UNIVERSITY of TENNESSEE
INSTITUTE of AGRICULTURE

Bloodborne Pathogens Exposure Control Plan

Revision 1
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An administrative manual for UT Institute of Agriculture personnel to outline required procedures for reduction of bloodborne pathogens occupational exposure risk.

Regulatory reference: 29 CFR 1910.1030

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Introduction

The UTIA 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 remains on target, to address occupational exposure risk to human body fluids that may contain bloodborne pathogens such as human immunodeficiency virus (HIV) and hepatitis B virus (HBV) in human healthcare settings. While this hazard may seem far removed from the UTIA 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.

The objectives of the Exposure Control Plan are to:

- Identify activities and tasks that involve the use of human-derived materials that are regarded as potentially infectious for bloodborne pathogens (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 made from human blood (i.e. plasma, albumin, immune globulins, factors 8 & 9).

Bloodborne pathogens (BBPs): Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Cerebrospinal fluid: Fluid from the spine.

Contaminated: 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, Pasteur pipettes, razor blades, 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.

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 the 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 as well as human cell/tissue/organ cultures not shown to be free of bloodborne pathogens. See Appendix D.
4. 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 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.

Sterilize: 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 UTIA occupational safety and health personnel determined which job classifications include potential exposure to bloodborne pathogens. Specific tasks that present a risk for BBP exposure were considered as part of this determination. The exposure determination was 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 the UTIA Bloodborne Pathogens Exposure Control Program.

Job Classification	BBP exposure-risk tasks
Occupational Health 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.
Medical Technologist/Diagnostic Lab technician	Manipulation of human-derived materials including cells or human blood products such as those used for controls in diagnostic testing.
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.
Maintenance Worker	Maintenance/repair of lab-associated plumbing.
Any job classification	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 UTIA/UTK Biosafety Officer at 974-1938 or the UTIA Safety Officer at 974-1153.*

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. Please see Appendix A 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 Officers
2. Supervisory Personnel (including Principal Investigators, Managers and Supervisors);
3. Employees.

Exposure Control Officers

The Exposure Control Officers will be responsible for management and support of the Bloodborne Pathogens Compliance Program. The UTIA/UTK Biosafety Officer and UTIA Safety Officer will serve as UTIA's BBP Exposure Control Officers. The UTIA Occupational Health Nurse will assist the Exposure Control Officers. Activities delegated to the Exposure Control Officers include:

- 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 assure that:

- All employees in their area who are at risk of exposure to bloodborne pathogens receive initial training (including site-specific training) and annual retraining in bloodborne pathogens as outlined in the "Training" section of this document;
- 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. All UTIA employees may also access the Exposure Control Plan online at http://biosafety.tennessee.edu.

Review and Update of the Plan

The UTIA Exposure Control Plan will be reviewed and updated at least annually by the Exposure Control Officers 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 the UTIA 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. The Exposure Control Officers 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 B) 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 (OPIM) 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 D).

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 plasma, albumin, factors 8 & 9, 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 UTIA/UTK Biosafety Officer or UTIA Safety Officer 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:

- Handwashing 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 eyewash stations must be in close proximity to workstations or work areas where employees perform tasks that may produce splashes of potentially infectious materials. Eyewash stations must be kept clear of items that hinder accessibility or proper function and must be flushed weekly.

- Autoclaves must be used to decontaminate solid biohazardous waste, unless waste is managed through a licensed medical waste hauler. Autoclaves used for biohazardous waste decontamination will be tested at least every 3 months to assure proper sterilization

conditions are being maintained. Please contact the UTIA/UTK Biosafety Officer for specifics regarding autoclave performance testing for waste decontamination.

- Biological Safety Cabinets (BSC) must be used for manipulations of blood or OPIM 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 and should never be used for handling potentially infectious, toxic or sensitizing materials. BSCs must be certified (i.e., leak tested and inspected using criteria of National Sanitation Foundation 49 Standard) on an annual basis.

