

# Bloodborne Pathogens Exposure Control Plan



**Revision:**  
November 2017

*An administrative manual for personnel working in UT research settings at the Knoxville area campuses (including the Graduate School of Medicine) to outline required procedures for reducing bloodborne pathogens occupational exposure risk.*

*This manual also applies to all personnel of the UT Institute of Agriculture who are at risk for occupational exposure to bloodborne pathogens based on required job tasks.*

**Regulatory reference: 29 CFR 1910.1030**

<b>Program-Related Contacts:</b>		
<b>Brian Ranger, MS, SM(NRCM), CBSP</b>	Biosafety Officer	(865) 974-1938
<b>Linda Hamilton, MPH</b>	Biosafety Specialist	(865) 974-9836
<b>Dr. Amy Knowles, PhD, RN, MPH, CIC</b>	Occupational Health Nurse	(865) 974-5728
<b>Steve Crouch, CHMM</b>	UTIA Safety Officer	(865) 974-4904

# Table of Contents

	<u>Page</u>
<u>Introduction</u>	4
<u>Definitions</u>	5
<u>Exposure Determination</u>	8
Exposure Control for First Aid & Blood Spill Responders	9
Exposure Control for Forensic Anthropology Personnel	9
Exposure Risk to Other Human Body Fluids (including wastewater)	9
<u>General Program Management</u>	9
Exposure Control Officer	9
Supervisory Personnel	10
Employees	10
Availability of the Exposure Control Plan to Employees	11
Review and Update of the Plan	11
<u>Methods of Compliance</u>	11
Universal Precautions	11
Engineering Controls	12
Sharps Injury Protection Program	13
<u>Work Practices</u>	14
<u>Personal Protective Equipment (PPE)</u>	16
<u>Housekeeping</u>	17
<u>Biohazardous Waste</u>	18
<u>HIV and HBV Research Laboratories and Production Facilities</u>	21
<u>Hepatitis B Vaccination, Post-Exposure Evaluation and Follow-Up</u>	21
Vaccination Program	21
Post-Exposure Evaluation and Follow-up	21
Medical Record Keeping	22
<u>Labels and Signs</u>	22
<u>Information and Training</u>	23
Training Methods	23
Initial Training Topics	23
Update Training	24
Training Documentation	24

## Table of Contents (Continued)

	<u>Page</u>
<a href="#"><u>Appendix A</u></a> : OSHA Interpretation Regarding Applicability of BBP Standard to Human Cells	25
<a href="#"><u>Appendix B</u></a> : First Aid & Human Blood Spill Responders' Exposure Control Guide	26
<a href="#"><u>Appendix C</u></a> : BBP Exposure Control Principles for Forensic Anthropology Personnel	28
<a href="#"><u>Appendix D</u></a> : Infection Control Awareness for Employees Exposed to Wastewater	30
<a href="#"><u>Appendix E</u></a> : BBP Training Checklist & Record for Research Personnel	31
<a href="#"><u>Appendix F</u></a> : Safer Sharps Device Initial Evaluation Form	33
<a href="#"><u>Appendix G</u></a> : Safer Sharps Devices Annual Review Form	35
<a href="#"><u>Appendix H</u></a> : BSL-2 Requirements	37
<a href="#"><u>Appendix I</u></a> : Biological Spill Response for Lab Releases	40
<a href="#"><u>Appendix J</u></a> : Hepatitis B Vaccination Offer Form	41
<a href="#"><u>Appendix K</u></a> : BBP Exposure/Sharps Injury Report	42

## Introduction

This Bloodborne Pathogens Exposure Control Plan (ECP) has been developed and implemented to meet the requirements of the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard codified at 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) in human healthcare settings. While this hazard may seem far removed from the Knoxville area campuses research activity focus, it is not uncommon for human-derived materials to be used in a variety of life science-related research applications, as well as for controls in clinical diagnostics.

While OSHA standards apply directly to employees (personnel who are paid by the employer to perform work), it is prudent for supervisors to provide information and training to all personnel under their supervision, regardless of employment status. This standard of practice will reduce BBP exposure risk for all personnel in the work environment.

The scope of this Exposure Control Plan is limited to two categories of UT personnel. These categories are:

1. All **research personnel** of the UT Knoxville campus, UT Institute of Agriculture, and the UT Graduate School of Medicine.
2. Non-research personnel of the UT Institute of Agriculture: 4H Lifeguards, and Camp Nurses.

The objectives of the Exposure Control Plan are to:

- Identify activities and tasks that involve the use of human-derived materials that may contain bloodborne pathogens and are regarded as potentially infectious (occupational exposure determination);
- Provide information to affected supervisors and employees on procedures and regulations regarding bloodborne pathogens;
- Protect affected employees from health hazards associated with bloodborne pathogens;
- Provide information on appropriate treatment and counseling to affected employees exposed to bloodborne pathogens.

The following principles must be applied when employees are potentially exposed to bloodborne pathogens:

- Minimize all exposures to bloodborne pathogens;
- Institute as many engineering and work practice controls as possible to eliminate or minimize employee exposure to bloodborne pathogens;
- Routinely employ universal precautions when exposure to blood or potentially infectious materials is anticipated.

## Definitions

The following is a list of common terms and their definitions as they are used in the Exposure Control Plan.

**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 that are 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.

**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, 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 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:

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, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
2. Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
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. See [Appendix A](#).
5. 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, 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; pathological and microbiological wastes containing blood or other potentially infectious materials.

**Sharps with engineered sharps injury protection:** 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 manner in which a task is performed.

## Exposure Determination

The OSHA Bloodborne Pathogens Standard states that all employees who have duties which potentially expose them to blood or other potentially infectious material are determined to have a **reasonably anticipated risk** of exposure to bloodborne pathogens and are acknowledged in the Exposure Control Plan.

The UT occupational safety and health personnel will annually review which job classifications include potential exposure to bloodborne pathogens. Specific tasks that present a risk for BBP exposure 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 which have a potential for BBP exposure are listed in the left hand column in the table below. Specific tasks that bear a BBP 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 bloodborne pathogens and must be included in this Bloodborne Pathogens Exposure Control Program.

