.

**Pleural fluid:** Fluid from lung tissue.

**Post-exposure follow-up:** In the case of an exposure incident, the mandatory course of action taken by the employer to provide medical services (i.e. medical assessment, vaccination, source testing, baseline testing, and counseling) to the exposed worker in order to reduce the risk of infection.

**Regulated waste:** Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials as a liquid or semi-liquid 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;

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pathological and microbiological wastes containing blood or other potentially infectious materials.

**Sharps with engineered sharps injury protection (SESIP):** Non-needle sharp or needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

**Source individual:** Any individual, living or dead, whose blood or other potentially infectious materials is a source of occupational exposure to the employee.

**Sterilization:** The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

**Synovial fluid:** Fluid from the joints such as the knees or elbows.

**Universal Precautions:** An approach to infection control. According to the concept of Universal Precautions, all blood and certain human body fluids are treated as if known to be infectious for HBV, HCV, HIV, and other bloodborne pathogens.

**Work practice controls:** Controls that reduce the likelihood of exposure by altering the way a task is performed.

## EXPOSURE DETERMINATION

The OSHA Bloodborne Pathogens (BBP) Standard states that all employees who have duties potentially exposing them to blood or other potentially infectious material are determined to have a reasonably anticipated risk of exposure to BBPs and are acknowledged in the Exposure Control Plan. The UTHSC Offices of Research Safety and University Health Services will annually review and determine which job classifications include potential exposure to BBPs. Specific tasks that present a risk of exposure to BBPs will be considered as part of this determination. The exposure determination will be made without regard to the use of personal protective equipment.

Job classifications with a potential for BBPs exposure are listed in the left-hand column in the table below. Specific tasks that bear a BBPs exposure risk are listed in the right-hand column. An employee whose job classification is listed below, and who performs tasks listed in the corresponding right hand column are considered to have occupational exposure for BBPs and must be included in this BBPs Exposure Control Program.

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Job Classification	BBP exposure-risk tasks
Clinical Researcher (Assistant, Technician, Nurse, etc.)	Collection of human blood or other human materials.
Principal Investigator/Research Associate (or equivalent)	Manipulation of human-derived materials including cells, and items contaminated with such materials.
Research Assistant/Research Technician (or equivalent)	Manipulation of human-derived materials including cells, and items contaminated with such materials.
Lab Aide	Handling lab-wares and wastes that are contaminated with human-derived materials.
Animal caretaker	Care of animals that have been challenged with a BBPs; care of animals that have been implanted with human-derived materials where there is a possibility of leakage or seepage of these materials from the implant site.
Safety/Biosafety Officer	Spill response involving human blood or OPIM.
Maintenance Worker	Maintenance/repair of lab-associated plumbing (as determined by lab risk assessment).
Any job classification required to administer first aid	Potential exposure to blood or OPIM while performing first aid as part of job duties.

Information regarding job classifications covered by the provisions of the Exposure Control Plan will be updated annually based on information received from affected departments.

**Note:** If a supervisor has an employee who has a reasonably anticipated risk of bloodborne pathogen exposure, but the employee’s job classification is not listed above, the supervisor should notify the Office of Research Safety at 448-6114

- **Exposure Control for First Aid & Blood Spill Responders**  
While this Exposure Control Plan includes all the basic principles to be followed for exposure control, it does not specifically address the unique considerations that apply to first aid and blood spill response activities. For job classifications where these activities are a required part of the job, these personnel are considered to have occupational exposure risk for bloodborne pathogens and as such, they must receive training and the hepatitis B vaccination offer.

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- Exposure Risk to Other Human Body Fluids (including wastewater)  
Most human waste products such as urine and feces may present an infectious disease transmission risk. Therefore, infection control-related training and adoption of hygiene-related practices are warranted for personnel whose work or research activities involve exposure or contact with these materials.

## **GENERAL PROGRAM MANAGEMENT**

The 3 primary areas of responsibility for the Exposure Control Plan (ECP) are Exposure Control Officer, supervisory personnel (including Principal Investigators, Managers, and Supervisors) and employees

### Exposure Control Officer

The UTHSC Biosafety Officer will serve as the primary Exposure Control Officer for all work environments covered by the scope of this plan. The Exposure Control Officer is responsible for management and support of the Bloodborne Pathogens Compliance Program. The University Health Services Manager will assist the Exposure Control Officer when appropriate in the execution of the following exposure control activities:

- Overseeing implementation of the Exposure Control Plan;
- Developing, in cooperation with administrators, any additional bloodborne pathogens related policies and practices needed to support the effective implementation of this plan;
- Revising, updating and improving the Exposure Control Plan at least on an annual basis and at other times when necessary;
- Assisting supervisors and employees in the development and implementation of procedures intended to reduce BBP exposure risk associated with site-specific tasks;
- Developing and/or identifying training resources, and providing training to the appropriate extent. (See “Information and Training” section.)
- Understanding current legal requirements concerning bloodborne pathogens;
- Conducting periodic audits and inspections of environments where occupational exposure risk is present to verify regulatory compliance.

