

University of Louisville



Bloodborne Pathogens Exposure Control Plan

The model plan is a guide in developing an individual Exposure Control Plan (ECP) for Occupational Exposure to Bloodborne Pathogens. A completed plan is required for all departments with employees at risk for occupational exposure to human blood, body fluids, tissues, cells, cell lines, blood products and other potentially infectious material. Individual plans must establish policies and procedures SPECIFICALLY addressing the hazards in each workplace and the appropriate exposure prevention.

Individual departments, clinics, laboratories and investigators (PI) can use this model document to design an ECP customized for their workplace by inserting the appropriate information as indicated in the model plan.

DEHS is available to assist units in adapting this model plan to their individual sites. Please contact the main office by e-mail (biosafe@louisville.edu) or by phone (852-6670).

Sections marked with a * require additional information specific to an individual lab.

NOTE: Additional safeguards are required for HIV and HBV research laboratories and production areas. Consequently, this model exposure control plan is not applicable to these facilities; please contact DEHS at 852-6670 for assistance.

Modified 2022

Identification *

In accordance with the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, the following exposure control plan applies to:

PI, Manager, or Responsible Supervisor	
Job Title or Position	
Department/School/Unit	
Building(s) and Room Number(s)	
Date of Preparation	

Introduction

In 1992, the Occupational Safety and Health Administration (OSHA) enacted the Bloodborne Pathogens Standard codified as 29 CFR 1910. 1030. The purpose of the standard is to protect workers from anticipated exposures to bloodborne pathogens including Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV).

The OSHA Bloodborne Pathogens Standard was modified in 2001 to include the Needlestick Safety and Prevention Act which includes new examples in the definition of engineering controls, requires exposure control plans reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens, requires employers to consider safer needle devices when they conduct their annual review of their exposure control plan and requires employers to solicit input from non-managerial employees responsible for direct patient care in the identification, evaluation and selection of engineering and work practice controls. It also requires the employer to document this input in the exposure control plan and requires employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

The Exposure Control Plan (ECP) is designed to minimize occupational exposure by identifying potentially exposed employees, routinely employing Universal Precautions and instituting engineering and work practice controls.

Review and Update of the Exposure Control Plan *

The responsible supervisor, PI, or Dept. Head will review and update the ECP at least annually and when necessary to reflect new or modified tasks, procedures, and employee positions that affect occupational exposure. The review and update of the plan will also: (1) Reflect changes in technology that eliminate or reduce exposure bloodborne pathogens; and (2) Documents annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

Name and Title of Reviewer	
Review Date	

Scope and Application

This Exposure Control Plan applies to all employees at risk of occupational exposure to bloodborne pathogens. Workers at risk are identified based on their Job Classifications or the Tasks and Procedures associated with the work they perform. Therefore, it is important to conduct an accurate Exposure Determination to identify all individuals covered by this plan.

Responsibilities

Department of Environmental Health & Safety

The Department of Environmental Health and Safety (DEHS) is responsible for the development of the University of Louisville Bloodborne Pathogens Program and will:

- Develop and evaluate the written University Bloodborne Pathogens Program
- Develop and evaluate the Model Exposure Control Plan
- Develop and provide the University general initial and annual refresher Bloodborne Pathogens training
- Provide consultation, workplace assessments, and other services as needed for University personnel

Directors, Deans and Department Chairs

Departments whose employees may have occupational exposure to blood or OPIM are responsible for the overall implementation of the Bloodborne Pathogens Program for their units.

- Ensure all PIs, faculty, and staff are aware of and follow the requirements of the ECP
- Assist PIs, faculty, and staff with allocation of appropriate funding for administration of the Hepatitis B Vaccine and Titer Check and other requirements of the ECP
- Ensure the continuity of recordkeeping, primarily when supervisors leave or are reassigned

Principal Investigators, Supervisors, Researchers, Laboratory/Clinical Managers, and Faculty

The Responsible Supervisor is ultimately responsible for ensuring that the unit-specific Exposure Control Plan (ECP) is completed, understood, and followed by the employees under their charge. While the supervisor is responsible for implementing each of the elements described within the written ECP, it is permissible to delegate some tasks to other capable employees, provided clearly documented and understood roles.

- Identify all employees (including full, part-time and temporary) with a reasonably anticipated exposure to blood or OPIM
- Complete and implement the Unit specific Exposure Control Plan
- Ensure effected employees are provided with the Hepatitis B Vaccine within 10 days of job assignment
- Ensure that employees, who initially decline the Hepatitis B vaccine, sign the Hepatitis B Declination statement as provided on the Hepatitis B Vaccine Offer form.
- Provide unit specific Bloodborne Pathogens training upon assignment to duties with occupational exposure
- Ensure employees participate in University Bloodborne Pathogens training, either online or classroom, initially and annually thereafter

- Maintain the training records and Hepatitis B vaccine forms, and other associated records as directed in this document
- Conduct ongoing worksite evaluations and annual review of the ECP to ensure the written ECP is effectively implemented

Employees

All employees performing work with occupational exposure to blood or other potentially infectious material must accept a responsibility for operating in a safe manner. Employees also have a responsibility to inform their supervisors of working conditions, accidents and work practices they believe hazardous to their health or the health of others. Employees are responsible for the following:

- Participating in both initial and annual Bloodborne Pathogens training
- Completing the Hepatitis B Vaccine Offer form
- When selecting to receive the vaccine, the employee is responsible for going to the University Health Services Office to receive the Vaccine. Employees are not responsible for the cost of the vaccine, in any manner.
- In the event of an exposure incident, seek medical evaluation immediately (within 1-2 hours).