Job Classification	BBP exposure-risk tasks
Occupational Health Nurse/ 4H Camp Nurse	Providing medical care/first aid to injured personnel.
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 labware and wastes that are contaminated with human-derived materials.
Animal caretaker	Care of animals that have been challenged with a BBP; 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.
4H Camp Lifeguard	Required to administer first aid or perform human blood/ OPIM spill response as part of job duties.
Maintenance Worker	Maintenance/repair of lab-associated plumbing (as determined by lab risk assessment).
<b>Any job classification</b>	Required to administer first aid or perform human blood/ OPIM spill response 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 UTK/UTIA/GSM Biosafety Office at 974-1938 or the UTIA Safety Officer at 974-4904.



## **Exposure Control for First Aid & Blood Spill Responders**

While this Exposure Control Plan includes all of 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. [Appendix B](#) outlines specific considerations for reducing BBP exposure risk in these settings. 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.

## **Exposure Control for Forensic Anthropology Personnel**

While this Exposure Control Plan includes all of the basic principles to be followed for exposure control, it does not specifically address the unique considerations that apply to the manipulation of human remains for forensic anthropology studies. [Appendix C](#) outlines specific considerations for reducing BBP exposure risk in these settings.

## **Exposure Risk to Other Human Body Fluids (including wastewater)**

Most human waste products such as urine and feces are not generally regarded as BBP-risk materials. Even so, these materials do 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. See [Appendix D](#) for more information.

# **General Program Management**

## **Areas of Responsibility**

The 3 primary areas of responsibility for the Exposure Control Plan (ECP) are:

1. Exposure Control Officer
2. Supervisory Personnel (including Principal Investigators, Managers and Supervisors);
3. Employees.

## **Exposure Control Officer**

The UTK/UTIA/GSM 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 UTIA Safety Officer and the Occupational Health Nurse 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;
- Collecting and maintaining a suitable reference library related to bloodborne pathogens;
- 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 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 bloodborne pathogens as outlined in the “Training” section of this document;
- All volunteer personnel in their area who are at risk of exposure to bloodborne pathogens 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 is available and in good working condition for all employees at risk of exposure to bloodborne pathogens; 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.

### **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:

- Attending the bloodborne pathogens initial training session and annual retraining sessions;
- Understanding which tasks have potential occupational exposure to bloodborne pathogens;
- Conducting all operations in accordance with established work practice controls, 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 and have it readily available to their employees. This Exposure Control Plan can also be accessed by employees and the general public at the following website: <http://biosafety.utk.edu> (“Bloodborne Pathogens” tab on left side of homepage).

## Review and Update of the Plan

This Exposure Control Plan will be reviewed and updated at least annually by the Exposure Control 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 bloodborne pathogens training (see “Training” section of this document), and employees will receive site-specific training related to BBP exposure control. UT health & safety professionals or other identified trainers will provide initial and refresher training, while site-specific training will be performed by the employee’s supervisor or designated trainer and will be documented using a checklist form ([see Appendix E](#)) to be signed by the trainer and the employee upon completion. A copy of this form should be kept on file by the PI/supervisor for regulatory review, if required.

## Universal Precautions

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

- ◆ 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.

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

The UT safety professionals, 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.
- Autoclaves must be used to decontaminate solid biohazardous waste, unless waste is managed through a medical waste contractor. Autoclaves used for biohazardous waste decontamination will be tested at least every 3 months to ensure proper sterilization conditions are being maintained. Contact the Biosafety Office for specifics regarding autoclave performance testing for waste decontamination.
- Biological Safety 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. Biological safety cabinets 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;
- retracting lancets with safety features; or
- disposable scalpels with shields and other safety features.

The use of sharps for procedures on living humans must be documented initially and annually with the Biosafety Office as outlined in the “Sharps Injury Protection Program” section of this Exposure Control Plan.

- Biohazardous sharps containers must be used to properly store and dispose of contaminated sharps. Disposable biohazardous sharps containers 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 biohazardous 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, are not acceptable containers for sharps collection or disposal.

Contact the Biosafety Office at (865) 974-1938 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 containers is required for any transportation or long-term storage of all potentially infectious materials.

## **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.

### *Applicability of the Act to Personnel Covered by this Exposure Control Plan*

In the event that a UTIA non-research employee is required to perform sharps-related procedures on living humans similar in nature to those procedures performed in a healthcare setting (i.e., phlebotomy), these procedures MUST be documented with the Biosafety Office. The Biosafety Office will assist the supervisor in completing initial and annual documentation for the device in use in accordance with the requirements of this Act (see [Appendix F](#) and [Appendix G](#)).

Laboratories or research settings on the Knoxville area campuses that plan to use human blood or OPIM in their applications must register their use of such materials with the Biosafety Office. Through this registration process, the Biosafety Office will work with PIs/supervisors to evaluate procedures for exposure risk including the use of sharps and to identify procedure changes that can reduce exposure risk. If procedures will require collection of blood or OPIM from a living human source, and collection will be performed by lab personnel, the Biosafety Office will assist the supervisor in completing initial and annual documentation for the device in use in accordance with the requirements of this Act (see [Appendix F](#) and [Appendix G](#)).

### *Resources for Identifying Safe Sharps Devices*

The following website has a comprehensive list of safe sharps devices that are now available. For additional assistance, contact the Biosafety Office or the Occupational Health Nurse.

<http://www.infectioncontroltoday.com/articles/321feat3.html>

When replacing a conventional sharp device with a safe sharp device, supervisors must ensure that the safe sharp device is properly evaluated before implementing the use of the device. Front line employees must be included in the evaluation process and the evaluation must be documented. Selection decisions must be based on employee acceptance, product reliability and safety. [Appendix F](#) is a sample initial evaluation form that can be used or adapted for UT's needs. [Appendix G](#) is a sample annual evaluation form that can be used or adapted for UT's needs.

Safe sharps devices resource links will be accessible through the Biosafety website at <http://biosafety.utk.edu/forms/>.

## **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;
  - 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.)

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 UT safety professionals should be consulted for assistance with PPE selection.

Principal Investigators (PI) or supervisors must ensure that PPE of appropriate type and size is 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. This training will be documented through the completion of the site-specific training checklist record (see [Appendix E](#)). 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.

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 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:

1. 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 solutions are also acceptable.**
2. 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;
  - 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.
3. Routinely inspect and clean all pails, bins, cans and other receptacles. These items must be properly decontaminated whenever visibly contaminated.
  4. 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!
  5. Immediately clean up spills of blood, body fluids, or any other potentially infectious materials. For lab spills, refer to [Appendix I](#) – Biohazard Spill Response Procedures. Refer to [Appendix B](#) for guidelines for managing spills associated with a first aid response scenario.
  6. 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

Note: 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 Biosafety Office at (865) 974-1938.