### Supervisory Personnel (including Principal Investigators, Managers and Supervisors)

Supervisory personnel are responsible for compliance in their areas. They shall work with the

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Exposure Control Officers and their employees to ensure that:

- All employees under their supervision who are at risk of exposure to bloodborne pathogens receive initial training (including site-specific training which must be completed in conjunction with an experienced person in the employee’s work environment). This training must be completed before the supervisor permits the employee to engage in work procedures with a BBP exposure risk.
- All employees under their supervision who are at risk of exposure to BBPs complete annual retraining in BBP as outlined in the “Training” section of this document;
- All volunteer personnel in their area who are at risk of exposure to BBP receive training and follow safe work practices commensurate with that of employees performing the same duties.
- Proper exposure control procedures are followed as outlined in the “Methods of Compliance” section of this document;
- Appropriate personal protective equipment/s in good working condition are made available for all employees at risk of exposure to BBPs; this includes alternatives if an employee is allergic to the gloves normally provided.
- Any employee who experiences an occupational exposure incident to blood or other potentially infectious materials is provided with post-exposure medical services as outlined in the “Post-Exposure Evaluation and Follow-Up” section of this document.
- Program-related documentation (i.e., training records, written procedures, sharps evaluation forms, equipment maintenance records) is available at the work site and is current with regulatory requirements.
- Bloodborne pathogens exposures that occur during the performance of work on an IBC, IRB or IACUC protocol may require additional reporting as detailed in the [Office of Research Safety Incident Reporting Policy – RS102](#).

#### Employees

Employees who have occupational exposure risk for BBPs are responsible for following procedures and practices as outlined in the Exposure Control Plan. This includes but is not limited to:

- Completing bloodborne pathogens initial training and annual retraining sessions;
- Understanding which tasks have potential occupational exposure to bloodborne pathogens;
- Conducting all operations in accordance with established work practice controls,

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including use of Universal Precautions;

- Developing and maintaining good personal hygiene habits;
- Reporting all occupational exposure incidents.

#### Availability of the Exposure Control Plan to Employees

All supervisors with personnel who have occupational exposure for BBPs should maintain a copy of the Exposure Control Plan or ensure that staff members are able to access it online via internet. This Exposure Control Plan can be accessed by employees and the general public at the Office of Research Safety Policies website.

#### Review and Update of the Plan

This Exposure Control Plan will be reviewed and updated at least annually by the Institutional Biosafety Officer with input from supervisors of personnel who have occupational exposure risk for BBPs.

### **METHODS OF COMPLIANCE**

Principal Investigators and Supervisors are responsible for ensuring compliance with this Exposure Control Plan. The plan addresses the following areas:

- Principles of Universal Precautions;
- Engineering controls;
- Work practice controls;
- Personal protective equipment;
- Housekeeping procedures;
- Post-exposure incident response.

Each area will be reviewed with employees during initial and refresher BBPs training (see “Training” section of this document), and employees will receive site-specific training related to BBP exposure control. Office of Research Safety, other identified trainers and internet-based resources will be used to provide initial and refresher training. Site-specific training will be performed by the employee’s supervisor or designated trainer and can be documented using a checklist form. A copy of this form should be kept on file by the PI/supervisor for regulatory review, if required.



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### Universal Precautions

All human blood\* and other potentially infectious materials (OPIMs) must be treated as if known to be infectious for HBV, HCV, HIV and other bloodborne pathogens which include OPIMs :

- Body fluids containing visible blood
- Semen and vaginal secretions
- Cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids
- Human cell, tissue, or organ cultures not shown to be free of bloodborne pathogens (See Appendix E).

Universal precautions currently do not apply to feces, nasal secretions, sputum (spit), sweat, tears, urine, vomit, or saliva unless they are visibly contaminated with blood. In circumstances where it is difficult or impossible to differentiate between body fluid types, all fluids are assumed to be potentially infectious except sweat.

The bloodborne pathogen standard allows for hospitals to use acceptable alternatives (OSHA Directive CPL 02-02-069, 2001, November 27) to universal Precautions:

Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These methods define **all** body fluids and substances as infectious. These methods incorporate not only the fluids and materials covered by the Blood borne Pathogens Standard but expands coverage to include all body fluids and substances.