Exposure Determination*

OSHA requires employers to determine (perform an exposure determination concerning) which employees may incur occupational exposure to blood or other potentially infectious materials (OPIM). The exposure determination is made without regard to the use of personal protective equipment (employees are considered to have potential exposure even if they wear PPE). This exposure determination contains the following:

Human Clinical Specimens

- Human blood
- Human blood products (e.g. albumin, Factor 8)
- Other body fluids (amniotic, semen, vaginal, any body fluids visibly contaminated with blood, etc.)

Research Materials Derived from Human/Primate Blood or OPIM

- Human primary or permanent cells, cell lines
- Other research materials derived from human/primate blood or OPIM
- Animal tissue/cells infected with HIV or HBV, HCV, etc. (see list of agents below)
- Non-human primate cell lines, tissues, body fluids

Other BBP exposure agents

- Bacteria (e.g. Brucella abortus, Corynebacterium diphtheriae, Neisseria Gonorrhoeae)
- Viruses (e.g. Cytomegalovirus, Epstein Barr Virus, Hepatitis D Virus, West Nile Virus)
- Animal specimens infected with human BBP (e.g. Herpes B Virus, Francisella tularensis, Coxiella burnetti, Leptospira interrogans, Rabies virus)

All employees must be informed of the associated activities in which occupational exposure to bloodborne pathogens may occur. Please be sure to consider all activities, both primary and ancillary to the research, in which occupational exposure may occur. In activities or tasks that only some employees may be assigned, ensure those employees know they will be involved in each activity.

Employee Name	Title/Job Classification	Tasks that may cause exposure to BBP

Method of Implementation

Engineering, work practice controls, and personal protective equipment, as outlined in this Exposure Control Plan will be used to eliminate or reduce employee exposure to Bloodborne Pathogens hazards.

The Exposure Control Plan will be reviewed and updated at least annually, and when necessary to reflect new or modified tasks and procedures, and to reflect new or revised employee positions that affect occupational exposure. The review will also document the consideration and implementation of changes in technology and safer needle devices that reduce or eliminate exposure. The Principal Investigator or supervisor is responsible for the overall implementation, developing site- specific procedures and specific policies, and the annual review and update of the Plan. The Department of Environmental Health and Safety is available to assist with development of the exposure control plan, employee training, and other consultative roles as related to the OSHA standard.

A copy of this plan must be accessible in the work place to all employees at risk for occupational exposure.

Compliance Methods

Universal/Standard Precautions

Universal or what is now often referred to as Standard Precautions is a simple approach to infection control and will be used with all blood or other potentially infectious materials (OPIM). Universal Precautions were developed by the Centers for Disease Control to help prevent the transmission of bloodborne diseases in the work place. Under Standard Precautions, all human blood, human body fluids, secretions and excretions, and other potentially infectious materials (OPIM) are considered infectious for HIV, HBV, HCV and other bloodborne diseases. Therefore, all human blood and OPIM are treated as though they are infectious and precautions are taken accordingly.

OPIM includes the following: body fluids—semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, 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

Any unfixed tissue or organ (other than intact skin) from a human (living or dead)

Blood products and blood components, albumin, factors 8 and 9, immune globulin

Human cells or tissue cultures, and HIV or HBV containing culture medium or other solutions,

Blood, organs and other tissues from experimental animals infected with Bloodborne pathogens or OPIM Human cells, cell lines, cell strains, tissue cultures, cell media,

Non-human primate cells, cell lines, cell strains, tissue cultures, cell media

Engineering Controls

Engineering controls are physical or mechanical means of isolating or removing bloodborne hazards from the work area. Engineering and work practice controls are used to eliminate or minimize exposure to employees. Where occupational exposure remains after institution of these controls, personal protective equipment will be used.

The following engineering controls are used:

