



STANFORD UNIVERSITY

---

ENVIRONMENTAL HEALTH & SAFETY

## **Bloodborne Pathogens**

### **Institutional Exposure Control Plan**

**2021**

## TABLE OF CONTENTS

<b>I. PURPOSE.....</b>	<b>1</b>
<b>II. SCOPE .....</b>	<b>2</b>
<b>III. RESPONSIBILITIES.....</b>	<b>2</b>
A. Principal Investigators/Supervisors .....	2
B. Supervised Personnel.....	2
C. Stanford University Occupational Health Center (SUOHC) .....	2
D. Department of Environmental Health & Safety (EH&S).....	3
<b>IV. EXPOSURE DETERMINATION .....</b>	<b>3</b>
<b>V. METHODS OF COMPLIANCE .....</b>	<b>5</b>
<b>A. Engineering Controls and Work Practices .....</b>	<b>6</b>
1. Universal Precautions .....	6
2. Engineering Controls General Requirements .....	6
3. Additional Requirements for Sharps .....	7
4. Work Practice Controls .....	8
4.1 Handling Specimens of Blood or OPIM.....	8
4.2 Prohibited Practices.....	8
4.3 Sharps Waste Containers.....	9
4.4 Handwashing .....	9
4.5 Handling Specimens of Blood or OPIM.....	10
4.6 Cleaning and Decontaminating Work Areas.....	10
4.7 Shipping .....	11
4.8 Servicing Contaminated Equipment .....	11
4.9 Waste Disposal .....	11
<b>B. PERSONAL PROTECTIVE EQUIPMENT (PPE) .....</b>	<b>11</b>
1. Provision .....	12
2. Use .....	12
3. Accessibility .....	12
4. Removal, Cleaning, Laundering, and Disposal.....	12
5. Gloves .....	13
6. Masks, Eye Protection, Face Shields, and Respirators .....	13
7. Gowns, Aprons, and Other Protective Body Clothing .....	13
<b>C. HBV, HCV AND HIV RESEARCH OPERATION REQUIREMENTS .....</b>	<b>13</b>
1. Workplace Controls and Practices.....	13
2. Personnel Experience & Proficiency.....	15
<b>VI. HAZARD COMMUNICATION TO PERSONNEL .....</b>	<b>15</b>
1. Biohazard Labels and Signs.....	15
2. Training.....	16
<b>VII. HEPATITIS B (HBV) VACCINATION.....</b>	<b>17</b>
<b>VIII. EXPOSURE INCIDENTS.....</b>	<b>18</b>
<b>A. Emergency Procedures.....</b>	<b>18</b>

<b>B. Post-Exposure Evaluation and Follow-up</b> .....	19
1. Information Provided to the Healthcare Professional .....	19
2. Source Individual Blood Testing .....	19
3. Medical Evaluation and Follow-up .....	20
4. Healthcare Professional’s Written Opinion .....	20
5. Workplace Evaluation and Follow-up .....	20
<b>C. Requirements for Sharps Injuries</b> .....	21
1. Sharps Injury Report.....	21
2. Sharps Injury Log.....	21
<b>IX. RECORDKEEPING</b> .....	21
1. Medical records .....	21
2. Training records .....	22
3. Sharps Injury Log .....	22
4. Availability.....	22
5. Transfer of Records.....	22
<b>APPENDIX A: Definitions</b> .....	24
<b>APPENDIX B: Non-safety Sharps Documentation</b> .....	28

## Stanford University - Bloodborne Pathogens Exposure Control Plan

The Stanford University Institutional Exposure Control Plan (Institutional ECP) addresses issues related to the elimination or minimization of personnel exposure to human blood, bloodborne pathogens, and other potentially infectious materials. Principal investigators and supervisors should refer to the Institutional ECP as a resource for exposure control background, issues and regulatory procedures.

### I. Purpose

“Stanford University makes all reasonable efforts to:

- Protect the health and safety of Stanford University faculty, staff, and students
- Provide safe work practices - academic, research, and administrative - for faculty, staff and students
- Provide information to faculty, staff, and students about health and safety hazards
- Identify and correct health and safety hazards and encourage faculty, staff, and students to report hazards
- Provide information and safeguards for those on campus and in the surrounding community regarding environmental hazards arising from operations at Stanford University”<sup>1</sup>

To fulfill this University policy and to comply with the State of California, Department of Industrial Relations, Division of Occupational Safety and Health (known as “Cal/OSHA”) Bloodborne Pathogens Standard set forth in *California Code of Regulations, Title 8, Section 5193*<sup>2</sup> (8 CCR 5193), this *Bloodborne Pathogens Institutional Exposure Control Plan* (hereafter referred to as “Institutional ECP” or “ECP”) has been developed to minimize personnel exposure to bloodborne pathogens (BBPs) in blood or other potentially infectious materials (OPIM).

Requirements outlined in this ECP are mandatory by the Bloodborne Pathogens Standard where the word “**shall**” is used and are advisory in nature where the word “**should**” is used. Stanford University requirements are noted where the word “**must**” is used.

---

<sup>1</sup> Health and Safety at Stanford University: Principles, Responsibilities, and Practices (Research Policy Handbook Section 7.2, October 2020, <https://doresearch.stanford.edu/policies/research-policy-handbook/environmental-health-and-safety/health-and-safety-principles>)

<sup>2</sup> Cal/OSHA Title 8 Section 5193 Bloodborne Pathogens Standard  
<https://www.dir.ca.gov/title8/5193.html>

## II. Scope

The ECP covers all Stanford University personnel who have potential for exposure to human/non-human primate blood and/or Other Potentially Infectious Materials (OPIM), including but not limited to principal investigators (PIs), supervisors, research personnel, and service/support staff.

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

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

Other Potentially Infectious Materials mean:

- (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 other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead)
- (3) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:
  - Cell, tissue, or organ cultures from humans or experimental animals
  - Blood, organs, or other tissues from experimental animals
  - Culture medium or other solutions

All definitions related to this ECP are included in Appendix A.