- Safe Sharps Devices (or sharps with engineered sharps injury protections) must be used for any manipulations involving human blood or blood products and human cell or tissue cultures. Whenever possible, the use of a sharp device must be eliminated. However, if this is not feasible or a needleless system is not available, the use of a safe sharp device must be adopted if available and feasible. Safe sharps devices include, but are not limited to:
    - self-sheathing needles/syringes
    - hypodermic syringes with "Retractable Technology" safety feature
    - phlebotomy needles with "self-blunting" safety feature
    - retracting lancets with safety features
    - disposable scalpels with shields and other safety features

- 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 UTIA/UTK Biosafety Officer (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 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.

Sharps Identification, Evaluation and Documentation: Research and Diagnostic Laboratory Applications

Laboratories that plan to use human blood or OPIM in their applications must register their use of such materials with the UTIA/UTK Biosafety Officer. Through this registration process, the Biosafety Officer will work with PIs/supervisors to assure that the use of sharps is identified, evaluated and documented both initially and annually.

Sharps Identification, Evaluation and Documentation: Other Applications

Aside from lab or clinical care environments, the required use of sharps for tasks that bear an occupational exposure risk are likely to be minimal for UTIA personnel. Even so, all supervisors of personnel who have occupational exposure for BBPs must be aware of the sharps use documentation requirements outlined above. Contact the UTIA Safety Officer or the UTIA/UTK Biosafety Officer for assistance if sharp devices are required for performance of tasks with occupational exposure risk.

Resources for Identifying Safe Sharps Devices

The following websites have comprehensive lists of safe sharps devices that are now available. For additional assistance, contact the UTIA/UTK Biosafety Officer or the UTIA Occupational Health Nurse.

www.healthsystem.virginia.edu/internet/epinet/safetydevice.cfm

http://www.nappsi.org/safety.shtml

When replacing a conventional sharp device with a safe sharp device, supervisors must assure 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. The Emergency Care Research Institute (ECRI) has developed an evaluation form that can be used or adapted for UTIA's needs. This form can be accessed at:

www.ecri.org/Products_and_Services/Products/special_Reports/SSNP_Assessment_form.pdf

These links as well as other BBP resource links will be accessible through the UTIA/UTK Biosafety website at http://biosafety.tennessee.edu.

Work Practices

Supervisors are responsible for assuring 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. Handwashing 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;

    Regular soap and warm water are appropriate for handwashing. If a waterless hand cleanser or antiseptic towelettes are used due to lack of available running water, the employee must follow up with a soap and water wash 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 can reasonably be anticipated to be found
   - Maintained upright throughout use
   - Replaced routinely and not overfilled. (Containers must be permanently closed and replaced when ¾ 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 UTIA/UTK Biosafety Officer 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 precautions are required for laboratories working with specimens of blood or body fluids (See Appendix C). Contact the UTIA/UTK Biosafety Officer 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 UTIA 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.

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 B).

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. In this event, these items may be decontaminated by autoclave before laundering on site, or these items may be placed in a biohazard bag and sent to a commercial laundry that is equipped for treating such contaminated items.

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.

   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.

4. Replace disposable gloves as soon as possible after contamination or immediately when torn, punctured or otherwise rendered unable to function as an exposure barrier.

5. Report any adverse reactions to glove material, or any known latex allergy to your supervisor so that appropriate alternative protective devices can be provided.

6. 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 disposed.

7. Wear eye protection and masks whenever there is a chance that a splash or spray may generate droplets of infectious materials.

8. Wear protective clothing (e.g. lab coat) whenever splashes or aerosols of human blood or OPIM are anticipated.

9. Wear fluid-resistant body covering (i.e. coated Tyvek coveralls) and shoe covers/boots in any instance where gross contamination is anticipated.

10. Remove and replace compromised or moderately contaminated PPE as soon as feasible.

11. 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.

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 UTIA Biosafety Officer 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 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; refer to Appendix E – Biohazard Spill Response Procedures.

6. When disposing of contaminated biological waste:
   - Discard in a biohazard bag placed inside a secondary biohazard waste container;
   - Locate containers for regulated waste within easy access 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 a licensed medical waste hauler.