- **Handwashing facilities** with appropriate hand cleaners and disposable towels are readily available in the work area, such as the laboratory, procedure room, or patient care area. Where it is not feasible to have handwashing facilities readily accessible, disinfectant hand cleaners (containing at least 60% alcohol) will be provided.
- **Sharps containers** are available where sharps are used. Appropriate containers are puncture resistant, labeled with a biohazard label or color coded, and leak proof on the sides and bottom. Sharps containers are located as close to the point of use as possible, preferably at eye level. Sharps containers may not be allowed to overfill.
 - Re-usable Sharps Containers will not be opened, emptied, or cleaned manually; or in any other manner that would expose employees to the risk of percutaneous injury.
 - A guide for the proper selection and use of sharps containers can be found at the following website: <http://www.cdc.gov/niosh/docs/97-111/>
- **Sharps safety devices** will be used to the extent feasible, appropriate, commercially available and effective to reduce employee exposure to blood or OPIM for withdrawing body fluids, accessing a vein or artery or administering medications or other fluids. Sharps with Engineered Sharps Injury Protections (SESIPs) encompasses a broad array of devices including: syringes with guards or sliding sheaths that shield the attached needle after use, needles that retract into the syringe after use, needless IV medication connection systems, and plastic capillary tubes. A list of safety devices with manufactures and specific products can be found at the following website: <http://www.tdict.org/>
- **Biological Safety Cabinets** (Class II) will in appropriate situations (i.e. labs) to provide worker protection during aerosol generating procedures with human blood and OPIM including human cells, tissue cultures, and blood products and blood components. Class II Biological Safety Cabinets, while providing laminar airflow to protect research material, are designed with inward flow to protect personnel, and filtered exhaust air for environmental protection as well.
- **Infectious waste** is discarded into biohazard containers, lined with a red plastic bag. If the waste could puncture the bags, it must first be placed in a sharps container.
- **Mechanical pipettes** must be used; mouth pipetting is prohibited.
- **Containers** for blood or OPIM: Specimens of blood or other potentially infectious material will be placed in a container that prevents leakage during collection, handling, processing, storage, transport and shipping.
 - The container for storage, transport, or shipping shall be labeled with the Biohazard warning symbol in fluorescent orange or orange-red, and closed prior to being stored, transported, or shipped.
 - If outside contamination of the primary container may have occurred, the primary container will be placed within a second container that prevents leakage during handling, processing, storage, transport, or shipping and is labeled with the Biohazard warning symbol in fluorescent orange or orange-red.

- If the specimen could puncture the primary container, the primary container will be placed within a second container that is puncture-resistant in addition to the above characteristics.
- **Autoclaves** are available in some labs, clinics or units for decontamination. Proper use of equipment is essential to ensure sterilization.
- **Transportation** refers to the packaging and shipping of materials by air, land or sea. Transfer refers to the process of exchanging these materials between facilities. When transporting blood or OPIM off site, all federal, state and local regulations for packaging transportation must followed. Please contact DEHS at 852-6670 for further information.
- **Contaminated equipment** will be decontaminated prior to servicing or shipping. Equipment that cannot be decontaminated will be labeled with a biohazard label. When using centrifuges, balanced tubes will be used and procedures immediately implemented to cleanup the equipment if an accidental spill occurs.
- **Plastic or Mylar coated capillary tubes** will be used instead of glass capillary tubes.

Needle Stick and Sharps Safety*

The supervisor/PI who has employees with direct patient contact must consider and, where appropriate, use effective engineering controls, including safer sharps devices or needleless systems for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments. This includes:

- Establish a program for evaluating safer sharps devices designed to eliminate or minimize occupational exposure. This program should include an identification process, an evaluation process and a selection process.
- Review the sharps that are being used on an annual basis.

Note: An appropriate safer sharps device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated.

The PI or supervisor must identify all sharp devices that have available products with safer engineering features and determine which products are to be evaluated. Consider products including syringes, scalpels, IV access devices, IV medication connectors, vacuum tube collection systems, dental syringes, lancets, capillary tubes, and other common sharps equipment.

In groups that have direct patient care, the PI or responsible supervisor alone cannot evaluate and select the safer sharps devices. Supervisors must choose non-managerial employees who perform tasks using the sharps also to be involved in this process:

Name	Job Title/Classification

- The PI or supervisor should encourage each evaluator to use evaluation forms. The Centers for Disease Control and Prevention (CDC) have sample screening and evaluation forms available.

- The PI or supervisor will be responsible for the completed sharps evaluation forms.
- If there is no safer option for a particular sharps device used where there is exposure to blood or OPIM, you are not required to use something other than the device that is normally used. This information must be documented. During your annual review of devices, you must inquire about new or safer options.

Once the evaluation process is complete and the safer sharp device has been chosen, the PI or supervisor must implement use of the safer sharps devices as soon as possible. The selection and implementation process cannot be postponed in order to use up supplies of non-safer sharps. Additionally, when the safer sharps are in place, supplies of the non-safer sharps may not be used.

The review and update of the Exposure Control Plan must reflect innovations in procedure and technological developments that eliminate or reduce exposure to bloodborne pathogens. This includes, but is not limited to, newly available sharps devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens.

The following web sites provide additional information on the Needlestick Safety Act, Needlestick injury prevention and available Sharps Safety Devices.

- How to Prevent Needle Stick Injury: [Bloodborne Pathogens - Overview](#)
- List of safety-engineered sharp devices and other products designed to prevent occupational exposures to bloodborne pathogens:
<https://www.cdc.gov/nora/councils/hcsa/stopsticks/safersharpdevices.html>

The PI or supervisor is responsible for maintaining and replacing engineering controls as necessary to ensure their effectiveness.

- Check that there is an adequate stock of supplies (e.g. sharps containers, red bags, gloves)
- Check the fill level of sharps containers and replace filled containers with new ones
- Check the fill level of infectious waste containers and appropriately close or seal containers when no more than $\frac{3}{4}$ full.
- Ensure controls are adequate for existing and new work tasks and infectious materials.
- Ensure controls are readily accessible to affected employees.
- Implement alternative controls if necessary (e.g. provide antiseptic towels or waterless antiseptic agents if no handwashing facility is available, provide secondary container if outside of primary is soiled or for transport).