## III. Responsibilities

Specific groups have responsibilities under this ECP which include but are not limited to:

### 1. Principal Investigators/Supervisors

PIs/Supervisors are responsible for the health and safety of their supervised personnel, with duties including implementing the Institutional ECP with areas/operations under their controls. The PI/Supervisors may delegate the implementation and management of safety duties for which he/she is responsible but must make sure that any delegated safety duties are carried out.

### 2. Supervised Personnel

For the purposes of this ECP, “supervised personnel” consist of Stanford University personnel who handle, use, or otherwise have potential occupational exposure to blood and/or OPIM. Responsibilities of these personnel include, but are not limited to:

- Completing and submitting the “[Hepatitis B Vaccine Declaration](#)” Form within 10 working days of initial assignment
- Completing required training

- Conducting operations according to ECP-established procedures and safe work practices
- Using proper personal protective equipment (PPE)
- Immediately reporting any exposure incident, including sharps injuries, near-misses, or unsafe procedures or work tasks to PI/Supervisors and/or EH&S

### **3. Stanford University Occupational Health Center (SUOHC)**

The responsibilities of the Stanford University Occupational Health Center (SUOHC) include, but are not limited to:

- a. Managing the HBV Vaccination Program
- b. Providing post-exposure evaluation, follow-up, and counseling to personnel exposed to blood or OPIM
- c. Maintaining for the University medical records required by 8 CCR 5193(h)(1)

### **4. Department of Environmental Health & Safety (EH&S)**

The responsibilities of the Department of Environmental Safety and Health (EH&S) include, but are not limited to:

- a. Overseeing Institutional implementation of the Bloodborne Pathogens Standard
- b. Developing the Institutional ECP that provides tools (e.g., guidance, forms, and templates) for use by Stanford University personnel to effectively minimize potential occupational exposures to blood or OPIM
- c. Recommending proper engineering controls, administrative controls, and PPE
- d. Preparing and maintaining the University's Sharps Injury Log
- e. Performing annual reviews of sharps injuries, preparing the Sharps Injury Annual Report, and disseminating findings as appropriate
- f. Performing annual reviews of commercially available needless systems and needle devices and sharps with engineered sharps injury protection and changes in technology that eliminate or reduce exposure to BBP
- g. Reviewing and updating the Institutional ECP at least annually

## **IV. Exposure Determination**

### **Job Classifications with Exposure**

At Stanford University, we have determined that some employees in the following job classifications have potential occupational exposure to bloodborne pathogens when performing certain tasks and procedures. The determination is made without regard to the use of personal protection equipment.

- Principal Investigator
- Staff Scientist
- Post-doctoral Research Fellow

- Student (Undergraduate and Graduate) Researcher
- Life Science Research Associate/Technician
- Phlebotomist
- Physician
- Registered Nurse
- Nurse Practitioner
- Medical Assistant
- Athletic Trainers/Coaches
- Lifeguards
- Department of Public Safety: Deputy, Sergeant, and Lieutenant
- Department of Land, Buildings & Real Estate: Grounds keepers, Plumbers, Water Shop Technicians, and Electricians
- Department of Environmental Health & Safety: Emergency Response Personnel

### **Exposure Determination**

The following questions are used to determine if an employee is considered to be at occupational risk of exposure to bloodborne pathogens and must be included in the Bloodborne Pathogens Program.

Does the employee ever:

1. Handle human blood or blood products, such as whole blood, plasma, serum, platelets, or white blood cells?
2. Handle human body fluids such as semen, cerebrospinal fluid, vaginal secretions, joint fluid, pleural fluid, peritoneal fluid, pericardial fluid, or amniotic fluid?
3. Work with non-human primates (NHPs) and/or handle blood and body fluids from NHPs?
4. Work with animals that are infected with human bloodborne pathogens or perform tasks where such animals are housed?
5. Handle unfixed human tissue or organs, including tissue culture cells and cell lines? (*Tissues and organs soaked in chemical preservatives such as alcohol or formaldehyde are "fixed"*)?
6. Handle blood, blood products, body fluids or unfixed tissues or organs (including tissue culture cells and cell lines) of animals infected with the bloodborne pathogens?
7. Work with bloodborne pathogens or with preparations, such as liquid solutions or powders, containing the hepatitis B virus?
8. Handle sharp instruments such as knives, needles, scalpels, or scissors which have been used by others working with human blood or OPIM to include human organs, tissue or body fluids or used by others working with similar body parts and fluids from animals infected with the bloodborne pathogens?
9. Enter areas where other individuals work with human or animal blood, body fluid, tissues or organs which are infected with bloodborne pathogens and perform task where these body substances may

come into contact with the laboratory worker's unbroken skin, broken skin, or mucous membranes?

10. Perform tasks which may potentially result in the worker's exposed skin or mucous membranes coming into contact with human or animal blood, body fluids, organs, or tissues, which are infected with the bloodborne pathogens?
11. Provide patient care?
12. Clean clinical areas or equipment?
13. Dispose of medical waste or soiled laundry?
14. Perform first aid where exposure to human blood or OPIM is possible?
15. Clean up spills of human/NHP blood or OPIM?

If the answer to any of the questions above is "YES", then the worker is considered to be at occupational risk of contracting bloodborne pathogens and must be included in the Bloodborne Pathogens Program.

### **Tasks and Procedures**

Procedures that may be performed by employees in job classifications with occupational exposure to bloodborne pathogens are shown below.