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 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 preferably 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 Biosafety Office 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 Biosafety Office for assistance with identifying disposal options.

## **Liquid biohazardous waste**

For BBP purposes, this includes all blood, blood products and body fluids and cell-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 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. Collection of containers (other than those generated at the Veterinary Teaching Hospital or GSM) will be coordinated by the Biosafety Office. Call (865) 974-1938 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 UTK/UTIA/GSM Biosafety Office 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, 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 incinerated unless other provisions apply (contact Biosafety Office for assistance).

## **HIV and HBV Research Laboratories and Production Facilities**

The UT campuses in the Knoxville area 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 Occupational Health Nurse, the University's Student Health Services, and Employee Health Services at the UT Medical Center.

### **Vaccination Program**

The University of Tennessee has implemented a vaccination program through UT Occupational Health. 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 Occupational Health 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 the program must complete a Hepatitis B Surveillance Program form ([see Appendix J](#)) and return it to the UT Occupational Health Nurse, regardless of whether they choose to accept or waive the vaccine.
- All GSM employees covered under the plan will receive the vaccination offer/declination through Employee Health at the UT Medical Center.

If a GSM employee desires to receive the vaccine, the Employee Health department will contact that individual to coordinate arrangements for this. If a non-GSM employee desires to receive the vaccine, the Occupational Health Nurse will write orders for the employee to proceed to UT Student Health Services to receive the immunizations. Student Health Services will provide the Occupational Health Nurse with dates of immunization, and the nurse will contact employee for post vaccination titer. For occupational groups whose work sites are outside the Knoxville metro area, the supervisor must contact the Occupational Health Nurse at (865) 974-5728 to identify vaccination options.

### **Post-Exposure Evaluation and Follow-up**

If an employee sustains an exposure to biological materials that are considered to be a bloodborne pathogens 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.
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 refers the employee and the source, if available, to UT Medical Center Emergency Room if located in the Knoxville area, or the closest available emergency 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. Complete, together with the supervisor, the Office of Risk Management's Incident Report Form (see <http://riskmanagement.tennessee.edu/forms.htm> or contact 865-974-5409).
8. If a GSM employee, complete follow-up actions outlined by Employee Health. If a non-GSM employee, follow-up with the Occupational Health Nurse within 3 working days of the exposure incident to follow up on immediate medical actions taken and to establish a medical surveillance plan.
9. Notify the Biosafety Office at (865) 974-1938 within 3 working days of the exposure to initiate required exposure investigation procedures. The Biosafety Office will evaluate all bloodborne pathogens exposure incidents and complete a BBP Exposure/Sharps Injury Report to capture all information currently required under the OSHA Bloodborne Pathogens standard ([see Appendix K](#)). All documentation related to an exposure incident will be recorded and maintained in such a manner as to protect the confidentiality of the employee.

## **Medical Record Keeping**

The Occupational Health 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.

## **Labels and Signs**

Biohazard labels consist of a red or fluorescent orange colored background with the traditional biohazard symbol in a contrasting color. The Biosafety Office 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.

### Training Methods

The UT health & safety professionals will provide in-person training for personnel whenever feasible. Other training methods may be adopted but all sessions conducted by the UT 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, UT 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 ([see Appendix E](#)).

### 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;
- UTK/UTIA/GSM'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;
- 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 UT health & 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 UT health & 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.



## Appendix A: OSHA Interpretation Regarding Applicability of BBP Standard to Human Cells

“... [T]he Bloodborne Pathogens Standard (BPS) provides protection to employees who have occupational exposure to human blood or other potentially infectious materials (OPIM). Established human cell lines\* which are characterized\*\* to be free of contamination from human hepatitis viruses, human immunodeficiency viruses, and other recognized bloodborne pathogens, are not considered to be OPIM and are not covered by BPS. Established human or other animal cell lines which are known to be or likely infected/contaminated with human microbes or agents classed as bloodborne pathogens, especially hepatitis viruses and human immunodeficiency viruses are covered by the BPS. The final judgment for making the determination that human or other animal cell lines in culture are free of bloodborne pathogens must be made by a Bio-safety Professional or other qualified scientist with the background and experience to review such potential contamination and risk, in accordance with the requirements of the BPS. Documentation that such cell lines are not OPIM should be a matter of written record and on file with the employer for OSHA review.

All primary human cell **explants** from tissues and **subsequent in vitro** passages of human tissue explant cultures (human cell "strains" \*\*\*) must be regarded as containing potential bloodborne pathogens and should be handled in accordance with the BPS. Non-transformed, human cell "strains", characterized by documented, reasonable laboratory testing as described in the attachment, to be free of human immunodeficiency virus, hepatitis viruses, or other bloodborne pathogens may be exempted from the standard's requirements. However, if such tissue explants or subsequent cultures are derived from human subjects known to carry bloodborne pathogens, such as hepatitis viruses or human immunodeficiency viruses or are deliberately infected with bloodborne pathogens, they must be handled in accordance with the precautions noted in the BPS. Likewise, animal tissues, explants or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to the BPS.

All laboratory work with primary human tissues or body fluids is covered by the BPS.”

### DEFINITIONS

\* A human cell **line** is defined as **in vitro** or animal passaged (e.g., nude mouse) cultures or human cells that fulfill traditional requirements of a cell line designation. That is, the cells are **immortalized** cells, transformed by spontaneous mutation or natural or laboratory infection with an immortalizing agent such as Epstein-Barr virus (EBV). EBV is a bloodborne pathogen. It should be noted that human cervical carcinoma cells or other transformed human cell lines like HeLa cells are sometimes adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures, or physically contaminated by other cell cultures handled in the same lab. In order to handle human HeLa cells, without having to comply with the requirements of the bloodborne pathogens standard (BPS), human HeLa cells should be documented to be pure HeLa cells and shown to be free of bloodborne pathogens by testing.

\*\*Characterization of human cells, for inclusion or exclusion from compliance with the BPS, would include screening of the cells lines or "strains" for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses or EBV, if the cells are capable of propagating such viruses. Most cell lines are screened for human mycoplasmas and are free of bacterial and mycotic contaminants. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology (polymerase chain reaction or nucleic acid hybridization) to identify latent viruses capable of infecting humans such as herpes viruses(e.g., EBV), or papilloma members of the Papovavirus group, etc. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the BPS.