PI or Responsible Supervisor	
Sharps Used in this Lab	
Safety Devices Available/Acceptable	
Date of Evaluation	

Work Practice and Administrative Controls

Work practice controls are behavioral means of reducing an individual's exposure potential by following established rules, procedures, or guidelines associated with a particular work task. Safe work practices used in conjunction with engineering controls and PPE may substantially decrease an individual's risk of incurring an exposure to blood or OPIM.

All employees must adhere to the following work practice controls:

- **Observe Universal/Standard Precautions** at all times. (See section 3. A. above)
- **Washing hands** with soap and water for at least fifteen seconds is required immediately after any exposure, and as soon as possible after removal of gloves or other personal protective equipment. If employees incur exposure to skin, wash those areas with soap and water.
- **Exposures to eyes or mucous membranes** require flushing with water.
- **Antiseptic towels or other waterless hand cleaners/disinfectants** may be used if handwashing facilities are not feasible for a particular situation. If these temporary alternatives are used, wash hands with soap and running water as soon as feasible.
- **Needles and sharps** will not be bent, recapped, removed, sheared or purposely broken. Needles and other sharps will be discarded into approved sharps containers. Recapping is permitted only if no other means are feasible and a mechanical device or one-handed technique is used.
- **Personal Protective Equipment** will be removed immediately upon leaving the work area. Lab coats, used as PPE, must not be worn outside the work area. Items visibly contaminated or likely to be contaminated with blood, OPIM, or infectious agents are to be discarded in infectious waste containers. Items that meet the definition of Regulated waste (see Section 3, Waste Disposal) are to be disposed in infectious waste containers.
- **Eating, drinking, applying cosmetics, and handling contact lenses** are prohibited in work areas where there is a possibility of occupational exposure. Food and beverages will not be stored in refrigerators, freezers, counters or bench tops where blood or OPIM are present.
- All procedures involving blood or OPIM will be conducted in a manner **minimizing spraying, splashing or generation of droplets.**
- **Post BIOHAZARD signs or labels** at entrances to work areas, refrigerators, freezers, fume hoods, biosafety cabinets, etc. where blood or OPIM is used or stored
- Consider **needleless systems or sharps with engineered sharps injury protectors** and use to the extent feasible for the collection of bodily fluids or withdrawal of body fluids, accessing a vein or artery, or administering medications or other fluids.

Personal Protective Equipment

Personal Protective Equipment (PPE) is specialized clothing or equipment worn by a worker for protection against a hazard. When there is a risk of occupational exposure to Bloodborne Pathogens, PPE is an effective means of protection when the proper type is used and its integrity maintained. PPE such as, but not limited to gloves, gowns, aprons, surgical caps, foot covers, lab coats, face shields, masks, and respirators will be provided to employees as appropriate.

All personal protective equipment (PPE) used will be provided, at no cost to the employees.

PPE is chosen based on the anticipated exposure. The PPE will be considered appropriate only if it does not permit blood or OPIM to pass through or reach the employee's clothing, skin, eyes, mouth, or mucous membranes under normal conditions of use and for the duration of time the PPE will be used.

At a minimum, individuals working with BBP will wear a lab coat & gloves while handling or processing blood or OPIM. Tasks or procedures that may produce aerosols, if not performed in a biosafety cabinet, require the use of appropriate face protection: a surgical mask with safety glasses or glasses with either side shields, or chin length face shield.

Employees exhibiting dermatitis, allergy or sensitivity to normally provided gloves will be provided with hypoallergenic, powder-free gloves or gloves of an alternative, equally protective material.

The Principal Investigator, or supervisor is responsible for ensuring that PPE in appropriate sizes is readily accessible to all employees and will ensure there is an adequate stock of supplies and PPE. The supervisor or PI must train all employees in the proper selection, use, limitations, donning and doffing, cleaning, and disposal of PPE that is appropriate for the tasks they will perform.

All employees must adhere to the following precautions when wearing PPE:

- Contaminated PPE will be removed as soon as possible.
- All PPE must be removed prior to leaving the work area, whether contaminated or not. This is especially important for gloves, since they are generally assumed to be contaminated. When disposable gloves are removed, they must be discarded in Biohazard containers.
- Gloves are worn when employees may have hand contact with blood, OPIM, mucous membranes or non-intact skin, or contaminated items or surfaces.
- Gloves must be replaced as soon as possible if they are torn, punctured, or when their ability to function as a barrier is compromised.
- Gloves must not be worn to transport blood or OPIM outside the work area, as a means to prevent skin contact. Instead, the primary container is placed in a clean secondary container for transport, making gloves unnecessary.
- Disposable gloves may only be used once. Gloves will be discarded when removed. They are not to be washed or decontaminated for re-use.
- Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are torn or punctured.
- Lab coats and other washable PPE must be laundered either by a laundry service or on-site, by machine using regular settings and detergent and bleach. These items and other contaminated garments must not be sent home with the employee for cleaning.
- Street clothes are not considered PPE. Scrubs are usually worn in a manner similar to street clothes; therefore, street clothes and scrubs should be covered by appropriate gowns, aprons or lab coats when splashes to the skin or clothes are reasonably anticipated.

Housekeeping*

Proper and routine cleaning and decontamination of work areas is an integral part of preventing environmental transmission of bloodborne pathogens.

The Principal Investigator or supervisor will ensure work areas will be maintained in a clean and sanitary condition. A written schedule for cleaning and methods of decontamination based on the location, type of surface to be cleaned, type of soil present, and the tasks or procedures done in the area will be implemented.