- Using bloodborne pathogens
- Phlebotomy or venipuncture of humans or primates
- Injections into humans or animals using primate or human specimens
- Other use of needles with human or primate specimens
- Handling human or primate tissue, including preparation, dissection, and cutting
- Pipetting, mixing, or vortexing human or primate blood, fluid, or tissue
- Centrifuging human or primate blood, fluid, or tissue
- Handling tubes or other container or human or primate blood, fluid, or tissue
- Handling contaminated sharps or other contaminated waste
- Cleaning spills of human or primate blood or other body fluids
- Preparing or handling primary human cell lines or cultures, or primate cell cultures
- Clean clinical areas and medical equipment
- Providing patient care including but not limited to collecting specimens including blood, urine, saliva, stool, etc.
- Performing first aid where exposure to human blood or OPIM is possible
- Perform job functions (e.g., law enforcement duties, sewer maintenance, etc.) which may potentially result in the worker's exposed skin or mucous membranes coming into contact with human or animal blood, body fluids, organs, or tissues, which are infected with the bloodborne pathogens

## **V. Methods of Compliance**

### **A. Engineering Controls and Work Practices**

Engineering controls and regulation of work practices are the primary means to eliminate or minimize



potential occupational exposure to blood or OPIM. As such, PIs/Supervisors shall examine, maintain, and replace engineering controls and evaluate and update work practice controls regularly to ensure their effectiveness.

All procedures involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances

## **1. Universal Precautions**

Universal precaution is an infection control approach whereby all human/non-human primate (NHP) blood or OPIM (e.g., human tissue and body fluids) are treated as if infected with HBV, Hepatitis C virus (HCV), human immunodeficiency virus (HIV), or other BBPs.

Stanford University personnel shall take this approach at all times when working with human/NHP blood or OPIM and utilize practices and procedures described in the *Stanford University Biosafety Manual*, a copy of which is available online at [https://ehs.stanford.edu/wp-content/uploads/2201\\_EHS\\_Biosafety\\_Manual\\_v5-final\\_web\\_comp\\_3.pdf](https://ehs.stanford.edu/wp-content/uploads/2201_EHS_Biosafety_Manual_v5-final_web_comp_3.pdf) (Page 33).

## **2. Engineering Controls General Requirements**

PIs/supervisors shall identify engineering controls currently available in the marketplace and select those that best eliminate or minimize potential occupational exposure to blood or OPIM.

Engineering controls include but not limited to biosafety cabinets, sealed centrifuge rotors, mechanical pipetting devices, needleless sharps, sharps with engineered sharps injury protection (“safety sharps”), plastic blood collection tubes, and sharps containers.

PIs/Supervisors are responsible for examining and maintaining engineering controls on a regular basis to ensure their effectiveness. Engineering controls will be replaced/modified as necessary to ensure safe working conditions.

Engineered Sharps Injury Protection means either:

- A physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms
- A physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident

Guidance on appropriate selection is available from:

- The University of Virginia Health Care Worker Safety Center maintains an extensive listing of safety devices and manufacturers: <https://www.medicalcenter.virginia.edu/epinet/new/safetydevice.html>
- The International Sharps Injury Prevention Society maintains a list of medical safety devices categorized within their medical application: <http://isips.org/>
- The Cal/OSHA publication, *A Best Practices Approach for Reducing Bloodborne Pathogens Exposure*,

available online at: [www.dir.ca.gov/dosh/dosh\\_publications/BBPBest1.pdf](http://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf)

- OSHA Bloodborne Pathogens and Needlestick Prevention [www.osha.gov/SLTC/bloodbornepathogens/evaluation.html](http://www.osha.gov/SLTC/bloodbornepathogens/evaluation.html)
- EH&S Biosafety Manual. Safety Engineered and Needleless Sharps [https://ehs.stanford.edu/wp-content/uploads/2201\\_EHS\\_Biosafety\\_Manual\\_v5-final\\_web\\_comp\\_3.pdf](https://ehs.stanford.edu/wp-content/uploads/2201_EHS_Biosafety_Manual_v5-final_web_comp_3.pdf) (Page 89)

EH&S is responsible for determining changes in technology that eliminate or reduce exposure to BBP and documenting consideration and implementation of appropriate commercially available needless systems and needle devices and sharps with engineered sharps injury protection at least annually.

- Screening criteria are applied to new products in order to eliminate those with readily identifiable problems (e.g., ineffective devices, safety issues)
- New products may be further evaluated by a group comprised of representatives from EH&S, SUOHC, PIs, researchers, clinical users, and other Stanford University personnel as appropriate

### 3. Additional Requirements for Sharps

For withdrawal of body fluids, administration of medication/fluids, and other similar tasks involving potential for exposure incidents, sharps devices shall be selected in the following order of preference:

- Needleless systems. Needleless systems shall be used for:
  - Withdrawal of body fluids after initial venous or arterial access is established
  - Administration of medications or fluids
  - Any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices
- Safety sharps. If needleless systems are not used, needles with engineered sharp injury protection shall be used for:
  - Withdrawal of body fluids
  - Accessing a vein or artery
  - Administration of medications or fluids
  - Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available
- Sharps without engineered sharps injury protection (“non-safety sharps”). Non-safety sharps shall be selected only if one of the following cases apply:
  - Safety sharps are not available in the marketplace
  - For patient care, a licensed healthcare professional directly involved in a patient’s care determines and documents that an engineering control will jeopardize a patient’s safety or the success of a medical, dental or nursing procedure involving the patient. Healthcare providers at the Stanford University are responsible for documenting the determination of non-safety sharps usage, if any. A documentation template is available in Appendix B
  - “Objective Product Evaluation Criteria” can demonstrate that an engineering control is not more effective in preventing an exposure incident than an alternative already in use
  - The basis for this determination may include, but is not limited to, studies providing

data on the device's performance and evaluations made by research entities that have no economic relationship with manufacturers

- Reasonably specific and reliable safety performance information is not available, and the PI/Supervisor is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents in the lab/work area
- It is generally sufficient for PIs/Supervisors to rely on peer organizations, academic studies, and professional journals to track currently available information on devices. It may be appropriate for large departments to make more direct efforts to evaluate devices

#### **4. Work Practice Controls**

PI/Supervisors will be responsible for instituting work practices that minimize potential exposure. They are responsible for evaluating work practices regularly to ensure effectiveness.

Handling of sharps such as needles, blades, and broken glass can present risk of occupational exposure to blood or OPIM. To minimize risk, use of sharps requires appropriate care and adherence to safety guidelines.