The CDC recommends **Standard Precautions** for the care of all patients, regardless of their diagnosis or presumed infection status.

**Standard Precautions** apply to 1) blood 2) all body fluids, secretions, and excretions except sweat, regardless of whether or not they contain visible blood 3) non-intact skin and 4) mucous membranes. Standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals.

\*Note: "Blood" includes human blood products such as serum, plasma, albumin, etc.

### Engineering Controls

Equipment such as hand washing facilities, eye wash stations, sharps disposal containers, biological safety cabinets, autoclaves, and safer sharps devices are to be used when appropriate. Examples of safer sharps devices include needleless systems and sharps with engineered sharps

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injury protection (SESIPs) (e.g. self-sheathing needles on syringes).

Personnel from the Office of Research Safety, in conjunction with appropriate supervisors, will review tasks and procedures performed to determine where engineering controls can be implemented or updated.

Engineering controls to be used for work with potentially infectious materials include:

- Hand washing facilities must be accessible to all employees who have a potential for exposure. Waterless antiseptic hand cleansers or antiseptic towelettes must be available to employees at risk of exposure if running water is not readily available. If waterless cleansers or towelettes must be used, the employee must follow up with a soap and water wash as soon as feasible.
- Emergency eye wash stations must be in close proximity to workstations or work areas where employees perform tasks that may produce splashes of potentially infectious materials. Eye wash stations must be kept clear of items that hinder accessibility or proper function and must be flushed regularly (weekly).
- Autoclaves must be used to decontaminate solid biohazardous waste, unless waste is managed through a medical waste contractor.
- Biosafety Cabinets (BSC) must be used for manipulations of blood or OPIM (including human cells) that will generate aerosols. BSCs are designed to provide personal, environmental and product protection when appropriate practices and procedures are followed. BSCs use high efficiency particulate air (HEPA) filters in their exhaust and/or supply systems. Biological safety cabinets must not be confused with other laminar flow devices or “clean benches”; in particular, horizontal flow cabinets, which direct air towards the operator should never be used for handling potentially infectious, toxic or sensitizing materials. BSCs used for manipulation of human-derived materials or infectious agents must be certified (i.e., leak tested and inspected using criteria of National Sanitation Foundation 49 Standard) when initially installed, moved, or at least annually.
- Safe Sharps Devices (or sharps with engineered sharps injury protections) should be used for any lab manipulations involving human blood or blood products and human cell or tissue cultures whenever feasible. Whenever a sharp device will be used for procedures on a living human (i.e. phlebotomy, vaccine administration), an engineered safer sharps device **MUST** be used. Safe sharps devices include, but are not limited to:
  - self-sheathing needles/syringes;
  - hypodermic syringes with retractable technology safety features;
  - phlebotomy needles with self-blunting safety features;

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- retracting lancets with safety features; or
  - disposable scalpels with shields and other safety features.
- Biohazardous sharps containers must be used to properly store and dispose contaminated sharps. Disposable biohazard sharps container must isolate the cut or puncture hazard associated with handling sharp items such as needles, scalpels, or Pasteur pipettes. Therefore, containers used for collection and disposal of contaminated sharps must be designed and manufactured for that specific purpose and used in accordance with the manufacturer's instructions. Disposable biohazard sharps containers must be:
    - Puncture-resistant;
    - Red in color or labeled with a biohazard warning label;
    - Leak-proof on the sides and bottom;
    - Closable.

Containers for reusable contaminated sharps must meet the same requirements as containers for disposable sharps; however, they are not required to be closable, and do not have to be manufactured specifically for that purpose. Reusable sharps must not be stored or processed in a manner that requires reaching into containers of contaminated sharps.

Food containers, such as coffee cans/jars, are not acceptable containers for sharps collection or disposal.

Contact the Office of Research Safety at (901) 448-6114 for assistance in identifying sources for sharps containers if needed.

- Storage and/or transport containers must be used to reduce the potential for an environmental release of potentially infectious materials. Primary containers should be designed to be leak-proof, puncture-resistant and capable of being closed. Single primary containers used for potentially infectious materials should be labeled with the biohazard symbol. If multiple primary containers are stored in a secondary container (such as a rack of specimen tubes contained in a cooler for transport), only the secondary container must be labeled with the biohazard symbol. Secondary containers are used for additional protection against an environmental release and therefore must be leak-proof, puncture-resistant and capable of being closed. Use of secondary container is required for transportation and/or long-term storage of any potentially infectious material.