\*\*\* Human cell **strains** are defined as cells propagated **in vitro** from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue culture for 20-70 passages. Human cell "strains" must be handled as potential biohazards unless characterized by testing to be free of bloodborne pathogens (i.e., WI-38 cells are often so documented).

## Appendix B: First Aid & Human Blood Spill Responders' Exposure Control Guide

### **Overview**

Employees who are required to provide first aid assistance, or clean up body fluids suspected to be contaminated with human blood, need to perform these duties in a manner that protects themselves and others in the immediate area where the event occurred. Because there are unique challenges associated with performing these duties, it is essential that the employees assigned to the duties have been appropriately trained, and have adequate supplies and resources available to carry out these duties effectively and safely.

### **First Aid Response Exposure Control Pointers**

It is strongly recommended that only personnel who have been trained in first aid response and have been specifically assigned that duty as a job responsibility render such services. Employees with this assigned job responsibility must complete bloodborne pathogens training before performing first aid services. Supervisors must ensure that employees under their direction understand clearly who is expected (and NOT expected) to provide first aid services and/or the proper procedure for dispatching emergency medical care personnel to the job site.

First aid responders must minimize their exposure risk while rendering first aid services by adhering to the following practices:

- Know where first aid kits are located, and that they are stocked and ready for service at all times.
- Keep at least 2 pair of gloves (in your size) immediately available for your use. Always wear gloves when contact with any body fluids is anticipated. Double glove when performing first aid services where visible blood is present.
- Always take note of where your closest running water is located in the event that you need it for first aid, hand washing, or for exposed skin flushing purposes.
- If injuries are minor, and the injured person is capable, provide supportive, rather than hands-on services. In other words, give the person direction for wound cleaning, bandage application, etc., but let them do it themselves.
- If an injured person is actively bleeding, try to get the person isolated from others and keep them in that location to limit the spread of blood contamination. In this scenario, post someone to keep others out of the area where the contamination is present.
- If your clothes become contaminated with an injured person's blood or OPIM, you must remove contaminated clothing items as soon as possible. If the contamination soaked through to your skin, you must thoroughly flush the exposed skin. (See exposure incident response procedure at the end of this guidance document.) Moderately or heavily contaminated clothing should be laundered on-site separate from other clothing using hot water and a bleach-based detergent. Alternatively, this clothing must be sent to a commercial laundry service that is equipped to process clothing contaminated with blood or OPIM. Contaminated clothing awaiting treatment must be stored in a closed leak-resistant plastic bag tagged with a biohazard symbol.
- Always wash your hands after rendering any first aid services and after glove removal.

### **Human Blood Spill Response Exposure Control Pointers**

First aid incidents involving a person who is actively bleeding commonly result in contamination of items in the area where the incident occurred. These contaminated areas and items must be isolated and properly disinfected by trained personnel before they are brought back into service.

Blood spill responders must observe the following practices to protect themselves and the public from exposure to human blood or OPIM:

- Know where spill cleanup kits are located, and that they are stocked and ready for service at all times.

- Have disposable gloves (in your size) readily available at all times. Wear two pair of gloves for all spill response activities.
- If a spill occurs, isolate the contaminated area immediately. Either post someone at the site to keep others out of the area, or close off the area.
- Other than very minor spills involving a few drops of blood, all spill response procedures should be carried out with 2 trained persons present if at all possible. If the spill is too large for you to manage with the supplies available in the spill kit, or if you are not confident that you can manage the spill on your own, you must notify your supervisor and request additional assistance.
- If the spill includes contaminated broken glass, you must use mechanical tools to pick up the broken glass. Contaminated broken glass should be placed in a sharps container for disposal if feasible. If this is not feasible, place broken glass in a puncture-resistant bucket. Permanently close the bucket with a lid and place the bucket into a biohazardous waste bag. Blood spill response waste must be disposed of as medical waste. While awaiting disposal, bags of spill waste must be stored in a secure area in a leak proof container with a lid that is labeled as a biohazard.
- If your clothes become contaminated with blood or OPIM, you must remove contaminated clothing items as soon as possible. If the contamination soaked through to your skin, you must thoroughly flush the exposed skin. (See exposure incident response procedure at the end of this guidance document.) Moderately or heavily contaminated clothing should be laundered on-site separate from other clothing using hot water and a bleach-based detergent. Alternatively, this clothing must be sent to a commercial laundry service that is equipped to process clothing contaminated with blood or OPIM. Contaminated clothing awaiting treatment must be stored in a closed leak-resistant plastic bag tagged with a biohazard symbol.
- Always wash your hands after glove removal or anytime they may have come into contact with body fluid contamination.

### **BBP Exposure Incident Response**

**A BBP occupational exposure incident occurs when human blood or OPIM enters your bloodstream through:**

- Splash to the eyes, nose, or mouth,
- Puncture wound with contaminated item,
- Contact with broken skin or prolonged contact (more than 5 minutes) with intact skin.

***Immediate response is required to reduce your chance of acquiring infection!***

**Take the following actions immediately:**

1. Flush the exposed skin or mucous membranes for 15 minutes.
2. Notify your supervisor if he or she is available.
3. Report to an emergency medical care facility for exposure evaluation. Identify yourself as a UT employee who has had a BBP exposure.

***Contact the Occupational Health Nurse at 865-974-5728 or Biosafety Office at 865-974-1938 within 3 days of the exposure for further follow-up.***

## Appendix C: BBP Exposure Control Principles for Forensic Anthropology Personnel

### **Overview**

Employees and volunteers whose responsibilities include handling human remains as part of the activities associated with the Forensic Anthropology Research Center (FARC) have a unique bloodborne pathogens exposure risk. The procedures carried out often involve significant manual manipulation of tissues and remains, and the use of sharp devices is common. It is essential that employees, volunteers and collaborating investigators complete training in the unique handling procedures required for their research tasks, especially those involving the use of scalpels and other sharp-ended devices. They should be able to demonstrate that they can perform these procedures safely before they are permitted to carry out these procedures unsupervised.

The persistence and viability of bloodborne pathogens in corpses or unfixed human tissues will be minimized in many cases by the field conditions under which the bodies are held for decomposition studies. Even so, all tissues and corpses will be handled using universal precautions practices. These practices will not only further minimize BBP risk, but also minimize other infectious disease or allergen exposure risks that may be present in the field (i.e., tetanus, agents present in scat, fungi growing on tissues and debris in the field).