##### **4.1 Handling Contaminated Sharps**

All procedures involving sharps shall incorporate safe handling practices that minimize risks of sharps injuries. These safe handling practices include, but are not limited to:

- a. Procedures involving the use of sharps in connection with patient care, such as withdrawing body fluids, accessing a vein or artery, or administering vaccines, medications or fluids, shall be performed using effective patient-handling techniques and other methods designed to minimize the risk of a sharps injury
- b. Place contaminated sharps in sharps waste containers immediately or as soon as possible after use
- c. Sharps containers shall be:
  - Easily accessible to personnel and located as close as feasible to the immediate areas where sharps are used or can be reasonably anticipated to be found
  - Maintained upright throughout use, where feasible
  - Replaced as necessary to avoid overfilling

##### **4.2 Prohibited Practices**

- Shearing or breaking of contaminated needles and other contaminated sharps is prohibited
- Contaminated sharps shall not be bent, recapped, or removed from devices
  - Contaminated sharps may be bent, recapped or removed from device if a) PI/Supervisor can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure; and b) The procedure is performed using a mechanical device or a one-hand technique
  - One-hand technique means a procedure wherein the needle or a reusable syringe is capped in a sterile manner during use. The technique employed shall require the use of only the hand holding the syringe so that the free hand is not exposed to the uncapped

needle

- Sharps that are contaminated with blood or OPIM 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
- Disposable sharps shall not be reused
- Broken glassware which may be contaminated shall not be picked up directly with hands. It shall be cleaned up using mechanical means, such as a brush and dustpan, tongs, or forceps
- Sharps containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of sharps injury
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas that have potential exposure to blood or OPIM
- Food and drink shall not be kept in refrigerators, microwaves, cabinets, countertops, or other areas where blood or OPIM may be present
- Personnel shall never use mouth pipetting or mouth suctioning of blood or OPIM

#### **4.3 Sharps Waste Containers**

Sharps are used in areas where the BBP standard applies, regardless of whether they are contaminated or not, shall be disposed in containers that are:

- Affixed with Biohazard Labels
- Rigid
- Puncture resistant
- Leakproof on the sides and bottom
- Portable
- Closeable
- Sealable
- Incapable of being reopened easily
- Non-reusable
- Easily accessible to personnel in the workplace
- Maintained upright
- Replaced as necessary to avoid overfilling

Waste can often involve a mixture of medical and non-medical waste (e.g., hazardous chemical waste, radioactive waste). Refer to Biosafety Manual Section 11 Waste for guidance on mixed waste disposal guidance.

#### **4.4 Handwashing**

- Handwashing facilities must be readily available to employees

- Personnel shall wash their hands with soap and running water immediately upon removal of gloves or other personal protective equipment
- Personnel shall wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as possible following contact of such body areas with blood or OPIM
- If handwashing facilities are not immediately available, personnel shall use appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes and then wash their hands with soap and running water as soon as feasible

#### **4.5 Handling Specimens of Blood or OPIM**

- Specimens of blood or OPIM shall be placed in biohazard-labeled containers that prevent leakage during collection, handling, processing, storage, transport, or shipping.
- A specimen container that is recognizable as containing a specimen does not require labeling when Universal Precautions are practiced in the handling of all specimens.
- The specimen container shall be placed in a biohazard-labeled secondary (outer) container if:
  - Contamination of the primary (inner) container occurs
  - The specimen can puncture the primary container
  - Leakage from the primary container may occur
  - If the specimen could puncture the primary container, the secondary container shall be puncture-resistant

#### **4.6 Cleaning and Decontaminating Work Areas**

PIs/Supervisors are responsible for ensuring that their workplaces shall be maintained in a clean and sanitary condition.

- Work surfaces shall be cleaned and decontaminated with an appropriate disinfectant immediately or as soon as feasible when:
  - A surface becomes, or may have become contaminated
  - There is a spill of blood or OPIM
  - Work procedures are completed
- All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or OPIM shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination
- 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 workday if they may have become contaminated
- Each PI and Supervisor of a worksite shall determine, implement, and maintain appropriate methods

and written schedules for cleaning and decontamination based upon the location within the workplace, type of surface, type of potential contamination present, and tasks or procedures performed in the area

- Resources available for determining the appropriate decontamination methods include:
  - Stanford University Biosafety Manual, Section 11, “Waste & Decontamination”
  - EPA-registered disinfectants
  - EH&S (723-0448)

#### **4.7 Shipping**

For shipping of blood or OPIM, all safe handling and labeling requirements noted in the ECP shall be followed. Personnel involved with shipping of blood, OPIM, or other biological agents must also:

- Follow guidelines in Stanford University Biosafety Manual, Section 10, “Transportation”
- Complete the STARS online training module “EHS-PROG-2700 Shipping Dangerous Biological Goods or Dry Ice” available online at [axess.stanford.edu](http://axess.stanford.edu)

#### **4.8 Servicing Contaminated Equipment**

Before servicing or shipping, all equipment which may become contaminated with blood or OPIM shall be examined and shall be decontaminated as necessary, unless the PI/supervisor can demonstrate that decontamination of such equipment or portions of such equipment is not feasible or will interfere with a manufacturer’s ability to evaluate failure of the device.

Equipment that cannot be decontaminated prior to servicing shall be labeled (ECP Section VI.1.). For shipping contaminated equipment, see ECP Section V.A.4.7.

#### **4.9 Waste Disposal**

Personnel must follow the “Biohazardous and Medical Waste Disposal Guidelines” and Section 11, “Waste & Decontamination” of the Stanford University Biosafety Manual.

Further information is available from EH&S at 723-0448.

### **B. Personal Protective Equipment (PPE)**

PIs/Supervisors have the primary responsibility for implementing the PPE Program in their work area by ensuring that workplace hazards have been evaluated, that the appropriate PPE is available, and that employees have received the necessary training.