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### Sharps Injury Protection Program

Statistics compiled by the National Institute of Occupational Safety and Health indicate that sharps handling practices after the point of use and through the process of disposal are largely responsible for needlestick injuries sustained in the U.S. healthcare environment. Because of this and other supporting factors, OSHA revised the BBP Standard to include elements of the “Needlestick Safety and Prevention Act.”

Under this Act, all sharp devices used in procedures in healthcare settings where device contamination with blood or OPIM is anticipated must be safe sharp devices as described in the previous section. Selection and use of safer sharps must be documented initially and annually\*\*. If no safe sharp option exists for the device in question, this must be documented as well. Finally, a sharps injury log must be maintained.

\*\* The review and update of the plan is required to "(A) reflect changes in technology that eliminate or reduce exposure to BBPs; and (B) document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Thus, the additional provisions require that employers, in their written Exposure Control Plans, account for innovations in procedure and technological developments that reduce the risk of exposure incidents. This would include, but would not be limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to BBPs. Consideration and implementation of safer medical devices could be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption; the method or methods used to evaluate devices and the results of evaluations; and justification for selection decisions. This information must be updated at least annually.

### **WORK PRACTICES**

Supervisors are responsible for ensuring that all personnel with occupational exposure risk complete training regarding applicable work practices to reduce exposure risk, and for assuring that these work practices are adopted and followed on the job.

The following work practice controls are to be implemented.

1. Hand washing\* must be performed:
  - After removal of gloves or other personal protective equipment;
  - When visible contamination with blood, body fluids, or other potentially infectious materials is present;

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- When work is completed and before leaving the laboratory;
- Before eating, drinking, smoking, applying makeup, changing contact lenses, or using the bathroom.

\*Note: Soap and water are the most effective means for hand washing. If a waterless hand cleanser or antiseptic towelettes are used due to lack of available running water, the employee must follow up with soap and water as soon as feasible.

2. Contaminated needles and other contaminated sharps must not be bent, recapped or removed unless it can be demonstrated that there is no feasible alternative. In this event, such bending, recapping or needle removal must be accomplished through the use of a mechanical device or one-handed technique.
3. Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers must be:
  - Puncture-resistant
  - Labeled with the biohazard symbol or color-coded in red
  - Leak-proof on the sides and bottom
  - Designed and used in such a manner that does NOT require employees to reach by hand into the containers.
4. Disposable contaminated sharps must be placed in appropriate containers (as described under "Engineering Controls") immediately, or as soon as possible, after use. These containers must be:
  - Closable
  - Puncture-resistant
  - Leak-proof on the sides and bottom
  - Labeled with the biohazard symbol or color-coded in red.

During use, containers must be:

- Located as close as feasible to the immediate area where sharps are used, or otherwise can be reasonably found;
- Maintained upright throughout use;
- Replaced routinely and not overfilled. (Containers must be permanently closed and replaced when  $\frac{3}{4}$  full.)

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Proper use of sharps container lids is required. These practices include:

- Lids must be properly installed before a disposable biohazardous sharps container is put into use.
  - When not in use, or when moving a container from one location to another, sharps container lids must be closed to further eliminate the potential for exposure.
  - Container lids must be permanently closed before handling containers for disposal.
- Contact the Biosafety Office for assistance in identifying appropriate sharps containers for your needs.

5. Eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, and food/drink storage is prohibited in all laboratory areas.
6. Mouth pipetting/suctioning of blood or other infectious materials is prohibited at all times.
7. Minimize splashing, spraying or other actions generating droplets of blood or other potentially infectious materials during all procedures. At a minimum, Biosafety Level 2 containment practices are required for laboratories working with specimens of blood or body fluids (See Appendix H). Contact the Biosafety Office for further information and assistance regarding these requirements.
8. Specimens of blood or other potentially infectious materials must be placed in designated leak-proof containers, appropriately labeled for handling and storage.
9. Primary containers of potentially infectious materials must be placed in puncture-resistant, leak-proof, closable secondary containers for transportation outside of the work area (i.e. from lab to lab where a common hallway is used, etc.).

### **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Personal protective equipment is available at no cost to all employees with an occupational exposure to blood or other potentially infectious materials. PPE items include gloves, gowns, laboratory coats, face shield/masks, safety glasses, goggles, mouthpieces, resuscitation bags, pocket masks, hoods, and shoe covers. Assignment of PPE for a given task must be based on the potential for exposure risk and the nature of that exposure. The Office of Research Safety should be consulted for assistance with PPE selection.

Principal Investigators (PI) or supervisors must ensure that PPE of appropriate type and size is

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available and easily accessible to employees. Employees must be trained regarding the use of appropriate PPE for their job classification and the tasks/procedures they perform.