### **Pointers for Field Procedures**

Proper training and strict adherence to procedures outlined by the FARC director, coordinators, and the supervising graduate assistants are absolutely critical for you to be able to perform your procedures in a manner that will minimize your exposure risk. It is YOUR responsibility to ensure that you consult with your supervisors before initiating a “new way” to carry out a procedure. It is also YOUR responsibility to ensure that new employees, volunteers or collaborating investigators are not permitted to perform procedures (especially those involving sharps) on which they have not been trained.

### **In the field, adhere to the following exposure control procedures:**

- If you haven't been given permission to do a procedure by your supervisor, you must not do it.
- Know where the closest running water is located. Also know where the portable water supply is located in case you sustain an exposure and need to immediately flush the exposed site.
- Do not eat, drink or smoke in the Forensic Anthropology Center or anywhere else where bodies, tissues or biological contamination are present.
- Avoid performing any procedures requiring handling of bodies or tissues in adverse weather conditions, especially rain. Such conditions will make bodies and tools difficult to handle and should be avoided whenever possible.
- Always wear fluid-resistant gloves when handling bodies or tissues. Wear a cut-resistant, puncture-resistant glove on your non-dominant hand if you will be performing any cutting procedures.
- Wear safety glasses whenever you are carrying out procedures that will result in actively disturbing the soil or debris.
- When carrying out procedures that require you to get on the ground or come in close contact with the bodies, ensure that you wear disposable fluid-resistant body coverings to the degree that all skin or clothing that is likely to get contaminated is adequately covered.
- When moving bodies, ensure that you have enough assistance to do the task without straining yourself or exerting excessive force. If you have to exert excessive force on the body or tools required for the procedure, you may be setting the stage for contaminated tools to “slip” which elevates your exposure risk.
- When using sharps in the field (i.e., scalpels, needles, knives, cleaning instruments), you must take a sharps container with you to the point of use so that you have an immediate method of disposal. If you are using a non-disposable form of a sharp, you must take a solid-walled container with a secure lid for storage and transport. This container should be configured so that the sharp end of the device placed inside is oriented away from your hand.

- If you are using a sharp, and the device breaks, snaps or slips, you must stop the procedure immediately and consult with the director, coordinator, or supervising graduate assistant before continuing with the procedure.
- When transporting sample materials out of the Center, contain these in suitable primary containers placed in a leak-proof secondary container with a secure lid. If fluids are present, place absorbents inside the secondary container. The secondary container should be labeled with a brief description of contents, contact information, and the biohazard symbol. (The same packaging principles should be used for moving biohazardous wastes.) Secondary containers should be cleaned inside and out with a hospital grade cleaner on a routine basis and anytime they become visibly contaminated.
- Always wash your hands after glove removal, or anytime they may have come into contact with contamination. Waterless hand cleaner may be used in the field if running water is not available but this is not a substitute for a soap and water hand wash. You must wash your hands with soap and water at the first available opportunity.

### **Pointers for Remains Processing Procedures**

Again, training is essential. You must be properly trained in cleaning procedures before performing these procedures on your own.

#### **Adhere to the following exposure control procedures:**

- Wear safety glasses when performing cleaning procedures.
- Wear appropriate fluid-resistant gloves and body coverings to the degree that all skin or clothing that is likely to get contaminated is adequately covered.
- When using water in the cleaning process, ensure that the water is running at a minimal setting to minimize splashes.
- When using cleaning tools, ensure that you do not use excessive force. If you are using a cleaning tool and the device breaks, snaps, or slips, you must stop the procedure immediately and consult with the director, coordinator, or the supervising graduate assistant before continuing with the procedure.
- Whenever feasible, perform procedures involving a cleaning tool with a sharp end in such a way that the non-dominant hand is NOT placed in front of the sharp end of the tool.

### **BBP Exposure Incident Response**

**A BBP occupational exposure incident occurs when human blood or OPIM enters your bloodstream through:**

- Splash to the eyes, nose, or mouth,
- Puncture wound with contaminated item,
- Contact with broken skin or prolonged contact (more than 5 minutes) with intact skin.

***Immediate response is required to reduce your chance of acquiring infection!***

#### **Take the following actions immediately:**

1. Flush the exposed skin or mucous membranes for 15 minutes.
2. Notify your supervisor if he or she is available. (Supervisors- escort the exposed employee or volunteer for medical follow-up if possible.)
3. Report to the UT Medical Center Emergency Room. Identify yourself as a UT employee (or Forensic Anthropology volunteer) who has had a BBP exposure. (If you are not in the Knoxville metro area at the time of the exposure incident, report to the closest medical emergency care facility.

***Contact the Occupational Health Nurse at 865-974-5728 or Biosafety Office at 865-974-1938 within 3 days of the exposure for further follow-up.***

## Appendix D: Infection Control Awareness for Employees Exposed to Wastewater

In relation to water contaminated with human body fluids and wastes, the applicability of the Bloodborne Pathogens Standard extends to those employees who come in contact with wastewater from a hospital, clinical or laboratory facility. However, it must be recognized that water contaminated with human or animal waste is likely to contain infectious organisms.

It is essential that employees who are exposed to hazards on the job be informed of such hazards and provided with training and equipment to adequately protect themselves. The UT safety & health personnel will assist departments in assuring that occupationally-acquired infectious disease risk is minimized through the following actions:

### Research Activities

1. Any supervisor of research activities that involve handling of water visibly contaminated with human or animal wastes should notify the Biosafety Office or Occupational Health Nurse of such activities.
2. The Biosafety Office and/or Occupational Health Nurse will evaluate the scope of activities to determine if the provisions of the BBP Standard apply and to determine the specific training needs for the group.
3. The Biosafety Office and/or Occupational Health Nurse will provide training for the employee group that will include information about: waterborne/foodborne pathogens, basic infection control practices and exposure management.

### Building Maintenance Activities

1. Any supervisor of personnel whose job responsibilities include contact with water visibly contaminated with human or animal wastes should notify the Biosafety Office or Occupational Health Nurse of such activities.
2. The Biosafety Office and/or Occupational Health Nurse will evaluate the scope of activities to determine if the provisions of the BBP Standard apply and to determine the specific training needs for the group.
3. The Biosafety Office and/or Occupational Health Nurse will provide training for the employee group that will include information about: waterborne/foodborne pathogens, basic infection control practices and exposure management.