Stanford University provides the Laboratory PPE Assessment Tool to complete this assessment. The PPE user is responsible for following the requirement of the PPE program. This involves: (1) Wearing PPE as required per the PPE Assessment Tool; (2) Attending PPE training sessions; (3) Cleaning and maintaining PPE as trained; and (4) Informing the supervisor of the need to repair or replace PPE.

## 1. Provision

- PIs/Supervisors are responsible for determination of documentation of the specific PPE for their employees based on anticipated employee exposure to blood or OPIM using the Laboratory PPE Assessment Tool
- Personnel will be provided, at no cost to the employee, with appropriate PPE for performing tasks which may result in exposure, such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection
- PPE will be considered appropriate only if it does not permit blood or OPIM to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, and other mucous membranes under normal conditions of use and for the duration of time which the PPE will be used

## 2. Use

The PIs/Supervisors shall ensure that employees use appropriate PPE as necessitated by their work tasks. However, under rare and extraordinary circumstances, employees may decline to use PPE temporarily and briefly if, in their professional judgment, its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. Should this happen, the circumstances will be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

## 3. Accessibility

- PIs/Supervisors shall ensure that appropriate PPE in the appropriate sizes is readily accessible at the worksite or is issued to employees
- Hypoallergic gloves, glove liners, powder-free gloves, or other similar alternatives shall be readily available to those employees who are allergic to the gloves normally provided

## 4. Removal, Cleaning, Laundering, and Disposal

- PPE shall be inspected, cleaned, and replaced as necessary
- If a garment(s) is penetrated by blood or OPIM, the garment(s) shall be removed immediately as soon as possible
- All PPE shall be removed prior to leaving the work area. Personnel are not permitted to take PPE outside of work areas (e.g., wearing PPE in hallways, offices, and cafeteria) or offsite (e.g., taking a laboratory coat home to clean)
- When PPE is removed, it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal
- Disposable PPE contaminated or potentially contaminated with blood or OPIM shall be disposed of as Medical Waste
- Reusable PPE (e.g., laboratory coats, uniforms, and other garments) potentially contaminated with blood or OPIM shall be either:
  - Immediately placed in nonpermeable bags affixed with biohazard symbols (to be supplied by Stanford University vendors) pending offsite laundering

- Disposed of as Medical Waste

## **5. Gloves**

- Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, and non-intact skin; when handling or touching contaminated items or surfaces; and when performing vascular access procedures
- Disposable gloves shall not be washed or decontaminated for re-use
- Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised
- Employees must wash their hands after glove removal

## **6. Masks, Eye Protection, Face Shields, and Respirators.**

- 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 OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated
- If respiratory protection is used, all procedures will be conducted in accordance with the Stanford University Respiratory Protection Program
- It is important to note that surgical masks are not respirators

## **7. 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 exposure situations. The specific type will depend upon the task and degree of exposure anticipated
- When gross contamination can be reasonably anticipated, surgical caps or hoods and/or shoe covers or boots shall be worn

## **C. HBV, HCV and HIV Research Operation Requirements**

### **1. Workplace Controls and Practices**

In addition to general engineering and work practice controls outlined in this ECP, research operations involving HBV, HCV, and HIV shall adhere to these measures and applicable provisions of Stanford's Biosafety Manual.

#### **a. Access**

- Keep laboratory doors closed when working with blood or OPIM involving HIV, HBV, or HCV
- Limit workplace access to those authorized by PIs/Supervisors

#### **b. Work Practices and Procedures**

- PIs/Supervisors are responsible for preparing, implementing, reviewing, and updating written biosafety procedures for their work site. These procedures are adopted into



the Administrative Panel on Biosafety (APB) protocol for the specific work site. Personnel are advised of the potential hazard and required to read and follow the written practices and procedures outlined in the protocol

- Personnel must take special care to avoid skin contact with OPIM and wear gloves when handling infected animals and when making hand contact with OPIM is unavoidable
- Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms
- Use hypodermic needles and syringes only for parenteral injection and aspiration of fluids from animals and diaphragm bottles
  - o Only needle-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 OPIM

**c. Engineering Controls**

- Conduct activities involving blood or OPIM in biological safety cabinets or within other physical containment devices
- No work with the blood or OPIM shall be conducted on the open bench
- Protect vacuum lines with liquid disinfectant traps and HEPA filters or filters of equivalent or superior efficiency and which are checked routinely and maintained as necessary
- 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 OPIM that pose a threat of exposure to droplets, splashes, spills, or aerosols
- Biological safety cabinets shall be certified that they meet manufacturer's specifications when installed, whenever they are moved, and at least annually
- Have eye and handwashing facilities readily available within the work area

**d. Decontamination Practices**

- Ensure that protective clothing is not worn outside of the work area and that it is decontaminated before being laundered
- Ensure that contaminated materials that are to be decontaminated at a site away from the work area are placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area
- Ensure that all spills are immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials
- Before disposal, all waste from work areas and from animal rooms are treated in accordance with Stanford University medical waste management plan. Stanford University contracts with a licensed medical waste vendor to properly handle and dispose of all medical waste

- Contaminated materials must be placed in durable, leak proof, labeled or color-coded containers that are closed before being removed from the work area for decontamination

## 2. Personnel Experience & Proficiency

Before being allowed to work with HBV, HCV and/or HIV or OPIM, PIs/Supervisors shall ensure that personnel:

- Have prior experience in the handling of human pathogens or tissue culture
- Demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the research/work area
- The PI/Supervisor shall provide training to personnel 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 employer shall assure that personnel participate in work activities involving infectious agents only after proficiency has been demonstrated

## VI. Hazard Communication to Personnel

### 1. Biohazard Labels and Signs

#### 1.1 Items Requiring Labels

Biohazard labels shall be either be an integral part of the container or shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

- Sharps waste containers
- Containers for handling, storing, or transporting specimens containing blood or OPIM
- Containers of Regulated Waste
- Refrigerators and freezers which may contain blood or OPIM
- Bags containing PPE to be laundered
- Contaminated equipment (label to note portions that are contaminated)

Red bags or red containers may be substituted for labels **except for sharp containers or regulated waste red bags**. Bags used to contain regulated waste shall be color-coded red and shall be labeled.

