

**SAINT LOUIS UNIVERSITY
EXPOSURE CONTROL PLAN FOR BLOODBORNE PATHOGENS**

POLICY

Saint Louis University is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following Exposure Control Plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA Standard 29 CFR 1910.1030, “Bloodborne Pathogens.”

PURPOSE

This policy is intended to prevent potential exposure of employees and visitors to blood borne pathogens whenever possible. The Saint Louis University Blood Borne Pathogen Exposure Control Plan is applicable to all divisions of the University that do not have a written plan in effect. This document is not intended to supersede any plan now in effect so long as that plan meets the requirements of OSHA and other applicable regulatory agencies.

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SECTION 1: DEFINITIONS

(Consistent with OSHA Standard 29CFR 1910.1030)

The following definitions are used:

“Blood” means human blood, human blood components, and products made from human blood.

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

“Clinical laboratory” means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

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

“Contaminated laundry” means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

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

“Decontamination” means 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.

“ECP” means Exposure Control Plan – this document.

“Employee” means any Saint Louis University faculty, staff, student, or volunteer.

“Engineering Controls” means controls (e.g., sharps disposal containers, self-sheathing needles, sharps with engineered sharps safety features, biosafety cabinets, etc.) that isolate or remove the bloodborne pathogens hazard from the workplace.

“Exposure Incident” means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee’s duties.

“Handwashing facilities” means a facility providing an adequate supply of running potable water, soap and single use towels or hot-air drying machines.

“HBV” means hepatitis B virus.

“HCV” means hepatitis C virus.

“HIV” means human immunodeficiency virus.

“IBC” means Institutional Biosafety Committee.

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

“**OPIM**” means other potentially infectious materials; see “Other Potentially Infectious Materials”.

“**Other Potentially Infectious Materials**” means:

- (1) 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, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- (2) Any unfixated tissue or organ (other than intact skin) from a human (living or dead);
- (3) All human derived cell cultures, including well established cell lines as described within Section 2 of this plan; and
- (4) HIV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV, HBV, or HCV.

“**Parenteral**” means piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

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

“**PPE**” means personal protective equipment; see “Personal Protective Equipment”.

“**Production facility**” means a facility engaged in industrial-scale, large-volume or high concentration production of HIV, HBV, or HCV.

“**Regulated Waste**” means 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**” means a laboratory producing or using research-laboratory-scale amounts of HIV, HBV or HCV. Research laboratories may produce high concentrations of HIV, HBV or HCV but not in the volume found in production facilities.

“**Source Individual**” means 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.

“**Standard Precautions**” refers to the general concept that all patients and all laboratory specimens should be handled as if they were infectious, capable of transmitting disease.

“**Sterilize**” means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

“**Universal Precautions**” is 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, HCV and other bloodborne pathogens.

“**Work Practice Controls**” means 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).

SECTION 2: POLICY ON THE USE OF HUMAN CELL LINES FOR LABORATORY PERSONNEL

Introduction

Human cell lines are commonly used in biomedical research, yet appropriate biosafety requirements for handling human cell lines are often subject to debate within the scientific community. In order to clarify the University's position on this matter, the Institutional Biosafety Committee has created the following policy.

Background

In 1991, the Occupational Safety and Health Administration (OSHA) issued the Bloodborne Pathogens (BBP) Standard to protect employees who have occupational exposure to human blood or other potentially infectious materials. While human blood, most body fluids, unfixed human tissues and organs were clearly included within the scope and application of the standard, the inclusion of human cell lines was ambiguous.

In 1994, OSHA issued an [interpretation](#) of the applicability of the BBP Standard towards human cell lines. According to the interpretation, human cell lines are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis viruses, HIV, Epstein-Barr virus, papilloma viruses and other recognized bloodborne pathogens.¹ In alignment with this interpretation, the American Type Culture Collection (ATCC) [recommends](#) that all human cell lines be accorded the same level of biosafety consideration as a cell line known to carry HIV or hepatitis virus.² Moreover, the Sixth Edition of the CDC publication, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, recommends that at a minimum, human and other primate cells be treated as potentially infectious and handled using Biosafety Level 2 (BSL2) practices, engineering controls, and facilities. Higher containment must be considered for cell lines harboring Risk Group 3 (RG3) and RG4 pathogens as indicated by the risk assessment.³

In consideration of the aforementioned regulatory interpretation and consensus guidelines and other factors, the Saint Louis University Institutional Biosafety Committee has adopted the following policy in regard to the use of human cell lines.

Policy

All cell and organ cultures of human origin, including well established cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL2) containment.

References

1. OSHA Letter of Interpretation: [VIEW URL](#)
2. American Type Culture Collection Frequently Asked Questions: [VIEW URL](#)
3. Biosafety in Microbiological and Biomedical Laboratories, 6th Edition, June 2020 URL: [VIEW URL](#)

SECTION 3: PROGRAM ADMINISTRATION

Task	Responsible Dept. and Contact Info.
Implementation of the ECP	Environmental Health and Safety, Employee Health, Human Resources
Maintain, review, and update the ECP at least annually and whenever necessary to include new or modified tasks and procedures*	Institutional Biosafety Committee/IBC Subcommittee: Saint Louis University, 1402 S. Grand Blvd., Caroline Bldg. Rm. 305, St. Louis, MO 63104. Phone No.: 314-977-6888
Maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard	Laboratory/Clinical Managers, Supervisors, Principal Investigators (P.I.s)
Ensure that all medical actions required are performed	Medical Director, Employee Health: Saint Louis University, 3655 Vista Avenue, West Pavilion Suite 116, St. Louis, MO 63110-2539. Phone No.: 314-257-8400
Responsible for making the written ECP available to employees, OSHA, and NIOSH representatives	Environmental Health and Safety: Saint Louis University, 1402 S. Grand Blvd., Caroline Bldg. Rm. 305, St. Louis, MO 63104. Phone No.: 314-977-6888
Appropriate OSHA records regarding needle stick injuries are maintained	SLU Risk Management: 3545 Lindell Blvd., Wool Center, St. Louis, MO 63103. Phone No.: 314-977-2633
Ensure that appropriate Employee Health records are maintained	Employee Health: Saint Louis University, 3655 Vista Avenue, West Pavilion Suite 116, St. Louis, MO 63110-2539. Phone No.: 314-257-8400
Supply post-exposure evaluation written opinion to employee	
Responsible for training and documentation of training via Skillsoft	Human Resources: 3545 Lindell Blvd., Wool Center, St. Louis, MO 63103. Phone No.: 314-977-2266

***Note: On an annual basis, the Institutional Biosafety Committee or a sub-committee meets to review, revise, and approve the ECP to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. Revisions shall also reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens. This is accomplished by review of employee exposure incidents to determine those tasks and procedures most commonly associated with employee exposures, by review of the CDC websites dealing with occupational health and safety (e.g., <https://www.cdc.gov/workplacehealthpromotion/tools-resources/workplace-health/occupational-safety.html>), and the OSHA website, and commercial websites such as SAFENEEDLE.org which highlights products and devices designed to eliminate or minimize occupational exposure in the workplace.**

SECTION 4: EMPLOYEE EXPOSURE DETERMINATION

(Note: The job classifications listings described in this section are currently under review. Updates to Appendices A and B will be included in the next update of the ECP and a new revision date assigned.)