*Remember: Students or volunteers who are performing tasks that put them at risk for BBP exposure should be provided with the same level of training, PPE, and supervision as employees.*

PPE is considered to be appropriate for protection against BBP occupational exposure only if it does not permit blood or other potentially infectious material to pass through or reach the employee's clothing, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used.

PIs and supervisors shall ensure that employees use appropriate PPE. If an employee declines to use PPE, the PI/supervisor must show that it was the employee's professional judgment that the use of PPE would have posed an increased hazard to the safety of himself/herself or a coworker. When the employee makes this judgment, the circumstances shall be investigated and documented to determine if changes can be made to prevent future occurrences.

The following practices must be utilized to ensure that PPE is not contaminated and is in appropriate condition to protect employees from potential exposure:

1. All PPE must be inspected periodically by the PI/supervisor and repaired or replaced as needed.
2. Reusable PPE (lab coats, safety glasses, face shields, etc.) must be cleaned or laundered and decontaminated as needed. Lab coats (and any personal clothing that becomes contaminated with blood or OPIM) must not be sent home with employees for laundering. For assistance with identifying on-site laundry or commercial laundry services, contact your departmental office or campus safety officer.
3. Single-use PPE that is contaminated with blood or OPIM to the extent where the material can drip or flake off of the item will be disposed of as biohazardous waste.
4. When using PPE, employees must:
  - Inspect PPE prior to use to verify that it is in good condition.
  - Remove all PPE before leaving the work area.
  - Wear gloves when:
    - Hand contact with potentially infectious materials is anticipated;
    - Handling or touching contaminated items or surfaces;
    - Working with or performing any procedures with lab animals.
5. Replace disposable gloves as soon as possible after contamination or immediately when

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torn, punctured or otherwise rendered unable to function as an exposure barrier.

6. Report any adverse reactions to glove material, or any known latex allergy to your supervisor so that appropriate alternative protective devices can be provided.
7. Decontaminate reusable gloves (i.e., heavy gauge nitrile or vinyl) before reuse; if utility gloves are cracked, peeling, torn or exhibit other signs of deterioration, they must be discarded.
8. Wear eye protection and masks whenever there is a chance that a splash or spray may generate droplets of infectious materials.
9. Wear protective clothing (e.g. lab coat) whenever splashes or aerosols of human blood or OPIM are anticipated.
10. Wear fluid-resistant body covering (i.e. coated Tyvek coveralls) and shoe covers/boots in any instance where gross contamination is anticipated.
11. Remove and replace compromised or moderately contaminated PPE as soon as feasible.
12. Wash hands after removal of PPE.

## HOUSEKEEPING

Employees working with potentially infectious materials must:

- Clean and decontaminate all equipment and surfaces after contact with blood or other potentially infectious materials. Visible contamination must be removed before applying disinfectants\* to surfaces to ensure product efficacy. Clean and disinfect:
  - Immediately (or as soon as feasible) when surfaces become contaminated;
  - After any spill of blood or potentially infectious materials;
  - At the end of the work shift, especially if the surface may have become contaminated during that shift.

**\*In accordance with the OSHA BBP Standard, disinfectants must be EPA-registered and capable of inactivating HIV and HBV. Freshly-made 1:10 (Vol:Vol) bleach solution is also acceptable.**

- Examine contaminated equipment prior to servicing or shipping. If it can be demonstrated that decontamination is not possible, then the following steps need to be taken:
  - Attach a biohazard warning label to any contaminated equipment, identifying the contaminated portions;



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- Inform affected employees, equipment manufacturer and the equipment service representative of remaining contamination prior to handling, servicing or shipping;
- If equipment must be shipped, contact the Biosafety Office before shipping.
- Routinely inspect and clean all pails, bins, cans and other receptacles. These items must be properly decontaminated whenever visibly contaminated.
- Pick up potentially contaminated broken glassware using mechanical means (such as tongs, forceps, or a dustpan and brush) and dispose of in a proper sharps container. Do not handle broken contaminated glass with your hands!
- Immediately clean up spills of blood, body fluids, or any other potentially infectious materials.
- When disposing of contaminated biological waste:
  - Discard in a biohazard bag placed inside a secondary biohazard waste container;
  - Locate containers for regulated waste so that they are readily accessible to employees and as close as possible to the source of the waste;
  - Maintain waste containers in an upright position and do not overfill;
  - Close containers when not actively in use and at the end of the day;
  - Autoclave waste in accordance with autoclave procedures established for effective waste decontamination and disposal; alternatively,
  - Contain and store waste in accordance with procedures outlined by the medical waste contractor when applicable.