Wastewater-related resources (<http://www.cdc.gov/niosh/docs/2002-149/pdfs/2002-149.pdf>) recommend that personnel who have exposure to wastewater have a current tetanus vaccination as a minimum level of protection. The UT health and safety personnel support this recommendation. For assistance with coordinating vaccinations, supervisors should contact the Occupational Health Nurse at (865) 974-5728.

## Appendix E: Site-Specific Training Checklist & Record

Trainee Name: \_\_\_\_\_

Title: \_\_\_\_\_

Site-Specific Trainer \_\_\_\_\_

Title: \_\_\_\_\_

<b>Biosafety Training Topic</b>	<b>Trainer initials PI/Supervisor (or Designee)</b>	<b>Trainee initials</b>	<b>Date completed</b>
Location and review of Biosafety Manual and/or IBC Registration			
Standard microbiological practices (SMP), lab hygiene, disinfection of work surfaces & equipment, and routine housekeeping			
Agent-specific training and exposure risk: <ul style="list-style-type: none"> <li>• Routes of transmission</li> <li>• Signs/symptoms of infection/disease manifestations</li> <li>• Medical conditions that may increase risk of transmission and/or the severity of disease</li> </ul>			
Procedure-specific training and associated safety precautions, including <b>engineering controls</b> and <b>work practice controls</b>			
Biological hazard communication and labeling (door placards & labels)			
Safety and use of lab equipment for containing/processing biological hazards (e.g. biosafety cabinets, autoclaves, and centrifuges)			
Location and use of hand washing sinks and emergency eye washes			
PPE training, including selection, use, and storage/disposal			
Identification, segregation and treatment of biohazardous wastes			
Lab-specific procedures for emergencies (including reporting): <ul style="list-style-type: none"> <li>• Spill containment, disinfection &amp; clean-up</li> <li>• Accidents, injuries, and exposures (includes near-misses)</li> </ul>			
<i>Bloodborne Pathogens topics (if working with human materials)</i> <ul style="list-style-type: none"> <li>• Location/availability of the <b>UT Exposure Control Plan</b></li> <li>• Activities/procedures that may involve exposure to human blood, tissues, cells, or body fluids</li> <li>• Selection and use of PPE (if different from above)</li> <li>• Emergency actions for incidents/exposures involving human materials (including reporting)</li> </ul>			

*SUPERVISOR/TRAINEE: Insert training dates and your signature below upon completion of all training elements.*

I provided site-specific training for the individual listed above as documented.	I received training as outlined above and was given an opportunity to ask questions related to safety expectations and my exposure risk.
<b>PI/Trainer Acknowledgment of Training (sign/date)</b>	<b>Trainee Acknowledgment of Training (sign/date)</b>

## Instructions for Completion of Biosafety Site-Specific Training Checklist & Record

This form is intended to help employees and supervisors meet the training and recordkeeping requirements of the UTK-area Biosafety program.

### **TRAINEE (EMPLOYEE/STUDENT)**

This record will be provided to you when you complete the required programmatic training covering standard microbiological practices, biosafety principles, biological safety/containment/security practices, and bloodborne pathogens (as applicable).

**You must then give this form to the PI, supervisor, or designated trainer in the lab so that they can provide you with site specific training. Both the trainer and the trainee must initial when each element of training is complete.**

**Once the PI or supervisor reviews this information with you, and you have had an opportunity to ask any questions that you have relative to working safely in the lab, sign the record in the designated box to complete the record.**

A copy is to be kept on file in the Biosafety Manual or with other Biosafety-related records.

### **PI/SUPERVISOR/WORKPLACE TRAINER**

The PI or laboratory supervisor must ensure that laboratory personnel, including faculty, staff and students, receive appropriate training regarding biological agents/hazards in use, the SOPs provided in the Biosafety Manual (or any other duties), necessary precautions to prevent accidents and exposures, accident/exposure evaluation procedures, and other general safety requirements specific to lab. Personnel must receive annual updates or additional training when procedural or policy changes occur.

Each trainee will be instructed to provide you with this form. When you receive this form, you, or a designated trainer who is familiar with the procedures and processes carried out in the lab, will need to provide site-specific training. The PI must also complete for form. The trainer in this instance may be the PI designate or the PI may self-sign. If there are questions from the form that arise, please contact the Biosafety Office.

When each training element has been covered, write your initials and date in the appropriate columns. When all training elements have been completed and the trainee has had an opportunity to ask questions, have the trainee sign in the appropriate box; you or the designated trainer will sign the box designated for the PI/trainer. Keep this training record on file and available for regulatory review.



## Appendix F: Safer Sharps Device Initial Evaluation Form

**This evaluation form (or equivalent) must be completed by any UTIA employee that is required to perform sharps-related procedures on living humans similar in nature to those procedures performed in a healthcare setting (i.e., phlebotomy, injections, etc.). Likewise, this form must be completed by any UTIA/UTK/GSM research personnel who will be collecting blood or OPIM from a living human source as part of a research protocol/process. Contact the Biological Safety Office at (865) 974-1938 if you have questions or need further information.**

Evaluator's Name: \_\_\_\_\_ Job Title: \_\_\_\_\_  
 Department/Clinic: \_\_\_\_\_ Date: \_\_\_\_\_  
 Supervisor/PI: \_\_\_\_\_ Telephone #: \_\_\_\_\_  
 Name of Device: \_\_\_\_\_  
 Name of Manufacturer: \_\_\_\_\_  
 Applications of device: \_\_\_\_\_

Circle the most appropriate answer for each question. A rating of one (1) indicates the lowest level of agreement with the statement, five (5) the highest. Not applicable (N/A) may be used if the question does not apply to this product.