As stated in the BBP Standard, each employer who has employees with occupational exposure to bloodborne pathogens, or other potentially infectious materials is required to prepare an exposure determination which states the job classification in which:

1. All employees in that job classification have occupational exposure:

See Appendix A

2. Some employees in the job classification have occupational exposure (Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals):

See Appendix B

SECTION 5: METHODS OF IMPLEMENTATION AND CONTROL

1. General

All employees are educated regarding the requirements of the OSHA Blood Borne Pathogen (BBP) Standard **prior** to assuming any duties, which have the potential of exposure to blood and body fluids or other potentially infectious materials. Employees that work in a laboratory will receive BBP awareness training during their initial Laboratory Compliance Training. It will also be reviewed in their annual refresher training. The awareness training will allow the employee to become familiar with the additional training required for work with BBP's. At-Risk employees who do not work within a laboratory will receive notification that the BBP training is available via interoffice communications.

Skillsoft: is an on-line computer-based training program used by various departments throughout the University to train employees. The [BBP training module](#) is a component of Skillsoft and is accessible from any computer that has access to an internet service provider. The instruction includes training specific to the Saint Louis University Exposure Control Plan, Universal Precautions, Engineering Controls, Personal Protective Equipment (PPE), Hand Hygiene and Personal Hygiene. Included is an explanation of the epidemiology and symptoms of blood borne diseases, an explanation of transmission of these diseases, and the methods for recognizing tasks and other activities that may involve potential exposure to blood borne pathogens.

A Record of BBP training will be documented online. Once an employee has completed Skillsoft BBP program, he/she will be tested by answering a short series of questions designed to assess his or her knowledge of the training that was provided on BBP's. Answers will be graded, and the employee will be provided a certificate of completion for their records. Skillsoft will automatically file the completed BBP test within the individual's HR records. Educational records will be maintained on each employee. Skillsoft will record the dates and contents of the educational sessions.

Skillsoft BBP records will be maintained for 30 years past the employee's last date of employment in the Department of Human Resources (314-977-2360).

2. Work Practice Controls

Work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, engineering controls and personal protective equipment shall also be used.

- A. Saint Louis University shall provide hand washing facilities which are readily accessible to employees.
- B. When provision of hand washing facilities is not feasible, the University shall provide either an appropriate hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. Hands or other skin surfaces that are visibly soiled must be washed with soap and water. Waterless alcohol-based hand hygiene agents are made available as needed.
- C. Saint Louis University shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.
- D. Saint Louis University shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.
- E. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.
- F. Food and drink shall not be kept in refrigerators, freezers, cabinets, or on shelves, countertops, or bench tops where blood or other potentially infectious materials are present.
- G. All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering and generation of droplets of these substances.
- H. Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

3. Engineering Controls

Engineering controls shall be used to eliminate or minimize employee exposure. Work practice controls and personal protective equipment shall also be used. Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

OSHA specifies that “safer medical devices, such as sharps with engineered sharps injury protections and needleless systems” constitute an effective engineering control, and must be used where feasible.

Sharps with Engineered Sharps Injury Protections is a term which includes non-needle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury. This description covers a broad array of devices, including:

- Syringes with sliding sheath that shields the attached needle after use;
- Needles that retract into a syringe after use;
- Shielded or retracting catheters
- Intravenous medication (IV) delivery systems that use a catheter port with a needle housed in a protective covering.
- Devices designed to safety recap needles.

Needleless Systems is a term defined as devices which provide an alternative to needles for various procedures to reduce the risk of injury involving contaminated sharps. Examples include:

- IV medication systems which administer medication or fluids through a catheter port using non-needle connections; and
- Jet injection systems which deliver liquid medication beneath the skin or through a muscle.

Specific engineering controls used are inclusive but not limited to those specified below:

A. Contaminated needles and other contaminated sharps:

- 1) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific procedure.
 - a) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.
- 2) Contaminated needles and other contaminated sharps shall be placed in appropriate containers until properly reprocessed. This must be done immediately or as soon as possible after use. These containers shall be:
 - a) puncture resistant;
 - b) labeled or color-coded in accordance with the BBP Standard as defined in Section 13 of this document;
 - c) leak proof on the sides and bottom; and

- d) used in accordance with the following practice: Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

B. Containers for blood specimens and other potentially infectious materials:

- 1) Containers shall prevent leakage during collection, handling, processing, storage, transport, or shipping.
- 2) Containers shall be labeled or color-coded in accordance with the BBP standard as defined in Section 13 of this document and closed prior to being stored, transported, or shipped. When a department utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with the “BBP Standard” is required when such specimens/containers leave the facility.
- 3) Containers shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of the “BBP Standard” as defined in Section 13 of this document if outside contamination of the primary container occurs.
- 4) Containers shall be placed within a secondary container, which is puncture-resistant in addition to the above characteristics if the specimen could puncture the primary container.

C. Contaminated Equipment: Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless it can be demonstrated that decontamination of such equipment or portions of such equipment is not feasible. The following procedures apply:

- 1) A readily observable label in accordance with the “BBP Standard” as defined in Section 13 of this document shall be attached to the equipment stating which portions remain contaminated.
- 2) The University shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, and prior to handling, servicing, or shipping so that appropriate precautions will be taken.

- D. **Containment Equipment:** Equipment used for containment shall be serviced and maintained according to current regulatory guidelines or accepted standards. The Biological Safety Officer can provide guidance relative to servicing and/or maintaining the equipment.

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

- 1) **Properly maintained class II biological safety cabinets 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 embryonated eggs.
 - b) **High concentrations of 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.

SECTION 6: PERSONAL PROTECTIVE EQUIPMENT (PPE)

1. Provision

When there is a potential for occupational exposure, the University shall ensure, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields, or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices are prescribed. Personal protective equipment will be considered “appropriate” only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

2. Use

The University shall ensure that the employee uses appropriate personal protective equipment unless it was the employee’s professional judgment that it would have posed an increased hazard to the safety of the employee or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

3. Accessibility

The University shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

4. Cleaning, Laundering, and Disposal

The University shall clean, launder, and dispose of personal protective equipment required by the BBP Standard, at no cost to the employee.

5. Repair and Replacement

The University shall ensure that repairs or replacement of personal protective equipment will be made as needed to maintain its effectiveness, at no cost to the employee.