## **BIOHAZARDOUS WASTE**

The information in this section addresses waste disposal as it pertains to items contaminated with human blood or OPIM. For information regarding disposal of wastes contaminated with other biohazards such as infectious agents and recombinant DNA materials, contact the Office of Research Safety at (901) 448-6114. There are categories of waste materials that may be a BBP exposure hazard and must therefore be appropriately segregated, labeled, decontaminated and disposed of in a manner that is different from unregulated wastes. Biohazardous waste in any form should not be left untreated and unsecured in areas that are accessible to the public (i.e., left in hallways). Treated biohazardous waste should be removed from the lab area and transported to waste holding areas for final disposal only by lab personnel.

- Solid biohazardous waste (non-sharps)  
In all work environments, this category includes any non-sharp item that is contaminated

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with blood or OPIM to the extent where the material can drip or flake off of the item. In the research lab environment, this also includes non-sharps wastes that are generated through the lab process that are contaminated with biologically-active/potentially infectious materials.

- Storage

This type of waste must be stored in biohazard bags that are autoclavable and bear a biohazard symbol and are red or orange in color. Autoclave bags should have a built-in or applied heat indicator that allows for verification of autoclave treatment. The bag shall be secured in a leak proof secondary container with a lid so as to prevent leakage in the event that the bag is punctured. The lid must be placed on the container when procedures are not underway. The secondary container must be marked with the biohazard symbol.

- Treatment and disposal

- On-site Treatment

Biohazard waste bags must be closed for transfer to the autoclave room. Bags must be placed in a secondary container (i.e., tray with raised sides), which is placed on a cart for movement to the autoclave facilities.

Autoclave treatment of this waste must be performed in accordance with the biohazardous waste treatment parameters posted at the autoclave. Contact the Office of Research Safety for assistance in establishing these parameters if not posted. Note: Only personnel who have received training regarding the operation of the autoclave should use this device.

Treated bags of waste must be tied shut and deposited to designated lined garbage bins for removal as treated special waste in accordance with Tennessee Department of Environment and Conservation (TDEC) regulations.

- Medical Waste Contractor

Refer to your department's contract with the medical waste contractor for specific requirements.

- Field Generation

Waste should be collected and stored as previously outlined. Contact the Office of Research Safety for assistance with identifying disposal options.

- Liquid biohazardous waste

For BBP purposes, this includes all blood, blood products and body fluids and cell-

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contaminated culture media. Note: Primary containers containing small quantities of liquids (less than 30 ml) should be managed as solid biohazardous waste.

- Storage

These liquids must be stored in closed, leak proof containers while awaiting treatment and disposal. Storage containers must be labeled with the biohazard label if the liquids will not be treated and disposed of within the shift.

- Treatment and disposal

Liquid wastes may be treated and disposed of by either one or the other of the following methods:

- Option 1: Add bleach to the collection vessel so that the bleach makes 10% of the final volume. Allow a contact time of at least 30 minutes. Carefully discharge the mixture to the sanitary sewer by way of the lab sink, and thoroughly rinse down the drain with water. Remember to wear splash goggles, gloves, and a lab coat for handling of bleach and bleach-treated liquids.
- Option 2: Place the closed collection vessel in a secondary container and transport by cart to the autoclave facilities. Treat by autoclave using the liquids cycle. (Remember to loosen or remove the closure on the vessel before placing in autoclave.) Discharge cooled, treated liquids to the sanitary sewer by way of the lab sink. Note: Only personnel who have received training regarding the operation of the autoclave should use this device.

- Biohazardous Sharps

A biohazardous sharp (for BBP purposes) is any device that is sharp enough to puncture the skin and that is contaminated with any biologically active specimen material or biological culture material.

*Examples include:*

- Hypodermic needles contaminated with human blood or OPIM
- Pasteur pipettes contaminated with blood or cell material
- Microscope slides contaminated with human body fluids or tissues that are not fixed
- Broken tubes of blood or OPIM
- Capillary tubes containing blood or OPIM.

- Treatment and disposal

Sharps must be placed in approved, properly assembled (i.e., lids installed) sharps containers. The sharps container should be appropriate in size and dimension to

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permit easy disposal of the item. All sharps containers must be permanently closed and disposed of when  $\frac{3}{4}$  full. Remember to follow all sharps safety practices outlined in the “Work Practices” section when handling biohazardous sharps containers for disposal. Additionally, if there is any potential for leakage from the container, place it in a closable, leak-proof secondary container. The secondary container must be labeled with the biohazard symbol.