<i>General Feature Assessment</i>	<i>Disagree.....Agree</i>					
1. The safety feature can be activated using a one-handed technique.	1	2	3	4	5	N/A
2. The user's hands remain behind the needle/sharp until activation of the safety mechanism is complete.	1	2	3	4	5	N/A
3. The safety feature does not interfere with normal use of this product.	1	2	3	4	5	N/A
4. Use of this product requires you to use the safety feature.	1	2	3	4	5	N/A
5. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.	1	2	3	4	5	N/A
6. The device is easy to handle while wearing gloves.	1	2	3	4	5	N/A
7. The device is easy to handle when wet.	1	2	3	4	5	N/A
8. This device does not require more time to use than a non-safety device.	1	2	3	4	5	N/A
9. The safety feature operates reliably.	1	2	3	4	5	N/A
10. The exposed sharp is blunted or covered after use and prior to disposal.	1	2	3	4	5	N/A
11. The safety feature works well with a wide variety of hand sizes and with a left-handed person as easily as with a right-handed person.	1	2	3	4	5	N/A
12. Use of this product does not increase the number of sticks to the patient.	1	2	3	4	5	N/A
13. Sterilization (if applicable) of this device is as easy as a standard device.	1	2	3	4	5	N/A
14. The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping.	1	2	3	4	5	N/A

- 15. The product does not require extensive training to be operated correctly. 1 2 3 4 5 N/A
- 16. The device can be used without causing more patient discomfort than a conventional device. 1 2 3 4 5 N/A

*Additional questions for I.V. Connectors:*

*Disagree.....Agree*

- 17. Use of this connector eliminates the need for exposed needles in connections. 1 2 3 4 5 N/A
- 18. The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles. 1 2 3 4 5 N/A
- 19. The connector can be secured (locked) to Y-sites, hep-locks, and central lines. 1 2 3 4 5 N/A

*Additional questions for Vacuum Tube Blood Collection Systems:*

*Disagree.....Agree*

- 20. The safety feature works with a butterfly. 1 2 3 4 5 N/A
- 21. The inner vacuum tube needle (rubber sleeved needle) does not present a danger of exposure. 1 2 3 4 5 N/A

**Would you recommend using this device?**

**Yes**

**No**

**Comments:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**This evaluation must be maintained with your safety records. A copy of this evaluation form must be remitted to the UTK/UTIA/GSM Biological Safety Office by fax at (865) 946-2574 or by mail to:**

**2431 Joe Johnson Drive  
336 Ellington Plant Sciences Bldg.  
Knoxville, TN 37996-4564**

## Appendix G: Safer Sharps Devices Annual Review Form

**This form (or equivalent) must be completed by any UTIA entity that performs sharps-related procedures on living humans similar in nature to those procedures performed in a healthcare setting (i.e., phlebotomy, injections, etc.). Likewise, this form must be completed by any UTIA/UTK/GSM research entity that collects blood or OPIM from a living human source as part of a research protocol/process. Contact the Biological Safety Office at (865) 974-1938 if you have questions or need further information.**

Reviewer's Name:

Job Title:

Department/Clinic:

Date:

Supervisor/PI Name:

Telephone #:

In accordance with OSHA's application of the "Needlestick Safety & Prevention Act", all sharps that are being used where there is exposure to blood or OPIM from human patients must be reviewed on an annual basis. This includes all needles, syringes with needles, IV's with needles attached, scalpels, capillary tubes, and lancets. During your annual review of devices, you must inquire about new or prospective safer options.

The purpose of this form is to document:

- ◆ sharps devices currently in use;
- ◆ the criteria used in the selection of the safer sharps devices in use, and;
- ◆ annual consideration of new safer sharps devices.

Complete the table on the reverse side of this page as completely as possible to document the sharps devices that are being used. Use multiple pages if necessary.

**This review form must be maintained with your safety records. A copy of this review form must be remitted to the UTK/UTIA/GSM Biological Safety Office by fax at (865) 946-2574 or by mail to:**

**2431 Joe Johnson Drive  
336 Ellington Plant Sciences Bldg.  
Knoxville, TN 37996-4564**

	<i>Device #1</i>	<i>Device #2</i>	<i>Device #3</i>
<b>Name of Sharps Device</b>			
<b>Manufacturer</b>			
<b>Model/Size in Use</b>			
<b>Procedure(s) Performed</b>			
<b>*Safer Sharps Device? (Y/N)</b>			
<b>Description of Safety Feature</b>			
<b>Initial Form on File? (Y/N)</b>			
<b>Justification for Selection</b> <i>(must consider newly marketed safer sharps devices)</i>			

\*A justification must be documented for any device that does **not** meet the criteria of a safer sharps device (see *Sharps with engineered sharps injury protection* in the “Definitions” section). Acceptable justifications include, but are not limited to:

- ◆ Use of a safer sharps device will jeopardize patient or employee safety.
- ◆ Use of a safer sharps device is medically inadvisable.
- ◆ Market unavailability of an appropriate safer sharps device.

Note that cost is not typically an acceptable justification.

**Description of procedure and justification for not using safer sharps device:**

---



---



---



---



---



---



---



---

## Appendix H: BSL-2 Requirements\*

**Biosafety Level 2** builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BSL-2:

### **A. Standard Microbiological Practices**

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
  - a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
  - b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
  - c. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
  - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
  - a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
  - b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required. See Appendix G.
11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy

changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

## **B. Special Practices**

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
2. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.
3. Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.
4. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
  - a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
  - b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
9. Animals and plants not associated with the work being performed must not be permitted in the laboratory.
10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

## **C. Safety Equipment (Primary Barriers and Personal Protective Equipment)**

1. Properly maintained BSCs (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:
  - a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
  - b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices).
3. Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
4. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with

other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.

5. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:
  - a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
  - b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
  - c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
6. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

#### **D. Laboratory Facilities (Secondary Barriers)**

1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
3. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
  - a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
  - b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
5. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.
6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
7. Vacuum lines should be protected with High Efficiency Particulate Air (HEPA) filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.
8. An eye wash station must be readily available.
9. There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
10. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to ensure proper safety cabinet performance and air system operation must be verified.
11. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

\*Information adopted from CDC/NIH Manual, 5<sup>th</sup> ed. 2007

## Appendix I: Biological Spill Response for Lab Releases

When responding to a spill, minimizing the spread of potentially infectious contamination is important. This can be achieved most effectively by having all spill supplies and a procedure assembled and readily accessible to lab personnel. A spill kit is the simplest way to facilitate this response.

### The following items should be included in a biological spill kit:

- **Disinfectant** – Prepare a fresh 1:10 bleach solution. In other words, a pre-measured amount of bleach in a spray bottle is placed in the spill kit, but the water required to dilute the bleach is not added until right before use. Otherwise use an EPA-registered disinfectant (effective against HIV and HBV) following manufacturer's instructions.
- **Absorbent material** (paper towel, absorbent powder)
- **Personal protective equipment** (e.g., disposable gloves, splash goggles) – Gloves and splash goggles must be worn when responding to a biological spill. It is necessary to review the PPE in the spill kit on a regular basis to verify quality. Gloves can degrade due to exposure to UV or fluorescent lighting, temperature extremes, and the effects of time. At the first sign of degradation (e.g., discoloration, brittleness, stickiness, tearing), replace the gloves in the spill kit with new ones. Likewise, the strap on splash goggles can undergo similar degradative processes.
- **Mechanical tools** (forceps or tongs, broom and dustpan) – Dispose of biohazardous waste after spill response. Purchase inexpensive plastic tools for this purpose.
- **Waste container** (biohazard bags) – By assembling all of the spill materials in a bucket or other leak-proof and puncture-proof container, you will have a secondary container readily available for proper containment of your biohazard bag.