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 UTIA/UTK Biosafety Officer at 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 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, bear a biohazard symbol, and have a built-in 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 UTIA/UTK Biosafety Officer for assistance in establishing these parameters if these are 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 placed in a non-see-through black bag for final disposal. Bags must be tied shut before removal from the autoclave room and transport to the dumpster for disposal as regular trash. A cart should be used for this activity to eliminate the possibility of leakage and for ease of movement.

Licensed Medical Waste Hauler
Refer to your department's contract with the licensed medical waste hauler for specific requirements.

Field Generation
Waste should be collected and stored as previously outlined. Contact the UTIA/UTK Biosafety Officer or UTIA Safety Officer for assistance with identifying disposal options.

Liquid biohazardous waste

For BBP purposes, this includes all blood, blood products and body fluids and cell culture media. Note: Primary containers containing small quantities of liquids (less than 20 mls) should be managed as solid biohazardous waste.

Storage

These liquids must be stored in closed, leakproof 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:

- 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, then thoroughly rinse down the sink with water. Remember to wear splash goggles, gloves, and a lab coat for handling of bleach and bleach-treated liquids.

- 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 properly assembled (i.e., lids installed) approved 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 ¾ 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 licensed medical waste hauler. Please 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) will be coordinated by the UTIA/UTK Biosafety Officer. Call 974-1938 for assistance with biohazardous sharps disposal.

<u>Licensed Medical Waste Hauler</u>
Refer to your department's contract with the licensed medical waste hauler for specific requirements.

<u>Field Generation</u>
Waste should be collected and stored as previously outlined. Contact the UTIA/UTK Biosafety Officer or UTIA Safety Officer 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 for disposal unless other provisions apply (contact UTIA Biosafety Officer).

HIV and HBV Research Laboratories and Production Facilities

The UTIA does 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 through the University of Tennessee Occupational Health Program and the University's Student Health Services.

Vaccination Program

The University of Tennessee has implemented a vaccination program through UTK 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, employees will receive information regarding the vaccination program. They will also receive a Hepatitis B Surveillance Program form to complete and return. All employees covered under the program must complete a form and return to the Occupational Health Nurse, regardless of whether they choose to accept or waive the vaccine.

Employees identified as having a reasonable anticipated risk of exposure to bloodborne pathogens will be registered in a master file with the UTIA Biosafety officer. All Hepatitis B Surveillance Program forms must be sent to the UTIA Occupational Health Nurse. If the employee has received the vaccination at another institution, the employee will provide either documentation of the vaccine series or a completed Hepatitis B Surveillance Program form (see Appendix F) to UTIA Occupational Health Nurse. The Hepatitis B Surveillance Program form will also include the name of the institution and the dates of the series.

If the employee desires to receive the vaccine, the UTIA 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.

Post-Exposure Evaluation and Follow-up

If an employee is involved in an incident where exposure to bloodborne pathogens may have occurred, the employee should seek medical consultation and treatment immediately. In these instances, actions should include the following:

- 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.
- 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.
- 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.
- Report the incident to a supervisor if available.
- Initiate medical follow-up immediately.
- The supervisor refers the employee and the source, if available, to UT Medical Center Emergency Room 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.
- Complete, together with the supervisor, the Supervisor's Report of Employee Accident form and the State of Tennessee Accident Report form.
- Follow-up with the UTIA 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.
- The UTIA Safety Officer or UTIA Biosafety Officer will evaluate all bloodborne pathogens exposure incidents and record the following information on the Exposure Incident Investigation Report:

    1. Date of incident
    2. Time of incident
    3. Department
    4. Job Title
    5. Supervisor
    6. Whether departmental-related incident reports (as identified above) were completed
    7. Route of exposure
    8. Description of device in use
    9. Incident description
    10. Engineering controls used
    11. Work practice controls used
    12. PPE used
    13. Date of last bloodborne pathogen training
    14. Comments/Recommendations/Corrective Action

- The UTIA Safety Officer or UTIA Biosafety Officer will also complete a Sharps Injury Report and Follow-up form for all bloodborne pathogens exposure incidents involving sharps (see Appendix G). 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 UTIA Occupational Health Nurse must establish 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 UTIA Biosafety Officer 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 store, 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 need 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. Please contact the UTIA Biosafety Officer prior to shipping any potentially infectious materials.
- Laundry bags/containers holding contaminated items or 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. Additionally, 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.

Training Methods

The UTIA health & safety personnel will provide in-person training for UTIA personnel whenever feasible. Other training methods may be adopted but all sessions conducted by the UTIA health & safety personnel 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 that cannot be captured in a general training session. Therefore, UTIA 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 B).

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;
- UTIA'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 assure 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 UTIA health & safety personnel and will focus on compliance weaknesses and new information relative to exposure control.

Training Documentation

Whenever a 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 UTIA health & safety personnel 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: 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 UTIA 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 UTIA Biosafety Officer or UTIA Occupational Health Nurse of such activities.
2. The UTIA Biosafety Officer and/or UTIA 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 UTIA Biosafety Officer and/or UTIA 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 UTIA Biosafety Officer or UTIA Occupational Health Nurse of such activities.
2. The UTIA Biosafety Officer and/or UTIA 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 UTIA Biosafety Officer and/or UTIA 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.

Waste water-related resources (http://www.cpwr.com/hazpdfs/hazsludge.pdf) recommend that personnel who have exposure to waste water have a current tetanus vaccination as a minimum level of protection. The UTIA health and safety personnel support this recommendation. For assistance with coordinating vaccinations, supervisors should contact Amy Knowles, UTIA Occupational Health Nurse at (865) 974-5728.

Appendix B: UTIA BBP Training Checklist & Record

Employee Name:_____ Title:_____

Program Trainer:_____ Title:_____

Program Training	Site Specific	Exposure Control Topic
X		**OSHA's Bloodborne Pathogens Standard and its availability;**
X		**Epidemiology, symptoms and modes of transmission of bloodborne diseases including HIV, HBV and HCV; existence of other bloodborne diseases;**
X	X	**UTIA's Exposure Control Plan and its availability;** *Supervisor/Trainer: Review location of ECP and other safety-related procedures*
X	X	**Methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;** *Supervisor/Trainer: Discuss job-specific tasks that may involve handling OPIM and how to perform such tasks in a manner that reduces risk of exposure.*
X	X	**Review of use and limitations of methods that will prevent or reduce exposure, including:** • **Engineering controls** • **Work practice controls** • **Personal protective equipment (PPE)** *Supervisor/Trainer: Review location and operation of eyewash, explanation of safe and proper equipment use (i.e., sharps containers, BSC, autoclave, safer sharps devices). Review proper waste segregation, treatment & disposal, and disinfection procedures.*
X	X	**Proper selection use and disposal of PPE;** *Supervisor/Traiiner: Review what PPE needs to be worn for procedures involving BBP exposure, and how this equipment is provided for employees. Assure that the employee understands the limitations of PPE and how to use it. (Ask questions, have employee demonstrate use if appropriate.)*
X	X	**Visual warning of biohazards including labels, signs and color-coded containers;** *Supervisor/Trainer: Review labeling requirements including those related to biohazardous waste.*
X		**Information on the hepatitis B vaccine, including its availability, efficacy, safety, benefits, administration, and HBV Vaccination Program;**
X	X	**Emergency actions for incidents involving blood or other potentially infectious materials;** *Supervisor/Trainer: Review spill cleanup procedures including location of the kit and supplies.*
X	X	**Incident reporting and post-exposure follow-up procedures;** *Supervisor/Trainer: Review the post-exposure follow-up procedure applicable to your location.*
X		**Post-exposure evaluation and follow-up including medical consultation.**
		SUPERVISOR/TRAINER: Insert training dates and your initials at the bottom of the applicable column.

I provided program training for the employee listed above as documented.	I provided site-specific training for the employee listed above as documented.	I received training as outlined above and was given an opportunity to ask questions related to my exposure risk.
Signature- Program Trainer	**Signature- Site Specific Trainer**	**Signature- Employee**

Instructions for Completion of UTIA Training Checklist & Record

This form is intended to help employees and supervisors meet the training and recordkeeping requirements of the OSHA Bloodborne Pathogens (BBP) standard.

EMPLOYEE
This record will be provided to you when you complete initial Bloodborne Pathogens Program training with a UTIA health & safety professional and will reflect that you have completed this portion of the training.