Chemotherapy, pathology and other particular Medical Waste have specific labeling requirements under the *California Medical Waste Management Act (Health and Safety Code Sections 118275 through 118320)*. PIs/Supervisors must contact the EH&S Waste Group at (650) 725-7529 if they anticipate generating these types of Medical Waste in the work area. Further information about medical waste can be found in the Stanford University Biosafety Section 11.1 Waste.

The following do not require biohazard labeling:

- Containers of blood or OPIM labeled as to their contents and released for transfusion or other clinical use

- Decontaminated Regulated Waste
- Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment or disposal

### 1.2 Label Specifications

Biohazard warning labels shall:

- Include appropriate universal biohazard symbols similar to the sample to the right and the word "BIOHAZARD"
- Be fluorescent orange or orange/red with lettering and symbols in contrasting color



Contact the EH&S Biosafety Group at (650) 723-0448 to obtain labels or further information on applicable labeling requirements.

### 1.3 Biohazard Area Signs

Biohazard warning signs must be posted on access doors to workplaces which contain blood or OPIM, and all work areas for HIV, HBV, or HCV research laboratories.

Biohazard signs shall:

- Include the Universal biohazard symbol
- List the name of the infectious agent(s) present
- Indicate special requirements for entering the workplace
- Provide the name and telephone number of PI/Supervisor for the workplace

Contact the EH&S Biosafety Group at 723-0448 to obtain biohazard signs.

## 2. Training

### a. Online Training Modules

All personnel with potential for occupational exposure to blood or OPIM must complete the following Stanford Training and Registration System (STARS) training modules (available through [axess.stanford.edu](https://axess.stanford.edu)) upon initial hiring:

- EHS-1500: Biosafety
- EHS-1600: Bloodborne Pathogens

These personnel must also complete the STARS module annually thereafter:

- EHS-1601: Bloodborne Pathogens

### b. Workplace-Specific Operations & Safe Practices

PIs/Supervisors shall ensure that supervised personnel receive workplace-specific training:

- Before beginning work with potential exposure to blood or OPIM
- Annually thereafter

- When changes affect occupational exposure. Examples of such changes include:
  - o Introduction of new engineering, administrative, or work practice controls
  - o Modification of tasks or procedures
  - o Institution of new tasks or procedures
- When investigation of an exposure incident identifies the need for additional training

## VII. Hepatitis B (HBV) Vaccination

The Hepatitis B vaccine and vaccination series is available to employees who may have occupational exposure after completing the hepatitis B training required in subsection (g)(2)(G)(9). The vaccine is offered free of charge within 10 working days of initial assignment to employees who have occupational exposure. If the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons, the employee shall sign the **“Stanford University Hepatitis B Vaccine Declaration Form”** as described below

The Stanford University Occupational Health Center is the administrator of the Hepatitis B vaccination program and shall ensure that all medical evaluations and procedures, including the Hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

- Made available at no cost to the employees
- Made available to the employee at a reasonable time and place
- Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional
- Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place

Personnel with the potential for occupational exposure to blood or OPIM shall:

- Review the “Occupational Exposure to Hepatitis B Virus”
- Complete the “Stanford University Hepatitis B Vaccine Declaration Form” and submit to the SUOHC within 10 working days of initial assignment

While Stanford University encourages employees to be vaccinated, accepting vaccination is not a condition of employment. Employees who decline to take the vaccine will also be required to sign the Hepatitis B Vaccine Declaration Form. However, employees who refuse the initial vaccine may change their decision and receive the vaccine at any time as long as they continue to have occupational exposure

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available

PI/Supervisors shall ensure that personnel electing to receive the Hepatitis B vaccine are provided sufficient time during normal business hours to obtain the vaccination from SUOHC

For additional information regarding the Hepatitis B vaccine and occupational exposure to the virus, please visit the EH&S website page (<https://ehs.stanford.edu/about-us/occupational-health-center>) or contact the SUOHC by calling 650-725-5308

First aid providers are not required to be offered pre-exposure hepatitis B vaccine if the primary job assignment of the employee is not the rendering of first aid

- Any first aid rendered is only as a collateral duty responding solely to injuries resulting from workplace incidents, generally at a location where the incident occurred. ***However, this exception does not apply to designated first aid providers who render assistance on a regular basis such as public safety personnel who are expected to render first aid in the course of their work and locations where injured employees routinely go for such assistance***

Additional requirements for first aid incidents:

- Hepatitis B vaccine shall be made available to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM (regardless of whether an actual exposure incident occurred)
- Post-exposure evaluation, prophylaxis, and follow-ups shall be available for those employees who experience exposure incidents

## VIII. Exposure Incidents

### A. Emergency Procedures

**In the event of an exposure incident involving blood or OPIM, the following actions must be taken immediately:**

- 1) Initiate first aid (as appropriate) in the workplace:
  - Wash contaminated skin, including any animal bite/scratch wounds, thoroughly for fifteen (15) minutes using soap and running water
  - Irrigate contaminated eyes and mucous membranes for fifteen (15) minutes with running water
- 2) Notify direct PI/Supervisor
- 3) File the incident report form available at <https://ehs.stanford.edu/esu-17>
- 4) Employees and students exposed to blood and OPIM in work-related situations should seek medical care at SUOHC located at Environmental Safety Facility, 484 Oak Road (Phone: 650-725-5308)

Students exposed to blood and OPIM in non-work-related situations (e.g., volunteer first aid) should seek medical care at Vaden Health Center, 866 Campus Drive (Phone: 650-498-2336).