### For a spill not involving sharps (i.e., culture container has tipped over), follow these steps:

- Isolate the area, inform others of the spill, retrieve spill materials, and review response procedure.
- Line a leak-proof, puncture-proof container with a biohazard bag for disposal of materials.
- Put on a lab coat, gloves and splash goggles.
- Cover the area with paper towels.
- Spray the spill area with freshly prepared bleach solution, working from the outside in.
- Wipe up the spill, place towels in a biohazard bag.
- Disinfect the spill area with the bleach solution, being sure to follow a 10 minute contact time.
- Disinfect the spill area again when appropriate.
- Follow up with a detergent cleaning to eliminate bleach residue if the surface is stainless steel or other material that is sensitive to corrosives.
- Autoclave bag of waste per indicated disposal procedures.

### For a spill involving sharps (i.e., flask of culture has been broken), follow these steps:

- Isolate the area, inform others of the spill, retrieve spill materials, and review response procedure.
- Line a leak-proof, puncture-proof container with a biohazard bag for disposal of materials.
- Put on a lab coat, gloves and splash goggles.
- Disinfect the spill area with the bleach solution, being sure to follow a 10 minute contact time.
- Remove sharps with an engineering control (e.g., tongs, forceps, broom and dustpan) to protect hands, and place these items into the biohazardous spill waste container.
- Cover the spill area with absorbent powder.
- Sweep up the powder/small glass shards using the broom and dustpan.
- Disinfect the spill area again as necessary.
- Follow up with a detergent cleaning to eliminate bleach residue if the surface is stainless steel or other material that is sensitive to corrosives.
- Place the entire container of waste inside an autoclave bag and autoclave the spill waste before disposal. Use care when handling this waste to avoid the possibility of injury. Place the entire contents of the treated waste into a cardboard box for final disposal to address this risk.
- Chemically disinfect splash goggles, forceps and other reusable items before storage. After notifying others (including the supervisor) of the completion of the spill clean-up, restock the spill kit for future use.



## Appendix J: Hepatitis B Vaccination Offer Form

### The University of Tennessee Hepatitis B Surveillance Program

Name \_\_\_\_\_ Net ID \_\_\_\_\_  
Personnel/student# \_\_\_\_\_ Job Title \_\_\_\_\_  
Date of Birth \_\_\_\_\_ Work Phone # \_\_\_\_\_  
Department \_\_\_\_\_ Email \_\_\_\_\_  
Location \_\_\_\_\_

#### Choose Option A or B

**OPTION A: If choosing to receive vaccine, sign the request and forward to Occupational Health Nurse (Amy Knowles, 336 Ellington Plant Sciences Bldg., [aknowles@utk.edu](mailto:aknowles@utk.edu), or fax to 865-974-4828).**

#### VACCINE REQUEST

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 elect to receive the hepatitis B vaccine at this time and at no cost to myself.

Signature \_\_\_\_\_ Date \_\_\_\_\_

**OPTION B: If choosing not to receive vaccine, sign declination.**

#### VACCINE DECLINATION

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 my declining this vaccine, I continue to be at risk of acquiring hepatitis B infection, 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. I will contact the Occupational Health Nurse ([aknowles@utk.edu](mailto:aknowles@utk.edu) or 865-974-5728) if I desire to receive the vaccination.

Signature \_\_\_\_\_ Date \_\_\_\_\_

(Initial below if applicable)

\_\_\_\_\_ I have already received the hepatitis B vaccine series:

\_\_\_\_\_ I am a GSM employee that has been offered the hepatitis B vaccine through UTMCK Employee Health:

Please send completed form to Occupational Health Nurse, Amy Knowles at 336 Ellington Plant Sciences, email to [aknowles@utk.edu](mailto:aknowles@utk.edu), or fax to (865) 974-4828.

## Appendix K: BBP Exposure/Sharps Injury Report

**This report will be completed by the Safety Officer based on information collected in interviews with the employee who had the exposure incident and the employee's supervisor.**

Date of the Incident: \_\_\_\_\_ Time of the Incident: \_\_\_\_\_

Department: \_\_\_\_\_ Supervisor: \_\_\_\_\_

Job Title of Exposed Employee: \_\_\_\_\_ Date of last BBP training: \_\_\_\_\_

Description of task being performed when exposure occurred: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Was the Supervisor's Report of Employee Accident form and the State of Tennessee Accident Report form completed and submitted for this incident? If NO, provide details:

\_\_\_\_\_

Did the employee seek immediate medical attention? If NO, provide details of circumstance:

\_\_\_\_\_  
\_\_\_\_\_

What was the route of exposure? \_\_\_\_\_

What engineering controls were in use at the time of the incident? \_\_\_\_\_

\_\_\_\_\_

What work practices were in use at the time of the incident? \_\_\_\_\_

\_\_\_\_\_

What PPE was in use at the time of the incident? \_\_\_\_\_

### **SHARPS INJURY INFORMATION**

Did the incident involve a sharp device?      YES                      NO

(If YES, provide the information requested in the following section. If NO, proceed to complete the comments/corrective actions section.)

What part of the body sustained the sharps injury? (Be specific.)

Was the device visibly contaminated with blood or OPIM?      YES                      NO

Describe the nature of the injury (i.e., scratch, puncture with visible blood, etc.): \_\_\_\_\_

\_\_\_\_\_

Describe the sharp device that caused the injury. (Include name/purpose of device, brand, model number, needle gauge.): \_\_\_\_\_

\_\_\_\_\_

Was the device a "safe sharps device"?                      YES                      NO

**COMMENTS/CORRECTIVE ACTIONS**

Complete this section with any additional information regarding the exposure incident that is relevant for correcting safety practices. With the supervisor, identify and record corrective actions to be taken to minimize the exposure risk identified by this incident. One copy will be maintained by the Safety Officer completing the form. One copy will be provided to the supervisor for recordkeeping purposes.

Safety Officer Completing Report: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Completion: \_\_\_\_\_