All employees must adhere to the following practices of housekeeping and infection control:

- **Protective coverings** such as imperviously backed absorbent paper, plastic wrap or aluminum foil used to cover equipment and environmental surfaces will be removed and replaced as soon as feasible after contamination.
- **Inspect regularly all bins, pails, cans,** and similar receptacles intended for reuse that may become contaminated. Receptacles will be cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
- **Broken glassware** that may be contaminated must never be picked up by hand. Mechanical means such as forceps, tongs, or dustpan and broom must be used. Tools used in cleanup must be properly disinfected or discarded. The broken glass must be placed in a sharps container.

Work Surfaces

Work surfaces and equipment will be cleaned and decontaminated at the completion of procedures, as soon as possible after contact with blood or OPIM, and at the end of the work shift if they may have been contaminated during the shift.

Appropriate Disinfectant

Cleaning of contaminated work surfaces after completion of procedures ensures that employees are not exposed to blood or OPIM remaining on a surface. Appropriate disinfectants include a diluted bleach solution and EPA registered tuberculocides (List B), and products registered against HIV/HBV (List D). OSHA Instruction CPL 2-2.69 (Nov. 19, 2001) does not include 70% alcohol among “appropriate disinfectants” and may not be used as a sole disinfectant.

Under this standard, OSHA has interpreted that, to decontaminate contaminated work surfaces, either an EPA-registered hospital tuberculocidal disinfectant or an EPA-registered hospital disinfectant labeled as effective against human immunodeficiency virus (HIV) and hepatitis B virus (HBV) is appropriate. Hospital disinfectants with such HIV and HBV claims can be used, provided surfaces are not contaminated with agents or concentration of agents for which higher level (i.e., intermediate-level) disinfection is recommended. In addition, as with all disinfectants, effectiveness is governed by strict adherence to the label instructions for intended product use.

The lists of the EPA Registered products are available from the EPA website:

<https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>

The EPA lists contain the primary registrants' products only. The same formulation is frequently repackaged and renamed and distributed by other companies. These renamed products will not appear on the list, but their EPA Registration number must appear on the label.

The following is just a sample of some commercially available disinfectants and is not meant to be a comprehensive list. Please consult the university stock room and other vendors for these and other "appropriate disinfectants".

- Bleach (Clorox) Solution (5.25% available chlorine in a 1/10 or 1/100 dilution in water)
- CiDecon Detergent Disinfectant (Decon Laboratories, Inc.)
- BDD Backdown (Decon Laboratories)
- Cavicide (Metex Research Corp.)
- Sani-Cloth (PDI)
- Amphyl (Reckitt Benckiser)
- Envirocide (Metex Research Corp.)

Any of the above mentioned products are considered effective when used according to the manufacturer's instructions provided the surfaces have not become contaminated with agents or volumes of concentrated agents for which a higher level of disinfection is recommended.

Spills

Spills must be cleaned up immediately. Use personal protective equipment (PPE) appropriate to prevent BBP or OPIM from coming in contact with your hands, mucous membranes, non-intact skin or penetrating protective clothing. For most spills, a lab coat or disposable gown and gloves should be sufficient.

Clean up and absorb liquid material with paper towels or other absorbent materials to prevent spill from spreading. Use tongs or similar device to pick up broken glassware or sharps and dispose in sharps container. Discard paper towels used to soak up spill in biohazard container, and any broken glass in a sharps container. Most organic material must be cleaned before disinfecting the area.

Disinfect spill area by first laying absorbent material over spill area, and then gently adding a 10% bleach solution or other "appropriate disinfectant" and allowing it soak for the required contact time (15-20 min. for bleach or see manufactures recommended contact time). Wash your Hands. After contact time has elapsed, wipe area with water or cleaning solution if indicated. Wash your hands. If you have a question about a biohazard spill, call DEHS at 852-6670. If this is an emergency call DPS at 852-6111.

The following table is a schedule of cleaning and decontamination based upon the specific research activities for this lab. At a minimum, work surfaces and equipment that come in contact with Blood or OPIM will be cleaned and disinfected at the completion of procedures and immediately or as soon as possible after a spill.

Surface	Disinfectant	Schedule (end of day, after completion of work, etc.)
General bench/lab surfaces		
Biosafety cabinet/fume hood		
Centrifuge		
Fridge/freezer		
Other equipment		

Regulated Waste Disposal

Regulated waste is defined by OSHA as liquid or semi-liquid blood or OPIM; contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM capable of releasing these materials during handling; contaminated sharps; all needles and syringes regardless of their use; and pathological and microbiological wastes. All employees will adhere to the following when disposing Regulated Waste:

- Immediately after use, sharps will be disposed of in closable, puncture resistant containers that are leak proof on sides and bottom, and labeled or color-coded (see Section 6 for label requirements).
- Sharps containers will be replaced routinely and not allowed to overfill.
- Reusable sharps containers will not be opened, emptied, or cleaned manually in a manner that would expose employees to the risk of percutaneous injury. Employees may NOT place their hands into containers whose contents include reusable sharps.
- All regulated waste must be segregated, packaged and discarded in accordance with the policies outlined in the University of Louisville Disposal Guide for Infectious Medical Waste. It is the responsibility of the department, or laboratory generating regulated waste to comply with these guidelines, and provide the appropriate packaging material (i.e. sharps containers and orange/red Biohazard bags).