Disposal of biohazardous sharps containers will be accomplished through a medical waste contractor. Do not dispose of biohazardous sharps containers in the trash, regardless of treatment status. Sharps containers may be sealed shut, placed into a red bag, and packaged in a shipping container provided by Stericycle or another regulated medical waste vendor. Call the Office of Research Safety at (901) 448-6114 for assistance with biohazardous sharps disposal.

- **Medical Waste Contractor**  
Refer to your department’s contract with the medical waste contractor for specific requirements.
- **Field Generation**  
Waste should be collected and stored as previously outlined. Contact the UTHSC Office of Research Safety for assistance with identifying disposal options.
- **Pathological waste**  
This includes all unfixed human organs, tissues and body parts except for teeth. It also includes unfixed animal tissues and carcasses that have been exposed to human-derived materials or bloodborne pathogens (i.e. HIV, HBV, and HCV).
  - **Treatment and disposal**  
This type of waste must be double-bagged in biohazard bags that bear a biohazard symbol. Bags must be stored in a manner that will minimize the potential for release of fluids during the storage and handling process. Storage of bags in a tray with sides, or secondary storage of bags in a sturdy plastic zipper bag is strongly recommended. Remember that these items must be labeled with the biohazard symbol. These items must be handled by a regulated medical waste vendor and disposed of by incinerated unless other provisions apply (contact the Office or Research Safety for assistance).

## **HIV AND HBV RESEARCH LABORATORIES AND PRODUCTION FACILITIES**

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The UTHSC do not have HIV or HBV research laboratories or production facilities that are engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV as defined by this standard at this time. The ECP will be modified to meet these requirements if the research status changes.

### **HEPATITIS B VACCINATION, POST-EXPOSURE EVALUATION AND FOLLOW-UP**

A Hepatitis B Vaccination Program and procedure for post-exposure evaluation and follow-up has been established jointly through the University Health Services Nurse, the University’s Student Health Services, and Employee Health Services at the UTHSC.

#### **VACCINATION PROGRAM**

The University of Tennessee has implemented a vaccination program through UTHSC University Health Services. This program is offered at no cost to all employees who have occupational exposure to bloodborne pathogens. The vaccination program consists of a series of three inoculations over a six-month period and a post-vaccine titer. At the time of the bloodborne pathogens training or University Health Services Program enrollment (if the employee will be working with animals or their products), employees will receive information regarding the vaccination program.

All non-GSM employees covered under this program must contact the UTHSC University Health Services Nurse for additional program details about verifying Hepatitis B vaccination status.

All GSM employees covered under the plan will receive the vaccination offer/declination through Employee Health at the UTHSC Medical Center.

#### **POST-EXPOSURE EVALUATION AND FOLLOW-UP**

If an employee sustains an exposure to biological materials that are considered to be a BBPs risk, the employee should seek medical consultation and treatment immediately. In these instances, actions should include the following:

1. If contact with blood or other potentially infectious material occurs on skin with cuts, rashes, acne or dermatitis, wash the area for 15 minutes with soap and water.
2. If blood or other potentially infectious material splashes in the eyes or on mucous membranes, flush the area for 15 minutes with water or normal saline.

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3. If there is a cut or puncture with a contaminated object (broken glass, needle, etc.), wash the area for 15 minutes with soap and water.
4. Report the incident to a supervisor if available.
5. Initiate medical follow-up immediately.
6. The supervisor and/or the employee must contact the CorVel 24-hour nurse line at 1-866-245-8588 to report the incident. CorVel will direct the employee to the closest appropriate care facility for immediate care and follow-up. The facility will follow current Centers for Disease Control and Prevention guidelines for a potential bloodborne pathogens exposure incident.
7. The Office of Research Safety Affairs is automatically notified of employee injuries once a claim is submitted to CorVel. The Office of Research Safety will respond by investigating the incident and collecting the data that needs to be recorded for needlestick incidents, such as the date, time location, type of device involved, etc.

### **MEDICAL RECORDKEEPING**

The University Health Services Nurse and the Employee Health department have established and maintain confidential employee medical records. Information will not be disclosed without the employee's written consent, except as required or permitted by law. These records will be maintained for at least the duration of the employee's employment plus 30 years.

### **OSHA RECORDKEEPING**

An exposure incident is evaluated to determine if the case meets OSHA's recordkeeping requirement (29CFR 1904). This determination and the recording activities are done by the University of Tennessee Office of Risk Management.

- **Sharp Injury Log**  
UTHSC shall maintain a Sharps Injury Log. At a minimum this log will record (A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred."  
  