Exceptions:

- If the exposure incident occurs outside of SUOHC clinic hours (8 AM to 5 PM weekdays, excluding holidays):
  - Report to the Stanford Hospital Marc and Laura Andreessen Adult Emergency Department at 1199 Welch Rd, Palo Alto, CA for immediate care
  - Report to the SUOHC on the following working day

**In the event of a first aid incident involving the presence of blood or OPIM:**

- All first aid incidents involving the presence of blood or OPIM must be reported to the employer before the end of the work shift during which the first aid incident occurred
- The incident must be reported using the incident report form available at <https://ehs.stanford.edu/esu-17> . The report shall include the following information:
  - The names of all first aid providers who rendered assistance, regardless of whether personal protective equipment was used and must describe the first aid incident, including time and date
  - A determination of whether or not, in addition to the presence of blood or OPIM, an exposure incident occurred. This determination is necessary in order to ensure that proper post-exposure evaluation, prophylaxis and follow-up procedures are made available immediately if there has been an exposure incident
  - The incident report shall be recorded on a list of such first aid incidents. It will be readily available to all employees and shall be provided upon request to the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations
  - Provision for the full hepatitis B vaccination series will be made available as soon as possible, but in no event later than 24 hours, to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM regardless of whether or not a specific exposure incident has occurred

**B. Post-Exposure Evaluations and Follow-Up**

**1. Information Provided to the Healthcare Professional**

The following information shall be documented and provided to the SUOHC:

- The route(s) of exposure, and the circumstances under which the exposure incident occurred
- A description of the exposed employee's job duties as they relate to the exposure incident
- Results of the source individual's blood testing, if available and applicable (ECP Section VII.B.2.)
- All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain

**2. Source Individual Blood Testing**

The PI/Supervisor shall identify and document the source individual, if applicable, unless the PI/supervisor can establish that identification is infeasible or prohibited by state or local law.

- The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV, HCV and HIV infectivity. If consent is not obtained, the PI/Supervisor shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented

- When the source individual is already known to be infected with HBV, HCV or HIV, testing for the source individual's known HBV, HCV or HIV status need not be repeated
- Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual

The PI/Supervisor must contact SUOHC for assistance in the process. The SUOHC will provide assistance, as needed and appropriate.

### **3. Medical Evaluation and Follow-up**

The SUOHC shall:

- Evaluate exposed personnel according to established medical protocols
- Collect the exposed employee's blood as soon as feasible and test after consent is obtained
  - o If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible
- Provide post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service

### **4. Healthcare Professional's Written Opinion**

Within fifteen (15) days of evaluation completion, SUOHC shall provide a written opinion to the PI/Supervisor and send a copy to the employee that is limited to the following information:

- That the employee has been informed of the results of the evaluation
- That the employee has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment

All other findings or diagnoses shall remain confidential and shall not be included in the written report

Personnel may refuse post-exposure evaluation and follow-up from the SUOHC and instead be provided, without cost, a confidential medical evaluation and follow-up from an independent healthcare professional selected by the SUOHC

### **5. Workplace Evaluation and Follow-up**

Within twenty-four (24) hours of a potential exposure incident, a Stanford University Incident Investigation Report (SU-17) must be filed. The SU-17 form is available online at <https://ehs.stanford.edu/esu-17>

As part of evaluating exposure incidents, PIs/Supervisors shall as soon as feasible:

- Review the hazard control measures and update it to reflect any corrective measures and improvements
- Provide training, as needed, to affected personnel and those with similar potential occupational exposures to prevent future exposure incidents

## C. Requirements for Sharps Injuries

### 1. Sharps Injury Report

Within twenty-four (24) hours of a sharps injury occurring, the PI/Supervisor shall ensure that a Sharps Injury Report, available online at <https://ehs.stanford.edu/forms-tools/sharps-injury-report>.

This is in addition to submitting the SU-17: <https://ehs.stanford.edu/esu-17>

### 2. Sharps Injury Log

EH&S is responsible for:

- Recording each sharps injury on the Sharps Injury Log within fourteen (14) calendar days of receiving a report of a sharps injury
- Retaining a copy of the Sharps Injury Log for a minimum of five (5) years
- The information in the Sharps Injury Log shall be recorded and maintained in such a manner as to protect the confidentiality of the injured person
- EH&S shall perform an annual review of collected Sharps Injury Log and document in the Sharps Injury Annual Report. Review will include, but not be limited to the following:
  - Area/Department involved
  - Type/model/brand/frequency of use of sharp
  - Description of incident
  - Training
- Any identified trend or concern may be further evaluated by a group comprised of representatives from EH&S, SUOHC, PIs, researchers, clinical users, and other Stanford University personnel as appropriate

## IX. Recordkeeping

### 1. Medical Records

The SUOHC shall maintain an accurate employee medical record of each employee with occupational exposure in accordance with *California Code of Regulations, Title 8, Section 3204 (8 CCR 3204)*. SUOHC is responsible for maintaining this record. This record shall include:

- The name and social security number of the employee
- A copy of the employee's HBV vaccination status, including the dates of any HBV vaccinations and any medical records relative to the employee's ability to receive vaccination as required by 8 CCR 5193(f)(2)
- A copy of all results of examinations, medical testing, and follow-up procedures as required by 8 CCR 5193(f)(3)
- A copy of the healthcare professional's written opinion as required by 8 CCR 5193(f)(5)



- A copy of the information provided to the healthcare professional as required by 8 CCR 5193(f)(4)(B)2, 3, and 4

Personnel medical records required by 8 CCR 5193 shall be kept confidential and not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by 8 CCR 5193 or as may be required by law.

The above-mentioned records shall be maintained for at least the duration of employment plus thirty (30) years in accordance with 8 CCR 3204.

## **2. Training Records**

- Bloodborne pathogen training course records will be maintained on Stanford Axxess database
- The training records include: 1) The dates of the training sessions; 2) The contents or a summary of the training sessions; 3) The names and qualifications of persons conducting the training; and 4) The names and job titles of all persons attending the training sessions
- Training records shall be maintained for 3 years from the date on which the training occurred

## **3. Sharps Injury Log**

The Sharps Injury Log shall be maintained 5 years from the date the exposure incident occurred.