Contaminated Laundry

The department, PI or supervisor is responsible for providing laundry services for contaminated lab coats, other contaminated re-usable garments, and any other contaminated non-disposable laundry items.

- Laundry contaminated with blood or OPIM will be handled as little as possible. Such laundry will be placed in appropriately marked bags (red bags) at the location where it is used.
- All employees who handle contaminated laundry will use appropriate PPE (gloves).
- Disposable articles may be used when feasible to reduce the generation of contaminated laundry.
- Laundry items should not be rinsed prior to being placed in laundry bags.
- Should employee owned clothing be contaminated, laundry services will also be provided. Home laundering of personal protective equipment or contaminated clothing is not permitted.

Labels and Signs

The PI or supervisor is responsible for ensuring labels and signs are available and posted as necessary to ensure adequate information is provided to workers and visitors entering the work area.

- Labels shall be affixed to containers of regulated waste, sharps containers, refrigerators, freezers, or other containers used to store, transport, or ship blood or OPIM.
- Red bags or containers may be substituted for labels as appropriate.
- Contaminated equipment will be labeled indicating contaminated surfaces and areas.
- The required labels will include the International Biohazard Symbol and BIOHAZARD written under the symbol.



- The labels will be fluorescent orange or orange-red with the letters and symbols in a contrasting color (Black).
- Labels will be affixed as close as feasible to the container, in a way that prevents their loss or unintentional removal.

Hepatitis B Vaccination Program

The Principal Investigator, or responsible supervisor, must ensure all employees identified as having occupational exposure to blood or OPIM are offered the Hepatitis B vaccine, at no cost to the employee, within 10 working days of assignment to a job with potential exposure.

- The PI or supervisor will have the employee complete the **Hepatitis B Vaccine Offer Form**, and will maintain a copy of the form. The form requires the employee to choose one of three options:
 - **Option A:** the employee elects to receive the vaccine at this time, at no cost to them.
 - **Option B:** is the OSHA declination statement, indicating the employee declines the vaccine at this time, but may elect to receive the vaccine at no charge if they continue to have occupational exposure.
 - **Option C:** the employee has been previously vaccinated or is unsure of vaccine status.

Accepting the Hepatitis B Vaccine and Titer Check

Supervisors must ensure that employees choosing to receive the hepatitis B vaccine or titer check, report to the Health Services Office within the 10 working day period.

Employees opting to receive the vaccine or titer check are to report to the Belknap or HSC Health Services Office within 10 working days. Employees will be provided with additional information about the vaccine, and will be provided the vaccine after a medical evaluation and signing a consent form. The vaccine will be provided in accordance with current US Public Health Service Centers for Disease Control Guidelines current at the time. Currently, the vaccine is given in a three dose series, followed by a titer check. A booster dose is not recommended at this time. Vaccine records, titer checks and all medical records will be maintained in the

Health Services Office. The vaccine is not mandatory, but is strongly encouraged, unless the employee has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

All employees are strongly encouraged to be vaccinated against Hepatitis B virus if their work may expose them to blood/OPIM including human cells, tissue cultures, blood products, or blood components.

Vaccines are provided on a walk-in basis. The Hepatitis B vaccination is available through:

UofL HSC Health Services Office
UofL Outpatient Care Center
401 East Chestnut Street, Suite 110
502-852-6446

UofL Belknap Health Services Office
Cardinal Station Center
215 Central Avenue, Suite 110
502-852-6479

The Health Service Office (HSO) requests the following when referring employees for immunizations.

- The employee must bring their UofL Employee ID number
- The Department or the employee's supervisor must provide the employee with a method of payment:
 - The PI's or Supervisor's UofL Procurement Card, or
 - A letter on departmental letterhead, stating the cost of the services will be covered by the Dept., PI, or Supervisor, and include the Procurement Card billing information, or
 - The department or the employee's supervisor must provide the employee with a letter on department letterhead stating that the cost of the services will be covered. This letter should include a mail address, phone number, and contact name.
- The Health Services Office no longer accepts IUT's;
- The employee must actually report to either one of the Health Services Offices to receive the Hepatitis B Vaccine series and the titer check (proof of immunity). Vaccines and titer checks are provided on a walk-in basis during normal office hours, or appointments can be arranged for groups by calling the Health Services Office. Supervisors and PIs are ultimately responsible for ensuring employees initiate and complete the vaccine series and titer check as required.
- Call the Health Sciences Center Health Services Offices at 852-6446 or Belknap Health Services Office at 852-6479 for additional information

Declination of the Hepatitis B Vaccine

The Principal Investigator or supervisor will ensure employees who decline the Hepatitis B vaccine sign the prescribed Declination Statement, as stated below and included in Option B in the Hepatitis B Vaccine Offer form.

The Principal Investigator or responsible supervisor must ensure that if an employee initially declines the Hepatitis B vaccine, but decides to accept it at a later date while still covered under the standard, the vaccine will be made available at that time at no cost to the employee.

Declination Statement: I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially

infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Post Exposure Evaluation and Follow Up

Any University of Louisville employee who sustains an occupational exposure (needle/instrument stick, splash exposure to mucous membranes, or exposure to cut or non-intact skin) will be provided post exposure evaluation and follow-up at no cost to the employee. The PI or responsible supervisor must ensure employees are not dissuaded from reporting or seeking medical evaluation for a Bloodborne Pathogens exposure incident. Contact information should be readily available in the work area at all times.

The Public Health Service currently recommends that evaluation be undertaken immediately, so that treatment prophylaxis, if indicated, can be started preferably within 1-2 hours post exposure.

Employees who experience a needle stick or other occupational exposure are to do the following:

- Clean the area involved thoroughly with soap and water. For splash to eyes, mouth or nose, flush with copious amounts of water.
- Notify their supervisor immediately. Supervisor completes the First Report of Injury available from the University of Louisville Department of Risk Management.
- Supervisor or employee should call the Health Service Office (852-6446) and notify them of the incident
- Go to the Health Service Office for initial evaluation, laboratory screening and follow-up treatment.

UofL HSC Health Services Office
UofL Outpatient Care Center
401 East Chestnut Street, Suite 110
502-852-6446

UofL Belknap Health Services Office
Cardinal Station Center
215 Central Avenue, Suite 110
502-852-6479

For further information on Workers Compensation for Bloodborne Pathogen Exposures, please contact the **Office of Risk Management** at 852-6925.

The Health Services Office will provide a confidential medical evaluation and follow-up including:

- Documentation of the route of exposure and circumstances related to the incident and HBV and HIV antibody status of the source (if known).
 - If the source person can be determined and permission is obtained, collection and testing of the source person's blood will be done to determine the presence of HIV or HBV. These results will be forwarded to the Physician. In laboratories, most sources will not be individuals. Potential sources include tissue samples, pooled blood, cell cultures, blood products and blood components.
- The employee will be offered the option of having their blood collected for testing of HIV/HBV status. Testing may be done at the time of exposure, or the blood sample will be preserved for up to 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline tested, such testing will be done as soon as feasible.

- The employee will be offered post exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service. The HSC Health Services Office will follow an approved protocol for evaluation, testing, treatment, counseling, and follow-up.
- The employee will be given appropriate counseling concerning precautions to take during the period after the exposure incident. The employee will be advised to report to the physician any febrile illness, flu-like symptoms, rash, lymphadenopathy, or other illness within 12 weeks of the incident.
- During the follow-up period after the exposure, exposed persons will be advised to follow the Public Health Service recommendations for preventing transmission of infectious agents.
- The employee should contact the HSC Health Services Office or the physician with any questions or concerns.
- Documentation of each incident and associated records will be kept in a central location in the HSC Health Services Office with limited access and strict confidentiality maintained.
- During all phases of the follow-up, confidentiality of the employee will be protected.

Healthcare Professional's Written Opinion

After the consultation, the HSC Health Services Office will furnish a copy of the written opinion to the exposed employee within 15 days of the evaluation. The written opinion will be limited to:

- Whether the Hepatitis B vaccination is indicated for the employee
- Whether the employee has received the Hepatitis B vaccination
- Confirmation that the employee has been informed of the results of the evaluation
- Confirmation that the employee has been told about any medical conditions resulting from the exposure incident, which require further evaluation or treatment

All other findings or diagnoses will remain confidential and will not be included in the written opinion.

Employees Routinely Working at Non-University Facilities

Some University employees that routinely work in Non-University hospitals or facilities, and experience an exposure incident may have the option to have their initial labs drawn or have the initial post-exposure evaluation conducted at that non-University facility. In these situations, the department, supervisor or PI is responsible for verifying the specific procedures and ensuring their employees are informed.

In addition to being seen at the non-University facility, the employee must report to the University HSC Health Services as soon as possible and complete all required paperwork.

Information and Training

The Principal Investigator, or supervisor is responsible for ensuring that all employees with occupational exposure receive Bloodborne Pathogens training at the time of initial assignment to tasks where exposure may take place, and annually thereafter. Bloodborne Pathogens training has of two components:

- Site Specific training provided by the supervisor or PI
- University specific training provided by DEHS

Site Specific Bloodborne Pathogens Training

The PI or supervisor is responsible for providing training in specific tasks and procedures relating to the employees occupational exposure to bloodborne pathogens. This training must include:

- An explanation of the Site Specific Exposure Control Plan, the employee must be provided with adequate time to read it, ask questions and acknowledge comprehension
- The specific use and limitation of appropriate PPE, its location, accessibility
- An explanation of the engineering controls and work practice controls used in the work area to eliminate or reduce the risk of exposure to bloodborne pathogens
- Instruction in the procedures and contacts in case of a spill or emergency involving blood or OPIM
- An explanation of the site specific procedures for provision of Hepatitis B Vaccine and post exposure evaluation and follow-up

If changes occur in tasks or procedures that may affect the employees' exposure, the PI or supervisor is responsible for providing timely training in those areas. The training records must be maintained by the department, PI, or supervisor for 3 years.

General Training

University Bloodborne Pathogens Training Classes

The course is required for all university employees who may have occupational exposure to human blood, body fluids, tissues or other potentially infectious materials (OPIM) including human cell lines. The course, in conjunction with the site-specific training given by the supervisor, meets the OSHA training requirements. The University Bloodborne Pathogens Training is available in an online format.