6. Contamination and Removal

If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible. All personal protective equipment shall be removed prior to leaving the work area. When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

7. Gloves

Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, and when handling or touching contaminated items or surfaces. Disposable (single use) gloves such as surgical or examination gloves shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Disposable (single use) gloves shall not be washed or decontaminated for re-use.

Utility gloves (e.g., heavy, rubber, dishwashing gloves) may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

8. Masks, Eye Protection, and Face Shields

Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

9. Gowns, Aprons, and Other Protective Body Clothing

Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopedic surgery, etc.).

SECTION 7: HOUSEKEEPING

1. General

Saint Louis University shall ensure that the worksite is maintained in a clean and sanitary condition. The University shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

All equipment and work surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant, typically freshly prepared 1:9 (10%) total volume bleach solution, with at least a 10 minute wet contact time, followed with 70% ethanol, or a disinfectant with an appropriate EPA label claim showing efficacy:

- A. after completion of procedures;
- B. immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and
- C. at the end of the work shift if the surface may have become contaminated since the last cleaning.

Protective coverings, such as plastic wrap, aluminum foil, or imperviously backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated before use and immediately or as soon as feasible upon visible contamination.

Broken glassware, which may be contaminated, shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dustpan, tongs, or forceps.

SECTION 8: REGULATED WASTE.

1. Contaminated Sharps: Discarding and Containment

Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

- A. closable;
- B. puncture resistant;
- C. leak proof on sides and bottom; and
- D. labeled or color-coded and shall include the legend "Biohazard" and/or display the biohazard symbol. These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

During use, containers for contaminated sharps shall be:

- A. Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries, BSC, vivariums);
- B. Maintained upright throughout use; and
- C. Replaced routinely and not be allowed to overfill.

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

- A. Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
- B. Placed in a secondary container if leakage is possible. The second container shall be:
 - 1) Closable;
 - 2) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
 - 3) Labeled or color-coded in accordance with the primary container.

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

2. Other Regulated Waste Containment

Regulated waste shall be placed in containers, which are:

- A. Closable;
- B. Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
- C. Labeled or color-coded and shall include the legend “Biohazard” and/or display the biohazard symbol. These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.
- D. Compliant with DOT regulations for shipping hazardous waste.
- E. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

If contamination of the regulated waste container exterior occurs, it shall be placed in a second container. The second container shall be:

- A. Closable;
- B. Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
- C. Labeled or color-coded and shall include the legend “Biohazard” and/or display the biohazard symbol. These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.
- D. Compliant with DOT regulations for shipping hazardous waste.
- E. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

SECTION 9: LAUNDRY.

1. General

Contaminated laundry shall be handled as little as possible with a minimum of agitation or tossing.

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded and shall include the legend "Biohazard" and/or display the biohazard symbol. These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color. When a department utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

The University shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded and shall include the legend "Biohazard" and/or display the biohazard symbol. These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

SECTION 10: HIV, HBV, AND HCV RESEARCH LABORATORIES AND PRODUCTION FACILITIES.

1. General

The requirements in this section apply to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV, HBV, and HCV. These requirements apply in addition to the other requirements of the standard. However, this section does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs.

- A. HIV, HBV, and HCV research laboratories and production facilities shall meet the following criteria:

Standard Microbiological Practices:

- 1) All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

Special Practices:

- 1) Laboratory doors shall be kept closed when work involving HIV, HBV, or HCV is in progress.
- 2) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leak proof, labeled or color-coded container that is closed before being removed from the work area.
- 3) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.
- 4) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning signs shall comply with paragraph (g)(1)(ii) of 29 CFR Part 1910.1030 or as defined in Section 11 of this document.
- 5) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

- 6) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the laboratory work area and shall be decontaminated before being laundered.
- 7) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.
- 8) Before disposal, all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.
- 9) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency, and which are checked routinely and maintained or replaced as necessary.
- 10) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only luer-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, recapped in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.
- 11) All spills shall be immediately contained and cleaned up in accordance with the current spill procedure by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.
- 12) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.
- 13) The supervising Principal Investigator shall prepare or adopt a laboratory specific biosafety manual that shall be periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.
- 14) Laboratory doors shall be kept closed when work involving HIV, HBV, or HCV is in progress.

Containment Equipment:

- 1) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.
 - 2) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.
- B. HIV, HBV, and HCV research laboratories shall meet the following criteria:

Safety Equipment:

- 1) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.
 - 2) An autoclave for decontamination of regulated waste or an approved regulated waste box that is collected by a third party shall be available.
- C. HIV, HBV, and HCV production facilities shall meet the following criteria:

Facility Design:

- 1) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.
- 2) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.
- 3) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot,

elbow, or automatically operated and shall be located near the exit door of the work area.

- 4) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.
- 5) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

D. Additional training requirements for employees in HIV, HBV, and HCV research laboratories and production facilities are specified below:

Training Requirements:

- 1) Employees in HIV, HBV, and HCV research laboratory or production facilities shall receive the following initial training:
 - a) The Principal Investigator shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV, HBV, or HCV.
 - b) The Principal Investigator shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV, HBV, or HCV.
 - c) The Principal Investigator shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed.

The Principal Investigator shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

SECTION 11: HEPATITIS B VACCINATION PROGRAM

1. General

- A. Saint Louis University will provide training through Skillsoft to at risk employees on Hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.
- B. The Employee Health department (314-257-8400) will provide Hepatitis B vaccination to employees at no cost at the time of pre-placement physical. If an employee initially declines vaccination, the vaccination would still be available should the employee opt for vaccination at a later date.
- C. This procedure is written to comply with 1910.1030 Occupational Safety and Health Standard – Toxic and Hazardous Substances – Bloodborne Pathogens.

Reference:

CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Post exposure Management. MMWR 2013: 62(10): 1-19.

Healthcare personnel (HCP) who have documentation of a complete 3 dose HepB vaccine series and subsequent post vaccination anti-HBs ≥ 10 mIU/ml are considered hepatitis B immune.

Testing unvaccinated or incompletely vaccinated HCP for quantitative anti-HBs is not necessary and is potentially misleading. Anti-HBs ≥ 10 mIU/ml as a correlate of vaccine induced protection has only been determined for persons who have completed an approved vaccination series.

One of #1 - #4 must be completed.

- 1. HCP provides documentation of completed three shot series and subsequent post vaccination anti-HB ≥ 10 mIU/ml.
- 2. HCP provides documentation of completed three shot series ONLY. Quantitative anti-HBs will be obtained.
- 3. If the HCP is in the process of getting the three-shot series, the series will be completed as appropriate. Subsequent post vaccination quantitative anti-HBs will be obtained.
- 4. If the HCP has not received the vaccine previously, the three-shot series is initiated. Subsequent post vaccination quantitative anti-HBs will be obtained.