You must then give this form to your supervisor or the lead training person in your workplace so that they can provide you with site specific training for the items that are checked under the "site specific" column of the record.

Once your supervisor or workplace trainer review this information with you, and you have had an opportunity to ask any questions that you have relative to your BBP exposure risk, sign the record in the box designated for the employee's signature and return the form to your supervisor.

If you would like a copy of the completed record for your files, request this from your supervisor.

SUPERVISOR/WORKPLACE TRAINER

Any employee who has an occupational exposure risk for bloodborne pathogens must complete training requirements as outlined in the OSHA Bloodborne Pathogens standard before he/she is assigned duties that expose them to such risk. The training requirements for employees who have not completed previous BBP training are quite specific. The UTIA Training Checklist & Record outlines these requirements in a table to assist you in assuring that your staff members have completed all necessary training topics.

The UTIA health & safety professionals will provide general training in the topics listed under the "BBP Program" column. Any at-risk employee who completes this portion of the training through the UTIA health & safety professionals will be provided with a copy of this form that reflects that they've completed this portion of the training.

Employees who complete this training will be instructed to provide you with this form. When you receive this form, you (or a designated trainer in your workplace who is familiar with the employee's tasks that pose a BBP exposure risk) will need to provide site specific training in the topics that are checked in the site specific column of the record.

For each of these topics, suggestions have been provided in italics to guide you in covering the necessary information. When this information has been covered, write your initials and date in the space provided at the bottom of the site specific column. Assure that the employee has had an opportunity to ask questions relative to any of the information covered.

Finally, have the employee sign in the appropriate box; you or the designated trainer will sign the box designated for the supervisor. Keep this training record on file and available for regulatory review.

Need further assistance?
Please contact Robin Trundy, UTIA/UTK Biosafety Officer at (865) 974-1938.

Appendix C: BSL-2 Requirements

Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2:

A. *Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of splashes or aerosols.

7. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.

8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

9. An insect and rodent control program is in effect (see Appendix G).

B. *Special Practices*

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.

2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e.g., immunization) may enter the laboratory.

3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

7. The laboratory director ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.

8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needleless systems, and other safety devices are used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.

9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10. Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

12. Animals not involved in the work being performed are not permitted in the lab.

C. *Safety Equipment* (Primary Barriers)

1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:

a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs.

b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

2. Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.

3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.

4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.

D. *Laboratory Facilities* (Secondary Barriers)

1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).

2. Consider locating new laboratories away from public areas.

3. Each laboratory contains a sink for handwashing.

4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.

5. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.

6. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

7. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets' air flow parameters for containment.

8. An eyewash station is readily available.

9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

10. There are no specific ventilation requirements. 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. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

• Information adopted from CDC/NIH Manual, 4th ed. 1999

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

"… the 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 judgement 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 immortalizating 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 Herpesviruses(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 E: Biological Spill Response

When responding to a spill, minimizing the spread of potentially infectious contamination is key. 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 are required for a biological spill kit:

- **Disinfectant** – Prepare a 1:10 bleach solution fresh. 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.
- **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. In addition, 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 and inform others of the spill
- Retrieve spill materials and review 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
- 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 before disposal as regular trash.

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

- Isolate the area and inform others of the spill
- Retrieve spill materials and review 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
- 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 using the broom and dustpan
- 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.
- Place the entire container of waste inside an autoclaveable 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 F: Hepatitis B Vaccination Form

The University of Tennessee
Hepatitis B Surveillance Program

Name_____
SS# _____
Date of Birth _____
Department _____
Location _____
Work Phone # _____

Choose Option A or B

OPTION A: If choosing to receive vaccine, sign the request and forward to Occupational Health Nurse (Amy Knowles, 109 Morgan Hall).

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 waiver. Also complete the vaccine information if previously vaccinated.

VACCINE WAIVER
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 or 865-974-5728) if I desire to receive the vaccination.

Signature _____ Date _____

If previously vaccinated, list dates: 1st _____ 2nd _____ 3rd _____

Titer date _____ Results _____ Facility _____

Please send completed form to UTK Occupational Health Nurse, Amy Knowles at 109 Morgan Hall.

Appendix G: 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:_____