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

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.

"OPIM" means other potentially infectious materials; see .

"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 unfixed 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 .

"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-laboratoriologiatory producing or

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 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):

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 . 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 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.

Work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls,

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 BT Q q 0.0000091 lc 6( )-109(a)S6( )3q 0.000029(ac 6(. G

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 conta 55imored, transported, or sh

D. **Containment Equipment:** Equipment used for containment

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

permit blood or other potentially infectious materials to pass through to or

eyes, mouth, or other muco

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,

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-
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 [redacted] Containment

Regulated waste sh[redacted]ced in containers, which are:

A. Closable

B. Construc[redacted]ntain all contents and prevent leakage of flu[redacted]
during h[redacted]ETQq0.00[redacted]612.792 re

C. Labeled [redacted]

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.

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 $\geq$ 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 $\geq$ 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 $\geq$ 10mIU/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 consi/

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 of one of the following: amniotic fluid, blood, cerebrospinal fluid, pericardial fluid, peritoneal fluid, pleural fluid, semen, synovial fluid, tissueA1al fluid, peritoneal

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.

b) Visible blood on the device causing the injury.
c) 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 sh5(luation of sour)3(c)-5(e)4(pa)4(ti)-13(e)4(nt)]TJETQq0.000000.00000912 0 0

HCP
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§ doses)	[redacted]				
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

[redacted]

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 2 qdi2 reW* nO /P <</MCIDd12>>BDC q1 0 0 0 0 9

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

B reg

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

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)

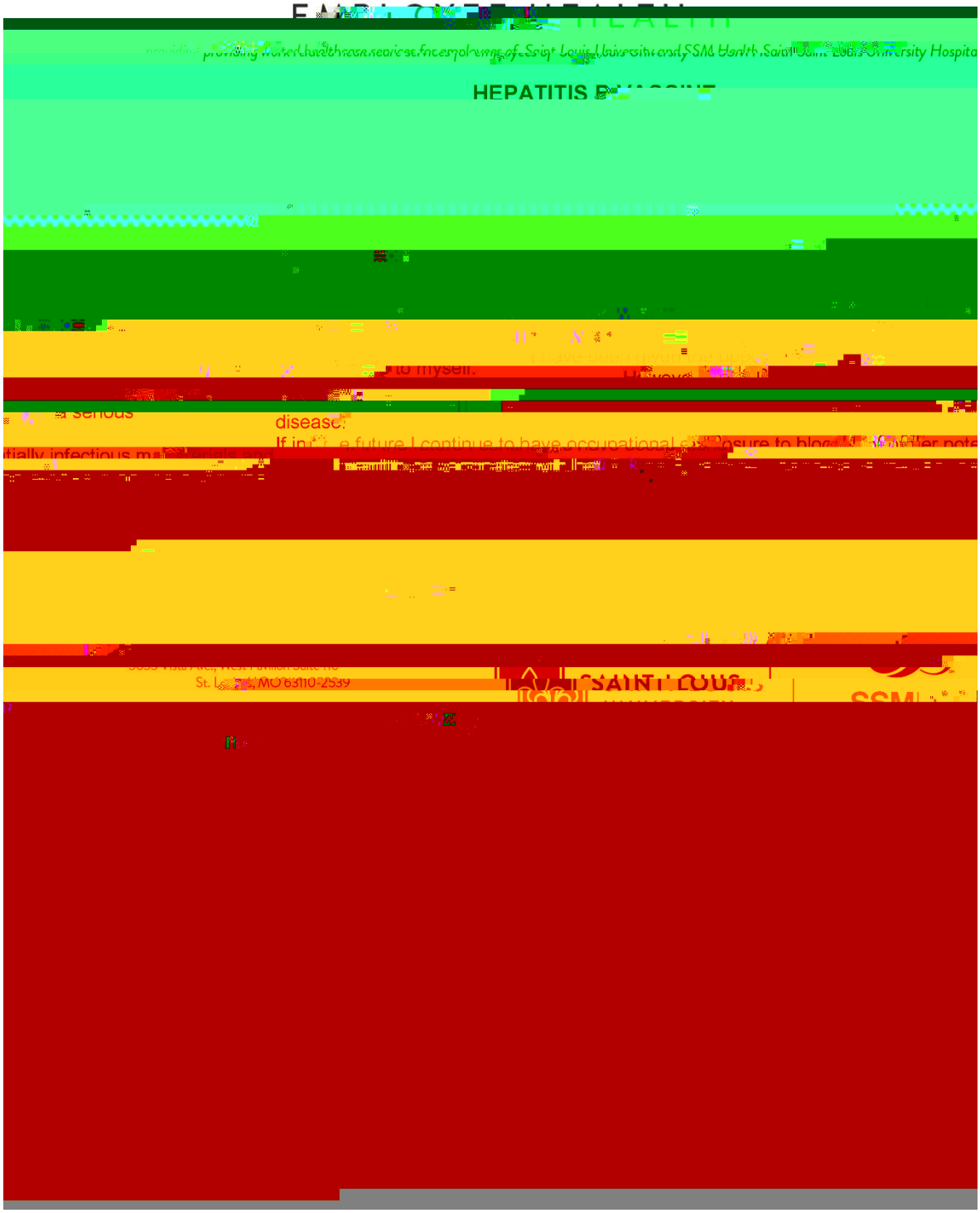
Appendix A:
Job classifications in which all employees have exposure to BBPs

Anatomy Assistant	Facilities Supervisor	Ophthalmic Assistant
Anesthesia Assistant	FT 12 Mo Faculty	Optician
Anesthesiologist	Health Assistant	Optician Assistant

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

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	


HEPATITIS B
disease.
SAINT LOUIS
SSM

Appendix D:
Safety Needle Devices

Classification	Device Name
Alternative Skin Closure Devices and Products	
Segment Sampling Devices Blood Donor Phlebotomy Devices	

Appendix E:
Table of Changes

Table of Changes

Date	Changes Made
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 new