5. HCP lacking documentation of HepB vaccinations are considered unvaccinated. The three-shot series is initiated. Subsequent post vaccination quantitative anti-HBs will be obtained.
6. When documentation for some HepB vaccine doses is lacking, HCP are considered incompletely vaccinated. Additional doses to complete a documented HepB series are provided. Subsequent post vaccination quantitative anti-HBs will be obtained.
7. If the HCP does not wish to receive the vaccine, an OSHA Hepatitis B vaccination refusal must be signed. Hepatitis B vaccination is encouraged before refusal is signed.
8. Follow up appointments.
 - a. One month and six-month vaccinations will be scheduled at Employee Health.
 - b. One month to two months following the completion of the three-shot series, quantitative anti-HBs will be scheduled at Employee Health.
 - 1) If quantitative anti-HBs is ≥ 10 mIU/ml, no further action needed.
 - 2) If quantitative anti-HBs is < 10 mIU/ml, a second three shot series is initiated. One month following the completion of the second dose of the three shot series.
 - a) If quantitative anti-HBs is ≥ 10 mIU/ml, no further action is needed.
 - b) If quantitative anti-HBs is < 10 mIU/ml, the HCP is considered a non-responder. HCP will be tested for HBsAg and anti-HBs to determine infection status. The HCP will be counseled regarding precautions to prevent HBV infection and the procedure for post-exposure evaluation in case of exposure to blood or other potentially infectious material. No specific work restrictions are recommended for vaccine non-responders.
9. Follow up testing for existing HCPs: Quantitative anti-HBs testing is done following blood borne pathogen exposures if not previously documented in the Employee Health HCP file.
10. Records of screening and/or vaccination will be maintained in the Employee Health HCP file.

SECTION 12: POSTEXPOSURE EVALUATION AND PROPHYLAXIS

Post-Exposure Evaluation and Prophylaxis

Blood Borne Pathogen Exposure: An exposure is defined as a percutaneous injury, mucous membrane contact, or non-intact skin contact with one of the following: amniotic fluid, blood, cerebrospinal fluid, pericardial fluid, peritoneal fluid, pleural fluid, semen, synovial fluid, tissue, vaginal secretions, or other body fluids containing visible blood. Any direct contact without barrier protection to concentrated HIV in a laboratory facility is considered an exposure. Prolonged contact of several minutes with contaminated blood, tissue, or body fluids involving a large area of intact skin is considered an exposure. Percutaneous injuries may include a needlestick or a cut with a sharp object. Non-intact skin is chapped, abraded or afflicted with dermatitis. Human bites and scratches may be included. In the absence of visible blood in the saliva, exposure to saliva from a person infected with HIV is not considered a risk for HIV transmission. Exposure to tears, sweat, non-bloody urine, or non-bloody feces does not require post-exposure follow up.

HIV Reference:

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis.

Authors: David T. Kuhar, MD; David K Henderson, MD; Kimberly A. Struble, PharmD; Walid Heneine, PhD; Vasavi Thomas, RPh, MPH; Laura W Cheever, MD, ScM; Ahmed Gomaa, MD, ScD, MSPH; Adelisa L. Panlilio, MD and for the US Public Health Service Working Group.

Source: *Infection Control and Hospital Epidemiology*, Vol. 34, No. 9 (September 2013), pp. 875-892.

HBV Reference:

CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. *MMWR* 2013; 62(10): 1-19.

HCV Reference:

CDC. Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus – CDC Guidance, United States, 2020. *MMWR* 2020; 69(6):1-8.

1. IMMEDIATE POST-EXPOSURE MEASURES:

- a. Exposure Site Immediate Care
 - 1) Percutaneous injury:
 - a) Wash the wound with soap and water.
 - b) Antiseptics are not contra-indicated. However, there is no evidence that use of antiseptics for wound care further reduces the risk of HIV/HBV transmission.
 - c) There is no evidence that expressing fluid by squeezing the wound

- further reduces the risk of HIV/HBV transmission.
 - d) The application of caustic agents such as bleach is not recommended.
 - e) Injection of antiseptics or disinfectants into the wound is not recommended.
 - 2) Non-intact skin exposure
 - a) Wash the area immediately with soap and water.
 - b) Antiseptics are not contra-indicated. However, there is no evidence that use of antiseptics for wound care further reduces the risk of HIV/HBV transmission.
 - c) The application of caustic agents such as bleach is not recommended.
 - d) Injection of antiseptics or disinfectants into the wound is not recommended.
 - 3) Mucous membrane exposure:
 - Irrigate continuously for 15 minutes using eyewash station, copious tap water, sterile saline, or sterile water.
 - b. HCP must notify the supervisor **immediately**. The Employee Report of Injury is completed by both the HCP and the supervisor. The original Employee Report of Injury is to be presented at Employee Health at the time of evaluation. It is not to be left with the staff in the emergency department when the initial evaluation is done in the emergency department.
 - c. HCP must report **immediately** to Employee Health during office hours. If the exposure occurs after office hours, the HCP must report **immediately** to SLU Hospital Emergency Department. If initial evaluation takes place in SLU Hospital Emergency Department, the HCP must follow up at Employee Health on the next working day.
2. **HIV**
- a. Risk assessment. Physician evaluation of specific exposure must take place. The risk assessment should be explained to the HCP so that it is understood. The circumstances of the exposure are recorded in the HCP's confidential medical record. Relevant information includes:
 - 1) Date and time of exposure.
 - 2) Job duty being performed by the HCP at the time of exposure.
 - 3) Details of the exposure including: amount of fluid, type of fluid or material, severity of exposure.
 - 4) For a percutaneous injury include the depth of the injury and whether fluid was injected.
 - 5) For skin or mucous membrane exposure include the extent and duration of contact and condition of the skin (chapped, abraded, intact).
 - 6) Description of source of exposure including, if known, whether the source material contained HIV, HBV, or HCV.
 - 7) Factors which increase the risk for transmission of HIV from an individual with documented HIV infection:
 - a) A deep injury to the HCP.

- b) Visible blood on the device causing the injury.
 - c) A device previously placed in the source patient's vein or artery.
 - d) A source patient with end stage Acquired Immune Deficiency (AIDS)
 - e) Direct contact with concentrated virus in a research lab.
- b. Post-exposure HIV prophylaxis (PEP)
- 1) If PEP is being considered, STAT fourth generation HIV (antibody/P24 antigen) lab based testing of the source patient should be done if possible.
 - 2) The physician must provide a risk assessment and information regarding current data on the efficacy and toxicity of post-exposure prophylaxis.
 - 3) The decision must be an informed decision.
 - 4) The exposed HCP must decide to accept or refuse post-exposure HIV prophylaxis.
 - 5) The exposed HCP is informed of the option to decline the post-exposure prophylaxis.
 - 6) Baseline history and physical exam are performed.
 - 7) Prophylaxis should be started as soon as possible. In general, it is recommended that prophylaxis start within one to two hours after the exposure.
 - 8) If source patient is unknown at the time of exposure, consideration of prophylactic medication will begin after assessing the type and severity of exposure. The setting in which the exposure took place needs to be taken into account.
 - 9) Medication must be available for immediate administration at the site of initial evaluation.
 - 10) For women of childbearing age, a urine pregnancy test will be performed prior to initiation of post-exposure prophylaxis medications.
 - 11) ALL baseline laboratory studies on the exposed HCP are to be drawn in Employee Health. If the initial evaluation is done in the Emergency Department, the exposed HCP must report to Employee Health on the next working day so that baseline laboratory testing can be obtained in a confidential manner.
 - 12) The HCP must sign a consent or refusal regarding post-exposure prophylaxis.
 - 13) Prophylactic regime is recommended as follows: .
 - a) Truvada (Tenofovir 300mg/Emtricitabine 200mg) one tablet daily.
 - b) Isentress (Raltegravir 400mg) one tablet every 12 hours.
 - 14) Alternative regimes may be recommended depending on the circumstances and after consultation with Infectious Disease.
 - 15) Tenofovir has been associated with renal toxicity. Alternative regimes should be sought for HCP who have underlying renal disease in consultation with Infectious Disease.
 - 16) Post-exposure prophylaxis (PEP) should start as soon as possible. PEP administration should not be delayed if a question exists concerning

- which antiretroviral drugs to use.
- 17) If PEP is offered/taken and the source patient is later determined to be HIV negative, PEP should be discontinued and no further HIV follow-up testing is indicated for the exposed HCP.
- c. Baseline testing for HIV:
- 1) Employee Health will provide pre-test counseling.
 - 2) Informed consent for baseline HIV testing will be obtained.
 - 3) Fourth generation HIV (antibody/P24 antigen) lab-based testing will be used.
 - 4) Results will be reported to the HCP.
 - 5) Employee Health will provide post-test counseling.
- d. Evaluation of source patient
- 1) Employee Health staff will provide pre-test counseling.
 - 2) Informed consent for HIV testing will be obtained from the source patient or proxy if the source patient is unable to give consent. The consent shall include consent to disclose the results to the exposed HCP.
 - 3) Fourth generation HIV (antibody/P24 antigen) lab-based testing of the source patient should be done if possible.
 - 4) If the source patient refuses to give consent for HIV testing the attending physician will be notified by Employee Health. If the source patient refuses to give consent for HIV testing after discussing the issue with the attending physician, the Infection Control Officer will be notified by Employee Health.
 - 5) Employee Health will notify the source patient's attending physician or designee of laboratory test results for HIV antibody/P24 antigen. The attending physician will advise Employee Health of any known risks. The attending physicians are encouraged to discuss testing with the source patient.
 - 6) Employee Health physician will evaluate the risk of the source patient by HCP's history of the source patient, review of available patient history, and any report from the source patient's physicians.
 - 7) Employee Health staff will provide HIV test results with post-test counseling to the source patient or proxy.
 - 8) Exposed HCP is notified of the source patient results.
- e. **Six week follow up:** Appointment will be scheduled at Employee Health. After informed consent, fourth generation HIV (antibody/P24 antigen) lab-based testing will be performed. Employee Health will provide pre-test counseling. Results will be reported to the HCP and post-test counseling will be provided. Appointment compliance is monitored by Employee Health only if the source patient has known HIV infection.
- f. **Four month follow up:** Appointment will be scheduled at Employee Health. After informed consent, fourth generation HIV (antibody/P24 antigen) lab-based testing will be performed. Employee Health will provide pre-test counseling. Results will be reported to the HCP and post-test counseling will be provided. Appointment compliance is monitored by

- Employee Health only if the source patient has known HIV infection.
- g. **12 month follow up:** Appointment will be not routinely scheduled at Employee Health. Twelve-month HIV follow-up will be scheduled for a HCP who becomes infected with HCV following exposure to an exposure source co-infected with HIV and HCV. After informed consent, fourth generation HIV (antibody/P24 antigen) lab-based testing will be performed. Employee Health will provide pre-test counseling. Results will be reported to the HCP and post-test counseling will be provided.
 - h. All HCP results are confidential.
 - i. All positive HIV results will be reported to the Missouri Department of Health as required by law and to the CDC COPHI coordinator (Cases of Public Health Importance) at 404-639-2050.
 - j. All evaluation, treatment, and testing are at no cost to the HCP or to the source patient.
 - k. All exposed HCPs are counseled regarding reducing the transmission of HIV after potential exposure. This includes:
 - 1. Avoiding blood donations for one year.
 - 2. Avoiding tissue donation especially during the first 6 – 12 weeks after exposure
 - 3. Use of barrier contraception.
 - 4. Deferring pregnancy.
 - 5. If an exposed woman is breast feeding, she should be counseled about the risk of HIV transmission through breast milk, and discontinuation of breast feeding should be considered, especially for high-risk exposures.
 - l. All exposed HCPs are advised of Employee Assistance Program services. These support services are available at the request of the HCP.
 - m. Records of the exposure will be maintained in the Employee Health HCP files for duration of employment plus 30 years.
2. **Hepatitis B Virus**
- a. Risk assessment -- High risk source patients for Hepatitis B are patients with suspected acute hepatitis, known chronic hepatitis, hematology-oncology patients, dialysis patients, hemophiliacs, and patients with other coagulopathy disorders, those who use illicit intravenous drugs, and other patients based on clinical judgment.
 - b. Baseline testing for hepatitis B surface antigen screen and hepatitis B core IgM antibody will be obtained at the time of the post-exposure evaluation. Quantitative anti-HBs will be obtained if not previously documented. Other baseline tests will be obtained as outlined in Table 6.
 - c. Evaluation of the source patient
 - 1) Employee Health staff will provide counseling regarding hepatitis B surface antigen screen testing.
 - 2) Hepatitis B surface antigen screen and hepatitis B core IgM antibody will be obtained.
 - 3) Attending physician or designee will be notified of lab results on the source patient.
 - 4) Employee Health physician will evaluate the risk of the source patient by

HCP's history of the source patient, review of available source patient history, and report from attending physician.

- 5) Exposed HCP will be notified of the source patient results.
- d. Post-Exposure Prophylaxis -- The hepatitis B vaccination status and the vaccine-response status (if known) of the exposed HCP should be reviewed. A summary of prophylaxis recommendations follows:

TABLE 1. Postexposure management of health-care personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by health-care personnel HepB vaccination and response status					
Health-care personnel status	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing†
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	
Documented responder§ after complete series (≥3 doses)	No action needed				
Documented nonresponder¶ after 6 doses	Positive/unknown	—**	HBIG x2 separated by 1 month	—	No
	Negative	No action needed			
Response unknown after 3 doses	Positive/unknown	<10mIU/mL**	HBIG x1	Initiate revaccination	Yes
	Negative	<10mIU/mL	None		
	Any result	≥10mIU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	—**	HBIG x1	Complete vaccination	Yes
	Negative	—	None	Complete vaccination	Yes

Abbreviations: HCP = health-care personnel; HBsAg = hepatitis B surface antigen; anti-HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin.

* HBIG should be administered intramuscularly as soon as possible after exposure when indicated. The effectiveness of HBIG when administered >7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG dosage is 0.06 mL/kg.

† Should be performed 1–2 months after the last dose of the HepB vaccine series (and 4–6 months after administration of HBIG to avoid detection of passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL).

§ A responder is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine.

¶ A nonresponder is defined as a person with anti-HBs <10 mIU/mL after ≥6 doses of HepB vaccine.

** HCP who have anti-HBs <10mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc.

- e. **Six month follow up:** Appropriate appointments will be scheduled at Employee Health as outlined in Table 2 above.
- f. All HCP results are confidential.
- f. All evaluation, treatment, and testing are done at no cost to the HCP or the source patient.
- g. All exposed HCPs are counseled regarding reducing the transmission of hepatitis B

virus. They should refrain from donating blood, plasma, organs, tissue, or semen. The exposed person does not need to modify sexual practices or refrain from becoming pregnant. If an exposed woman is breast feeding, she does not need to discontinue.

- h. Records of the exposure will be maintained in the Employee Health HCP file.

3. **Hepatitis C Virus**

- a. Risk assessment -- High risk source patients for Hepatitis C are patients with suspected acute hepatitis, known chronic hepatitis, hematology-oncology patients, dialysis patients, hemophiliacs and patients with other coagulopathy disorders, those who use illicit intravenous drugs, patient with blood products administration before 1993, and other patients based on clinical judgment.
- b. Baseline testing for antibody to hepatitis C virus, ALT, and PCR HCV RNA will be obtained at the time of post-exposure evaluation.
- c. Evaluation of the source patient:
 - 1) Employee Health will provide counseling regarding Hepatitis C testing.
 - 2) Antibody to Hepatitis C virus will be obtained.
 - 3) Attending physician or designee will be notified of lab results on the source patient.
 - 4) Employee Health physician will evaluate the risk of the source patient by HCP's history of the source patient, review of available source patient history, and report from attending physician.
 - 5) Exposed HCP will be notified of the source patient's results.
- d. Exposed employee follow up if the source patient antibody to Hepatitis C virus is positive:
 - 1) Two weeks post-exposure follow up:
 - a) PCR HCV RNA
 - b) If the HCP has a positive PCR HCV RNA, the patient is referred to Gastroenterology- Hepatology service for evaluation and possible treatment.
 - 2) Six-month post-exposure follow up: Antibody to Hepatitis C virus and ALT
- e. All HCP results are confidential.
- f. All evaluation, treatment and testing are done at no cost to the HCP or the source patient.
- g. All exposed HCPs are counseled regarding reducing the transmission of hepatitis C virus. They should refrain from donating blood, plasma, organs, tissue, or semen. The exposed person does not need to modify sexual practices or refrain from becoming pregnant. If an exposed woman is breast feeding, she does not need to discontinue.
- h. Records of the exposure will be maintained in the Employee Health HCP file.

SECTION 13: COMMUNICATION OF HAZARDS TO AT RISK EMPLOYEES

1. Labels

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided below:

- A. Red bags or red containers may be substituted for labels.
- B. Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements.
- C. Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment, or disposal are exempted from the labeling requirement.
- D. Regulated waste that has been decontaminated need not be labeled or color-coded.

Labels required by this plan shall include the following legend:



BIOHAZARD

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

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

Employees are to notify the Biological Safety Officer (314-977-6888) if they discover regulated waste containers, refrigerators containing blood or other potentially infectious materials, contaminated equipment, etc. without proper labels. Please note that labels required for contaminated equipment shall be in accordance with this section and shall also state which portions of the equipment remain contaminated.

2. Signs

The University shall post signs at the entrance to work areas specified as HIV, HBV, and HCV Research Laboratory and Production Facilities, which shall bear the following legend and information as indicated:



BIOHAZARD

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

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

SECTION 14: INFORMATION AND TRAINING

1. All employees who have occupational exposure to bloodborne pathogens receive general awareness training provided by Saint Louis University – Environmental Health and Safety. This initial training and annual training are provided at no cost to the employee and during working hours. Specific BBP training is completed through Skillsoft.
2. All employees have an opportunity to review this plan at any time during their work shifts. The plan is documented within your safety manual and is kept in each department. Environmental Safety may be contacted at 314-977-6795 for details regarding the plan.
3. If requested, an employee will receive a copy of this ECP free of charge within 15 days of request.
4. Training content includes:
 - A. Explanation of the OSHA standard.
 - B. Explanation of the ECP and how to obtain a copy.
 - C. Explanation of methods to recognize tasks and other activities that may involve exposure to blood and other potentially infectious materials, including what constitutes an exposure incident.
 - D. Explanation of the use and limitations of engineering controls, work practices, and PPE.
 - E. Explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE.
 - F. Explanation of the basis for PPE selection.
 - G. Information on hepatitis B vaccine: efficacy, safety, method of administration, benefits, and availability at no charge to the employee.
 - H. Information on appropriate actions to take and person to contact in an emergency involving blood or other potentially infectious materials.
 - I. Explanation of procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow up that will be made available.
 - J. Information on the post-exposure evaluation and follow up that the employer is required to provide for the employee following an exposure incident.
 - K. Explanation of the signs and labels and/or color coding required by the OSHA standard and used at this facility.
 - L. Opportunity for interactive questions and answers with the person conducting the training session. See Section 2: Program Administration.
 - M. Training materials are available through Saint Louis University – Environmental Health and Safety (314-977-6888).

SECTION 15: RECORD KEEPING

1. Training Records
 - A. Training records are completed for each employee upon completion of training for 30 years past the last date of employment at Saint Louis University – Office of Human Resources (314-977-2360).
 - B. Content of the records:
 - 1) Dates of training sessions.
 - 2) Summary of training session educational content.
 - 3) Name and qualification of person(s) conducting training.
 - 4) Names and job titles of employees attending the training sessions.
 - C. Training records are provided upon request of the employee or the employee authorized representative within 15 working days through Saint Louis University – Office of Human Resources (314-977-2360).
2. Medical Records
 - A. Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, “Access to Employee Exposure and Medical Records.”
 - B. Employee Health Medical Director (314-257-8400) is responsible for the maintenance of medical records.
 - C. These confidential records are kept at the Employee Health office/storage for at least the duration of employment plus 30 years.
 - D. Medical records are provided upon request of the employee or the employee authorized representative within 15 working days through Employee Health (314-257-8400).
3. OSHA Recordkeeping
 - A. Exposure incidents are evaluated to determine if the case meets OSHA’s recordkeeping requirements (29 CFR 1904).
 - B. Determination and recording are done by SLU Risk Management (977-2633).
4. Sharps Injury Log
 - A. In addition to the 29 CFR 1904 recordkeeping requirement, all percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log. This is done by SLU Risk Management (314-977-2633)
 - B. Sharps Injury Log content:
 - 1) Date of Injury
 - 2) Type and brand of device
 - 3) Department where the exposure incident occurred
 - 4) Explanation of how the incident occurred
 - C. Sharps Injury Log is reviewed annually as part of the annual evaluation of the program. This is completed by SLU Risk Management.
 - D. Sharps Injury Logs are maintained for 5 years following the end of the calendar year that they cover.
 - E. If the Sharps Injury Log is provided to anyone, the personal identifiers are removed from the report.

SECTION 16: PROCEDURES FOR EVALUATING CIRCUMSTANCES OF EXPOSURE INCIDENT

1. Employee Health (314-257-8400) and/or the Biological Safety Officer (314-977-6888) will review the circumstances of all exposure incidents to determine:
 - A. Engineering controls in use at the time
 - B. Work practices followed
 - C. Description of the device being used (including type and brand)
 - D. Personal protective equipment that was used at the time of the exposure incident
 - E. Location of the incident
 - F. Procedure being performed when the incident occurred
 - G. Employees training
2. SLU Risk Management (314-977-2633) will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log.
3. The Biological Safety Officer, in conjunction with the Institutional Biosafety Committee (IBC) or the IBC subcommittee on Exposure Control Plan for Bloodborne Pathogens, will ensure that appropriate changes are made to the ECP if it is determined that revisions need to be made.

Appendix A:
Job classifications in which all employees have
exposure to BBPs

Anatomy Assistant	Facilities Supervisor	Ophthalmic Assistant
Anesthesia Assistant	FT 12 Mo Faculty	Optician
Anesthesiologist	Health Assistant	Optician Assistant
Assistant Clinical Lab Supv.	Health Physicist	Optometrist
Assistant Supervisor	Histology Technologist	Orthopaedic Training Specialist
Associate Pathologist	Housestaff Resident	Orthoptist
Athletic Trainer	Immunology Technologist	Pathologist Assistant
Behavioral Therapist	Lab Animal Technician	Patient Coordinator
Biological Safety Officer	Lab Supervisor	Patient Coordinator, Sr.
Biosafety Specialist	Laboratory Assistant	Perfusionist
Biohazard Coordinator	Laboratory Technician	Pharmacist
Cert. Ophthalmic Assistant	Laboratory Technician, Sr.	Pharmacy Technician
Cert. Ophthalmic Technician	Low Vision Assistant	Physician
Chemical Hygiene Officer	LPN	Physician Assistant
Clinic Nurse Manager	Maintenance A Worker	PT Adm/Prf/Tch-Exc
Clinical Nurse	Medical Assistant	PT Adm/Prf/Tch-Pos
Clinical Nurse Specialist	Medical Assistant, Non-Registered	Radiation Safety Officer
Clinical Supervisor	Medical Assistant, Registered	Radiation Safety Technician
Clinical Technologist	Medical Director	Registered Nurse FT & PT
Communications Officer	Medical Photographer	Research Assistant
Courier	Medical Technologist	Research Assistant, Sr.
Custodial Services Manager	Medicolegal Death Investigator	Research Coordinator
Custodial Supervisor	Nuclear Med Technologist	Research Lab Supervisor
Custodian	Nurse Anesthetist CRNA	Research Nurse
Dental Assistant	Nurse Coordinator	Research Technician
Dental Hygienist	Nurse FT	Sr. Radiation Safety Tech
Dietician	Nurse Manager	Social Worker-MSW
Dir-Env Health and Safety	Nurse Practitioner	Sonographer, Reg.
Dir-Perfusion Services	Nurse Supervisor	Sr. Pt Coordinator
E.R. Physician	O/P Social Services Dir	Staff Nurse
Echo Technician		VA Physician

Appendix B:
Job classifications in which some employees have
exposure to BBPs

Academic Department Chair	Research with BBP and OPIM
Administrative Assistant	Send/Receive packages containing OPIM
Aquatics/Safety Instructor	Administering First Aid
Aquatics/Wellness Coordinator	Administering First Aid
Area Coordinator	Patient Contact
Assistant Director	Patient Contact, Administering First Aid
Assistant Vice President	Administering First Aid
Associate Dean	Research with BBP and OPIM
Asst Supervisor	Administering First Aid
Billing Coordinator	Patient Contact
Billing Representative	Patient Contact
Building Maintenance	Work tasks involve BBP and OPIM
Business Manager	Patient Contact
Camp Coordinator	Administering First Aid
Clinical Instructor	Patient Contact
Community Development Coord.	Patient Contact
Coordinator	Patient Contact
Dept Chairman	Research with BBP and OPIM
Dept Director	Research with BBP and OPIM
Dietician	Patient Contact
Director	Patient Contact
Field Supervisor	Administering First Aid
Financial Coordinator	Patient Contact
Fitness Coordinator	Administering First Aid
Fitness Instructor	Administering First Aid
FT 12 Mo Faculty	Research with BBP and OPIM
FT 9/11 Mo Faculty	Research with BBP and OPIM
Graduate Assistant	Research with BBP and OPIM
Grant in Aid	Research with BBP and OPIM
Grants Development Specialist	Research with BBP and OPIM
Intramural & Sport Club Coordinator	Administering First Aid
Investigator	Administering First Aid
Laboratory Technician	Research with BBP and OPIM
Manager	Administering First Aid
Membership & Services Coordinator	Administering First Aid
Office Assistant	Send/Receive packages containing OPIM
Office Manager	Send/Receive packages containing OPIM
Operations Assistant, Sr.	Send/Receive packages containing OPIM
Patient Coordinator	Patient Contact
Patient Coordinator, Sr.	Patient Contact
Post-Doctoral Fellow	Research with BBP and OPIM
Program Coordinator	Administering First Aid
Protective Services Officer	Administering First Aid

Protective Services Officer BP	Administering First Aid
PT 12 Mo Faculty	Research with BBP and OPIM
PT Faculty	Research with BBP and OPIM
PT Professional	Research with BBP and OPIM
PT Spec Assgn Faculty	Research with BBP and OPIM
PT Support Staff - Pos	Research with BBP and OPIM
Public Safety Officer	Administering First Aid
Recreational Instructor	Administering First Aid
Research Nurse	Research with BBP and OPIM
Research Technician	Research with BBP and OPIM
Secretary, Administrative	Send/Receive packages containing OPIM
Secretary, Medical	Patient Contact
Shift Commander	Administering First Aid
Student Worker	Research with BBP and OPIM/First Aid
Supervisor	Administering First Aid

Appendix C:
Hepatitis B Vaccine
Informed Refusal and Release

EMPLOYEE HEALTH

providing work related healthcare services for employees of Saint Louis University and SSM Health Saint Louis University Hospital

HEPATITIS B VACCINE INFORMED REFUSAL AND RELEASE

Employee: _____
Date of birth: _____
Soc. Sec. # (last four only): XXX – XX -- _____
Department: _____

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 vaccine 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.

Signature: _____

Date: ____ -- ____ -- ____

Witness: _____



**SAINT LOUIS
UNIVERSITY**



SSMHealth
Saint Louis University Hospital

EMPLOYEE HEALTH
3655 Vista Ave., West Pavilion Suite 116
St. Louis, MO 63110-2539

p | (314) 257-8400
f | (314) 257-8401

Appendix D:
Safety Needle Devices

Classification	Device Name
Alternative Skin Closure Devices and Products	
Segment Sampling Devices	
Blood Donor Phlebotomy Devices	
Blood Tube Holders	
Closed Venous Sampling System	
Collection Set with Safety Wing	Collection Set with Safety Wing 21g x 3/4"
Collection Set with Safety Wing	Collection Set with Safety Wing 23g x 3/4"
Plastic Blood Collection Tubes	BD Vacutainer Plus Plastic Tubes
Microcuvettes for Hemoglobin Measurements	Hemocue Microcuvettes
Plastic Blood Collection Tubes with Screw Caps	
Plastic Fingertick Sampling (Capillary) Blood Collection Tubes	
Safety-Engineered Blood Collection Needles	BD Vacutainer Eclipse Blood Collection Needle
Safety-Engineered Blood Collection Needles	BD Vacutainer Safety-Lock Blood Collection Set
Safety-Engineered Blood Collection Needles	BD Vacutainer Safety-Lock Blood Collection Set 23G
Safety-Engineered Blood Collection Needles	BD Vacutainer Safety-Lock Blood Collection Set 21G
Safety-Engineered Blood Collection Needles with Tube Holders	
Umbilical Cord Sampling	
Winged Steel Needle (Butterfly)	Portex Saf-T Wing Blood Collection Set
Blood Collection Sets	
Bone Marrow Collection System	
Catheter, Insyte Winged 24Gx.56"	Becton Dickinson #381511
Catheter, Insyte Winged 22Gx1"	Becton Dickinson #381523
Catheter, Insyte Winged 20Gx1.16"	Becton Dickinson #381534
Needle, Safety 25Gx1"	McKesson MedSurg #102-N251S
Needle, Safety 25Gx5/8"	McKesson MedSurg #102-N2558S
Needle, Safety 21Gx1"	McKesson
Cut- or Puncture-Resistant barrier products	
Fluid Sampling Devices	
Hemodialysis and Apheresis Devices	
Safety wing infusion set	
Hypodermic Needles and Syringes	BD Eclipse Needles w/Luer lock Syringe
Hypodermic Needles and Syringes	BD - Monoject 18g-29g
Hypodermic Needles and Syringes	BD SafetyGlide Syringe for Insulin
Hypodermic Needles and Syringes	BD SafetyGlide Syringe for Insulin 29g
Hypodermic Needles and Syringes	BD SafetyGlide Tuberculin Syringe
Hypodermic Needles and Syringes	BD Safety-lok syringes and needles
Hypodermic Needles and Syringes	BD SafetyGlide Injection Needles
Hypodermic Needles and Syringes	B. Braun Safety Huber Needle
Hypodermic Needles and Syringes	Terumo Tuberculin Needle/Syringe

Hypodermic Needles and Syringes	Invirosnap syringes, 25g x 5/8, 25g x 1 inch, 20 g x 1 1/2 inch.
Hypodermic Needles and Syringes	Invirosnap syringes, 25g x 1 inch
Needleless Jet Injection	Invirosnap syringes 20 g x 1 1/2 inch.
Retractable Needles and Syringes	Portex Needle Pro
Retractable Needles and Syringes	Portex Needle Protective Device
Retractable Needles and Syringes	BD-Safety Glide Needle 25G x 1"
Shielded or retracting peripheral IV catheters	BD Insyte Autogard
Needle guards for pre-filled medication cartridges	
Needleless valve/access ports and connectors	BC IV 23g x 3/4" with 12" Extension Line
Needleless valve/access ports and connectors	Saf-T-Intima 24g x 3/4"
Laboratory Devices: Plastic Capillary Tubes	Saf-T-Intima 22g x 3/4"
Plastic Fingertick Sampling Blood Collection Tubes	
Laboratory Devices: Protected needle for Blood Culture Vial Access	
Laboratory Devices: Slide Preparation Devices	
Laboratory Devices: Vacuum Tube Stopper	
Laboratory Devices: Needles	Tyco (Kendall) 20G x 1 1/2
Laboratory Devices: Needles	BD 25G x 5/8 Inch
Laboratory Devices: Needles	BD 25G x 1 1/2 Inch
Laboratory Devices: Needles	Fisher 26G x 3/8Inch 14-826-10
Laboratory Devices: Needles	Fisher 23G x 1 Inch 14-826-A
Laboratory Devices: Needles	Fisher 26G x 1 1/2 Inch 14-826-5D
Lancets: Blood sampling	
Lancets: Laser Lancet	BD Microtainer Lancets #366594
Pressure Lancet	McKesson (SunMark) Pressure Activated Safety Lancet
Retracting Lancet	
Disposable scalpel	
Strip Lancet	
Medication Vial Adaptors	
Nuclear Medicine Devices	
Other Catheter Equipment: Central Venous Catheters	
Other Catheter Equipment: Guidewire	
Introducers for Venous and Arterial Percutaneous Access	
Other Catheter Equipment: Peripherally Inserted Central Catheters	
Other Catheter Equipment: Radial Artery Catheters	
Other Safety Products: Catheter Securement Products	
Spinal Needle	Braun Spinocan Spinal Needle 27 G 3.5in (Vocal Cord Injections)

IV Catheter	Smith Medical IV Catheter
IV Medication Delivery System	Needleless valve/access port
Mini Spike dispensing Pin	Braun
IV Starter Kits	Various
Safety Syringes 3cc	Various
Safety Vacutainers	Various

Appendix E:
Table of Changes

Table of Changes

<u>Date</u>	<u>Changes Made</u>
12/01/2015	Revision of titles, contact information, and Post Exposure (PEP) treatment.
12/15/2016	Revised titles, contact information. No new PEP or recommendations by OSHA, Position titles changed based on 2015 input from employees.
10/04/2017	Updated titles of organizations, review of any OSHA updates to the standard, no major changes to the Exposure Control Plan
05/21/2021	Updated web links, added newer reference for HCV-CDC guidelines for post exposure prophylaxis.
<u>06/01/2021</u>	Revised language referencing Healthcare worker (HCW) and replaced with Healthcare personnel (HCP). Attached newly revised Hepatitis B Vaccine Refusal within Appendix C. Revised phone number for Employee Health throughout document by replacing 314-268-5499 with 314-257-8400.
06/03/2021	Add area code 314 to all phone numbers.