Information in the sharps injury log will be recorded and maintained in a manner that protects the privacy of the injured employee. If any data from the log is made available to other parties, any information that directly identifies an employee (e.g., name, address, social security number, payroll number) or information that could reasonably be used to identify indirectly a specific employee (e.g., exact age, date of initial employment) will be withheld.

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## LABELS AND SIGNS

Biohazard labels consist of a red or fluorescent orange colored background with the traditional biohazard symbol in a contrasting color. The Office of Research Safety will keep a supply of labels meeting these criteria and these will be available upon request.

The following items must be labeled:

- Entrances to all laboratory areas where blood, cell cultures, or other potentially infectious materials are used;
- Containers of regulated waste;
- Refrigerators, freezers, incubators, or other equipment containing blood, cell cultures, or other potentially infectious materials;
- Sharps disposal containers;
- Containers used to storage, transport or ship blood and other potentially infectious materials. When a primary container holds a number of smaller items containing the same potentially infectious substance, only the primary container needs to be labeled. All employees handling these containers must be informed of their contents and the need to use Universal Precautions when handling such items. Items that are transported or shipped need to comply with local and federal transportation regulations. Contact the Biosafety Office prior to shipping any potentially infectious materials.
- Laundry bags/containers holding contaminated items. Alternately, laundry may be placed in a biohazard bag. Employees handling laundry must be informed of the potential for contamination and/or infectivity of the biohazard bags.
- Contaminated equipment.

## INFORMATION AND TRAINING

All employees who have occupational exposure to human blood or OPIM are required to complete bloodborne pathogens training **before** engaging in job tasks with an exposure risk.

Employees must complete annual update training to keep their knowledge current. Other training must be conducted as needed to address new tasks or procedures that affect occupational exposure. Remember: Volunteers who are performing tasks that put them at risk for BBP exposure should be provided with the same level of training, PPE, and supervision as employees.

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- **Training Methods**  
The UTHSC Office of Research Safety will provide online training for personnel either in-person or online (**blackboard**). All sessions conducted by the UTHSC health & safety professionals will be tailored for the audience's learning needs and will offer an opportunity for employees to ask questions. However, it must be noted that the OSHA-required training elements include site-specific components. These cannot be captured in a general training session without the inclusion of task-specific training to be provided by an individual experienced in the specific tasks expected to be carried out by the work group. Therefore, UTHSC health & safety trainers will provide each attendee with a training record/checklist that must be completed and maintained by the supervisor as documentation of completed training.
  
- **Initial Training Topics**  
Per the minimum requirements of the OSHA BBP Standard, bloodborne pathogens training for new employees who will have occupational exposure to human blood or OPIM will include the following mandatory topics:
  - OSHA's Bloodborne Pathogens Standard and its availability;
  - Epidemiology, symptoms and modes of transmission of bloodborne diseases including HIV, HBV and HCV; existence of other bloodborne diseases;
  - UTHSC's Exposure Control Plan and its availability;
  - Methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;
  - Review of use and limitations of methods that will prevent or reduce exposure, including:
    - Engineering controls
    - Work practice controls
    - Personal protective equipment (PPE);
  - Proper selection, use and disposal of PPE;
  - Visual warning of biohazards including labels, signs and color-coded containers;
  - Information on the Hepatitis B vaccine, including its availability, efficacy, safety, benefits, administration, and HBV Vaccination Program;
  - Emergency actions for incidents involving blood or other potentially infectious materials;



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- Incident reporting and post-exposure follow-up procedures;
- Post-exposure evaluation and follow-up including medical consultation.

If a supervisor chooses to perform their own training, he or she must ensure that all of these topics, as well as site-specific training information are included. This training must be conducted in a manner that includes an interactive question and answer component. The supervisor must document the training event as outlined under the “Training Documentation” section.

### **UPDATE TRAINING**

Supervisors must provide a brief update training anytime that a new task or procedure is adopted that affects occupational exposure risk. This training should be documented as outlined in the next section. At a minimum, annual update training must be completed, regardless of any procedural changes. This training may be provided by supervisors in conjunction with the UTHSC Office of Research Safety personnel and will focus on compliance weaknesses and new information relative to exposure control.

### **TRAINING DOCUMENTATION**

Whenever BBP training is conducted, the following information must be documented:

- Dates of all training sessions;
- Contents/summary of the training sessions;
- Names and qualifications of the instructors;
- Names and job titles of employees attending the training sessions.

Although the UTHSC safety professionals will maintain records of the training sessions that they provide, this does not constitute a complete training record. Therefore, supervisors must maintain records for their personnel in their workplace. These records must be available for inspection upon request. Training records must be maintained for at least 3 years from the date of the event.