On-Line Training: DEHS has developed an on-line training course to assist employees meet the Bloodborne Pathogens training requirements. This training is primarily designed as refresher training for those who have previously taken the University Bloodborne Pathogens training, or are familiar with the OSHA requirements from previous experience. Upon successful completion of the course, the employee will be able to print a certificate, a copy of which must be given to the supervisor or PI. Questions and comments regarding the on-line training may be directed to DEHS at 852-6670.

The Bloodborne Pathogens training program consists of the following elements:

- Availability of the Bloodborne Pathogens Standard and explanation of its contents
- A general explanation of the epidemiology and symptoms of bloodborne diseases
- An explanation of the modes of transmission of bloodborne pathogens
- An explanation of this individualized Exposure Control Plan including location and availability of copies
- Appropriate methods for recognizing tasks and other activities that may involve exposure to blood or OPIM.
- An explanation of the use and limitations of exposure controls including engineering controls including sharps safety devices, work practices, and personal protective equipment
- Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment
- An explanation of the basis for the selection of personal protective equipment

- Information on the Hepatitis B vaccine including its efficacy, safety, method of administration, benefits and how to receive the vaccine at no cost to the employee
- Actions to take and persons to contact in case of a spill or other emergency involving human blood or OPIM
- The procedures to follow if an exposure incident occurs, including procedures for reporting and the medical follow-up that will be made available
- Information of the post exposure evaluation and follow-up that will be provided following an exposure incident
- Explanation of the signs, labels, and color-coding

An opportunity for interactive questions and answers with the person conducting the training program will be provided. Those people conducting the training must be knowledgeable in the OSHA Bloodborne Pathogens Standard, the unit's Exposure Control Plan, and the elements contained in the training program as they relate to the unit.

Direct requests for training assistance to DEHS at 852-6670.

Recordkeeping

Accurate recordkeeping is essential for compliance and is the responsibility of the PI or supervisor. In addition, The Department must develop a plan to ensure the continuity of all recordkeeping when a supervisor leaves or is reassigned.

- **Medical records** will be established and maintained for each employee who has an occupational exposure incident. These records will be maintained in the University HSC Health Services Office. These records are maintained for at least the duration of the individual's employment plus 30 years.
- **Sharps safety log** is maintained by DEHS for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log is recorded and maintained in such manner to protect the confidentiality of the injured employee and is kept for a minimum of 5 years. The sharps injury log includes the following information:
 - The type and brand of device involved in the incident
 - The department or work area where the exposure incident occurred
 - An explanation of how the incident occurred
- **Training records** must be retained for 3 years. These records will be established at the time of training and maintained by the Principal Investigator or responsible supervisor. These are important compliance records and must be maintained by the supervisor or designee for the duration of employment of each individual receiving the training. DEHS also maintains training files for online and classroom training.
- **Hepatitis B Vaccine Offer Form** is not a medical record and will be provided and maintained by the PI or responsible supervisor for the duration of the employee's employment with the unit plus 3 years. All employees identified as having an occupational exposure to bloodborne pathogens must complete this form. These are important compliance records and must be maintained.

Definitions

For the purpose of this plan, the following definitions will apply:

Blood: human blood, human blood components, and products made from human blood. The term “human blood components” includes plasma, platelets, and serosanguinous fluids (e.g. exudates from wounds). Also included are medications derived from human blood, such as immune globulins, albumin, and factors 8 and 9.

Bloodborne Pathogens: 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) human immunodeficiency virus (HIV) and hepatitis C virus (HCV). While HBV and HIV are specifically identified in the standard, the term includes any pathogenic microorganism that is present in human blood or OPIM and can infect and cause disease in persons who are exposed.

Clinical Laboratory: a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

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

Contaminated Laundry: laundry that has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps: any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, scissors, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination: the 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 transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Engineering Controls: controls (e.g. sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems.) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident: a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an employee’s duties. “Non-intact skin” includes skin with dermatitis, hangnails, cuts, abrasions, chafing, acne, etc.

Handwashing Facilities: a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional: a person whose legally permitted scope of practice allows him or her to independently perform the activities required by the Hepatitis B Vaccination and post-exposure Evaluation and Follow-up section of this plan.

HBV: hepatitis B virus.

HIV: human immunodeficiency virus.

Occupational Exposure: reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of any employee’s duties.

Other Potentially Infectious Materials (OPIM): the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, all body fluids in situations where it is difficult or impossible to differentiate between body fluids, Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. Included are human cells, tissue cultures, and blood products and blood components containing known or suspected bloodborne pathogens, unless documented to be free of human bloodborne pathogens.

Needleless Systems: a device that does not use needles for:

- (1) The 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 due to percutaneous injuries from contaminated sharps.

Parenteral: piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment: specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g. uniforms, pants, shirts, or blouses) are not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility: a facility engaged in industrial-scale, large volume or high concentration production of HIV or HBV.

Regulated Waste: liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi liquid state 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; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory: a laboratory producing or using research laboratory scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protectors: a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or 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 may be a source of occupational exposure to the employee. Examples include, but are not limited to hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize: the use of physical or chemical procedures to destroy all microbial life including highly resistant bacterial endospores.

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

Work Practice Controls: controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g. prohibiting recapping of needles by a two-handed technique).