## **4. Availability**

- Stanford University shall ensure that all records required to be maintained by this section shall be made available upon request to the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations or designated representative ("Chief") and NIOSH for examination and copying
- Employee training records required by this subsection shall be provided upon request for examination and copying to employees, to employee representatives, to the Chief, and to NIOSH
- Employee medical records required by this standard shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Chief, and to NIOSH
- The sharps injury log required by this standard shall be provided upon request for examination and copying employees, to employee representatives, to the Chief, to the Department of Health Services, and to NIOSH

## **5. Transfer of Records**

- The employer shall comply with the requirements involving transfer of records
- If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify NIOSH at least three months prior to their disposal and transmit them to NIOSH, if required by the NIOSH to do so, within that three month period

## APPENDIX A – Definitions

**"Aerosols"** means particles less than 10 microns in diameter, and are not typically visible to the naked eye, can remain airborne for extended periods of time, and may be inhaled.

**"Biological Cabinet"** means a device enclosed except for necessary exhaust purposes on three sides and top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user, and in which virulent pathogens are used. Biological cabinets are classified as:

- 1) Class I: A ventilated cabinet for personnel protection with an unrecirculated inward airflow away from the operator and high-efficiency particulate air (HEPA) filtered exhaust air for environmental protection.
- 2) Class II: A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, HEPA filtered laminar airflow for product protection, and HEPA filtered exhaust air for environmental protection.
- 3) Class III: A total enclosed, ventilated cabinet of gas-tight construction. Operations in the cabinet are conducted through attached protective gloves.

**"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, hepatitis B virus, hepatitis C virus and human immunodeficiency virus.

**"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 a surface or in or on an item.

**"Contaminated Laundry"** means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

**"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. Decontamination includes procedures regulated by California Health and Safety Code Section 118275<sup>4</sup>.

**"Engineering Controls"** mean controls (e.g., sharps disposal containers and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

**"Engineered Sharps Injury Protection"** means either:

- 1) A physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms; or
- 2) A physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident.

**"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.

**"Licensed Healthcare Professional"** is a person whose licensed scope of practice includes an activity which this section requires to be performed by a licensed healthcare professional.

**"Medical Waste"** according to California Health and Safety Code Sections 117600 through 118360<sup>5</sup>, commonly known as the "California Medical Waste Management Act", includes but is not limited to the following:

- Human or animal specimens or infectious cultures;
- Sharps, including needles and syringes (clean or dirty);
- Cultures and stocks of infectious agents;
- Wastes from the production of bacteria, viruses, or the use of spores, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;
- Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents contagious to humans; and
- Waste which contains recognizable blood, fluid blood products, containers or equipment containing blood, or blood from animals known to be infected with diseases which are communicable to humans.

**"Needle"** or **"Needle Device"** means a needle of any type, including, but not limited to, solid and hollow-bore needles.

**"Needleless System"** means a device that does not utilize needles for:

- 1) The withdrawal of body fluids after initial venous or arterial access is established;
- 2) The administration of medication or fluids; and
- 3) Any other procedure involving the potential for an exposure incident.

**"NIOSH"** means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

**"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.

**"One-Hand Technique"** means a procedure wherein the needle of a reusable syringe is capped in a sterile manner during use. The technique employed shall require the use of only the hand holding the syringe so that the free hand is not exposed to the uncapped needle.

**"OPIM"** means other potentially infectious materials, which consist of:

- 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 other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response;
- 2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- 3) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:
  - a. Cell, tissue, or organ cultures from humans or experimental animals;
  - b. Blood, organs, or other tissues from experimental animals; or
  - c. Culture medium or other solutions.

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

**"Personal Protective Equipment"** is specialized clothing or equipment worn or used 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.

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

**"Regulated Waste"** means waste that is any of the following:

- 1) Liquid or semi-liquid blood or OPIM;
- 2) Contaminated items that:

- a. Contain liquid or semi-liquid blood, or are caked with dried blood or OPIM; and
  - b. Are capable of releasing these materials when handled or compressed
- 3) Contaminated sharps.
  - 4) Pathological and microbiological wastes containing blood or OPIM.
  - 5) Regulated Waste includes "Medical Waste".

**"Research Laboratory"** means a laboratory producing or using research-laboratory-scale amounts of blood or OPIM with or potentially containing HIV, HBV or HCV. Research laboratories may use or handle large quantities of blood or OPIMs, but not in the volume found in production facilities.

**"Sharp"** means any object used or encountered in the industries covered by 8 CCR 5193 Subsection (a) that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, broken capillary tubes, exposed ends of dental wires and dental knives, drills and burs.

**"Sharps Injury"** means any injury caused by a sharp, including, but not limited to, cuts, abrasions, or needlesticks.

**"Sharps Injury Log"** means a written or electronic record satisfying the requirements of 8 CCR 5193 Subsection (c)(2).

**"Sharps Injury Annual Report"** means a Stanford University written document evaluating Sharps Injury Logs collected on an annual basis.

**"Source Individual"** means any individual, living or dead, whose blood or OPIM may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinical 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.

**"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 HBV, HCV, HIV, and/or other bloodborne pathogens.

**"Work Practice Controls"** means controls that reduce the likelihood of exposure by defining the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique and use of patient-handling techniques)

## Appendix B: Non-safety Sharps Documentation

**Use this form to document the rationale for using non-safety sharps for patient safety**

Employees are NOT required to use engineering controls (i.e., needleless systems, needle devices, or non-needle sharps) if a licensed healthcare professional:

- Determines that the new control will jeopardize the patient’s safety or the success of a medical, dental, or nursing procedure
- Is directly involved in the patient’s care
- Exercises reasonable clinical judgment

If this exception applies, the healthcare provider is responsible for completing the form below and submit to the Stanford University Biosafety Officer, Dr. Ellyn Segal via [esegal@stanford.edu](mailto:esegal@stanford.edu)

**Patient Safety Determinations for Exceptions to the Use of Engineering Controls** (add additional pages as necessary)

Control Under Consideration	Name of Licensed Healthcare Professional Making the Determination	Department/Unit	Date of the Determination	Reason(s) for the Applicability of This Exception with This Patient

Comments: