

STANFORD UNIVERSITY

Environmental Health & Safety

Bloodborne Pathogens

Institutional Exposure Control Plan

2012

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Stanford University - Bloodborne Pathogens Exposure Control Plan

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."¹

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 5193² (*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.

II. Scope

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

A Local Bloodborne Pathogens Exposure Control Plan (Local ECP), completed by the PI/Supervisor, acts as a supplement to the Institutional ECP. The Local ECP covers laboratories, work areas, and/or work operations under the direction of the PI/Supervisor.

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 Health and Safety at Stanford University: Principles, Responsibilities, and Practices (Research Policy Handbook Section 6.2, April 1991, <u>http://rph.stanford.edu/6-2.html</u>) ² http://www.dir.co.gov/title8/C102.html

² <u>http://www.dir.ca.gov/title8/5193.html</u>

A. Principal Investigators/Supervisors

Pls/Supervisors are responsible for the health and safety of their supervised personnel, with duties including but not limited to:

- Completing a Local ECP
- Implementing the Institutional ECP and Local ECP in areas/operations under their control;
- Reviewing and updating the Local ECP every 12 months and when:
 - There are new or revised personnel positions with potential occupational exposure to blood or OPIM;
 - New or modified procedures and work tasks affect potential occupational exposure to blood or OPIM;
 - Changes in technology present the opportunity to eliminate/reduce exposures to blood or OPIM; and
 - o BBP-related safety deficiencies are identified.
- Involving supervised personnel when updating the Local ECP;
- Keeping and making copies of Local ECPs available in workplaces; and
- Contacting EH&S (723-0448) for assistance with completing Local ECPs.

B. 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); and
- Immediately reporting any exposure incident, including sharps injuries, near-misses, or unsafe procedures or work tasks to PI/Supervisors and/or EH&S.

C. Stanford University Occupational Health Center (SUOHC)

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

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

D. Department of Environmental Health and Safety (EH&S)

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

- Overseeing Institutional implementation of the Bloodborne Pathogens Standard;
- 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;
- Recommending proper engineering controls, administrative controls, and PPE;
- Preparing and maintaining the University's Sharps Injury Log;
- Performing annual reviews of sharps injuries, preparing the Sharps Injury Annual Report, and disseminating findings as appropriate; and
- Reviewing and updating the Institutional ECP at least annually.

IV. Exposure Determination

PIs/Supervisors shall identify all job classifications and work procedures within their oversight that may potentially incur occupational exposure to blood and/or OPIM and document in the Local ECP through completion of the "Exposure Determination" or other acceptable methods. The determination of potential exposure to blood or OPIM shall be made without regard to the use of personal protective equipment.

V. HBV Vaccination

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

- Review the "Occupational Exposure to Hepatitis B Virus" and "Hepatitis B Vaccination FAQ"; and
- Complete the "Stanford University Hepatitis B Vaccine Declaration Form" and submit to the SUOHC within 10 working days of initial assignment.

HBV-related documents are available online at: web.stanford.edu/dept/EHS/prod/researchlab/medsurv/.

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.

VI. 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.

1. Universal Precautions

Universal precautions is an infection control approach whereby all 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 blood or OPIM and utilize practices and procedures described in the *Stanford University Biosafety Manual*, a copy of which is available online at http://web.stanford.edu/dept/EHS/prod/researchlab/bio/Biosafety_Manual/Biosafety_B

2. Preventing Accidental Ingestion of Blood or OPIM

- 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.

3. Selecting Engineering Controls

Pls/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. Examples of engineering controls include needleless sharps, sharps with engineered sharps injury protection ("safety sharps"), plastic blood collection tubes, and sharps containers. Guidance on appropriate selection is available from:

- www.healthsystem.virginia.edu/pub/epinet
- Product Vendors
- 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
- <u>www.osha.gov/SLTC/bloodbornepathogens/evaluation.html</u>
- EH&S Biosafety Program

a. Selection Requirements

PIs/Supervisors must evaluate/revaluate and select appropriate engineering controls for use:

- Prior to new or modified procedures which affect occupational exposure;
- Whenever an exposure incident occurs;
- At least every 12 months to determine if new technologies are available in the marketplace which reduce potential occupational exposure to blood or OPIM; and

 Whenever the PI/Supervisor becomes aware of engineering controls that better eliminate or minimize potential exposure to blood or OPIM than the ones currently being used.

b. 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:

- 1) Needleless systems.
- 2) Safety sharps.
- 3) Sharps without engineered sharps injury protection ("nonsafety sharps"). Nonsafety 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.
 - "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.

Evaluation and selection of all sharps shall be documented in the Local ECP. For nonsafety sharps, evaluation shall include determining if safety sharps are available for use.

4. Sharps Safety

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.

a. 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:

- Place contaminated sharps in sharps waste containers immediately or as soon as possible after use.
- Never open, manually clean, or otherwise access contents of a sharps waste container.
- Never shear or break contaminated needles or other sharps.
- Never handle broken glassware with bare hands.
 - Broken glassware shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.
- Never bend, re-cap, or remove devices from contaminated sharps, except:
 - If the PI/Supervisor can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure; and
 - The procedure uses a mechanical device or a one-handed technique.

b. Sharps Waste Containers

All sharps, 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;
- Nonreusable;
- Easily accessible to personnel in the workplace;
- Maintained upright; and
- Replaced as necessary to avoid overfilling.

5. Handwashing

Personnel shall wash their hands with soap and running water immediately upon removal of gloves or other PPE.

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.

6. Handling Specimens of Blood or OPIM

a. Primary Containers

Blood or OPIM specimens 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.

b. Secondary Containers

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; or
- Leakage from the primary container may occur.

If the specimen could puncture the primary container, the secondary container shall be puncture-resistant.

7. Cleaning and Decontaminating Work Areas

Workplaces shall be maintained in a clean and sanitary condition.

a. Work Surfaces

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; or
- Work procedures are completed.

b. Waste Receptacles

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.

c. Coverings

Protective coverings, such as plastic wrap, aluminum foil, or imperviouslybacked 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.

d. Methods and Schedules

Each PI/Supervisor shall determine and implement methods and schedules for cleaning and decontamination that are appropriate for the:

- Workplace location;
- Types of surfaces and equipment to be cleaned;
- Contamination present; and
- Tasks or procedures performed in the workplace.

Resources available for determining the appropriate decontamination methods include:

- <u>Stanford University Biosafety Manual</u>, Section 9, "Waste & Decontamination"
- <u>www.epa.gov/oppad001/chemregindex.htm</u> (a list of EPA-registered disinfectants)
- EH&S (723-0448)

The PI/Supervisor shall document the workplace cleaning schedule in the Local ECP.

8. 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 <u>Stanford University Biosafety Manual</u>, Section 8, "Transportation"
- Complete the STARS online training module "EHS-2700: DOT: Shipping Biological Goods or Dry Ice" available online at <u>axess.stanford.edu.</u>

9. 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.D.1.). For shipping contaminated equipment, see ECP Section VI.A.9.

10. Waste Disposal

Personnel must follow the "Biohazardous and Medical Waste Disposal Guidelines" and Section 9, "Waste & Decontamination" of the <u>Stanford University Biosafety</u> <u>Manual</u>. Further information is available from EH&S at 723-0448.

B. Personal Protective Equipment (PPE)

PI/Supervisors shall provide appropriate PPE to supervised personnel for protection from potential occupational exposure to blood and OPIM when needed and without cost.

Appropriate PPE prevents blood or OPIM from reaching the work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes of personnel.

1. Selection

PPE shall be selected and properly worn as described below to prevent occupational exposures to blood or OPIM during normal workplace operations, with alternatives considered for personnel with allergies to certain materials (e.g., latex).

PPE:	Required for:	Basic requirements:
Basic protective clothing (e.g., laboratory coats or gowns)	Work areas (e.g., laboratories) having potential exposure to blood or OPIM	 Select protective clothing based on work task and foreseeable/ expected exposure to blood or OPIM.
Additional protective clothing (e.g., surgical caps or hoods and shoe covers or boots)	Foreseeable/expected gross contamination (e.g., autopsy, orthopedic surgery)	 If a garment is penetrated by blood or OPIM, remove immediately or as soon as feasible.
		• Remove before touching common equipment (e.g., phone, computer).
	 Expected/foreseeable hand contact with: Blood or OPIM Mucous membranes Nonintact skin 	Remove disposable gloves:
		 immediately when damaged in any way; or
Gloves		 as soon as practical when contaminated.
		 Do not wash/decontaminate disposable gloves for re-use.
	 Contaminated surfaces 	 Utility gloves may be decontaminated for reuse if their integrity is not compromised

PPE:	Required for:	Basic requirements:
Surgical masks in conjunction with eye protection (i.e., safety goggles or glasses) OR Eye protection in conjunction with face shield	Foreseeable/expected blood or OPIM contact with mucous membranes of the eye, nose or mouth	 Ensure eye and face protection meet American National Standards Institute (ANSI) Z87.1 standards. Regular prescription glasses do not provide adequate eye protection. NOTE: Surgical masks do not provide respiratory protection.
Respirators (e.g., N95, P100)	Respiratory hazards present	• Contact EH&S at 723-0448 for Respiratory Protection Program requirements, including medical clearance, fit-testing, and training.

2. Inspection and Removal

- PPE shall be inspected, cleaned, and replaced as necessary.
- Protective clothing shall be removed immediately or as soon as feasible if penetrated by blood or OPIM.
- Disposable gloves shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or otherwise damaged.
- PPE shall be removed prior to leaving work areas and placed in designated areas for reuse (e.g., coat-check), laundering (designated containers or bags), or disposal (e.g., Medical Waste bag).
 - 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).

3. Cleaning and 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:
 - 1) Immediately placed in nonpermeable bags affixed with biohazard symbols (to be supplied by Stanford University vendors) pending offsite laundering; or
 - 2) Disposed of as Medical Waste.
- Utility gloves may be decontaminated for reuse if the integrity of the glove is not compromised.

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.

a. Access

- Keep laboratory doors closed when working with blood or OPIM.
- Limit workplace access to those authorized by PIs/Supervisors.

b. Work Practices and Procedures

- Prepare written biosafety procedures and adopt them into the Local Exposure Control Plan.
- Take special care to avoid skin contact with OPIM and wear gloves when handling infected animals.
- Use hypodermic needles and syringes only for parenteral injection and aspiration of fluids from animals and diaphragm bottles.
 - 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.
- 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.
- Have eye and handwashing facilities readily available within the work area.
- Have autoclaves available for decontaminating Regulated Waste.

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.

2. Containment Equipment

 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.

3. Personnel Experience & Proficiency

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

- Have prior experience in the handling of human pathogens or tissue cultures; and
- 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.

D. Hazard Communication to Personnel

1. Biohazard Labels

a. Items Requiring Labels

Biohazard labels shall be firmly affixed to:

- 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; and
- Contaminated equipment (label to note portions that are contaminated).

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.

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; and
- Decontaminated Regulated Waste.

b. Label Specifications

Biohazard warning labels shall:

- Include appropriate universal biohazard symbols similar to the sample to the right and the word "BIOHAZARD"; and
- 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.



2. Biohazard Area Signs

a. Areas Requiring Signs

Biohazard warning signs must be posted on access doors to workplaces which contain blood or OPIM.

b. Sign Specifications

Biohazard signs shall:

- Include the Universal biohazard symbol;
- List the name of the infectious agent(s) present;
- Indicate special requirements for entering the workplace; and
- 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.

3. 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 <u>axess.stanford.edu</u>) 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 workplacespecific training:

- Before beginning work with potential exposure to blood or OPIM.
- Annually thereafter.
- When changes affect occupational exposure. Examples of such changes include:
 - $\circ\;$ Introduction of new engineering, administrative, or work practice controls.
 - Modification of tasks or procedures.
 - o Institution of new tasks or procedures.
- When investigation of an exposure incident identifies the need for additional training.

c. Recordkeeping

All workplace-specific training shall be documented in the Local ECP and be maintained by PI/Supervisor for three (3) years.

All training records shall be made available upon request for examination and copying by EH&S, personnel and/or personnel representatives, and governing regulatory agencies.

VII. 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.
- Report to the SUOHC located at <u>Environmental Safety Facility</u>, <u>480 Oak Road</u>, Room B15 (725-5308).

Exceptions:

- If the exposure incident occurs outside of SUOHC clinic hours (8 AM to 5 PM weekdays, excluding holidays):
 - Report to the <u>Stanford Hospital Emergency Department</u> for immediate care; and
 - Report to the SUOHC on the following working day.
- If the exposure incident occurs while working within the Stanford Hospital & Clinics/Lucile Packard Children's Hospital (SHC/LPCH):

- Page 1-STIX to speak with the on-call Occupational Health clinician by dialing 222 inside the SHC/LPCH (or 723-8222 outside) and pager #17849 (1-STIX);
- Follow the instructions provided regarding immediate care; and
- Report to the SUOHC on the following working day.

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;
- Results of the source individual's blood testing, if available and applicable (ECP Section VII.B.2.); and
- A description of the exposed employee's job duties as they relate to the exposure incident.

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;

- 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; and
- 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 occurring, a Stanford University Incident Investigation Report (SU-17), available online at <u>web.stanford.edu/dept/Risk-Management/docs/</u>, must be submitted by the PI/Supervisor to Risk Management (FAX # 723-9456).

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

- Review the Local Exposure Control Plan and update it to reflect any corrective measures and improvements; and
- 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 [TBD], is completed and submitted to EH&S (FAX # 725-3468). This is in addition to submitting the SU-17 to Risk Management (ECP Section VII.B.5.).

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; and
- 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.

D. Recordkeeping

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 3204³ (*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); and
- 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.

³ <u>http://www.dir.ca.gov/title8/3204.html</u>

APPENDIX – 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 118275⁴.

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

⁴ http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/MedicalWasteManagementAct.pdf

"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 118360⁵, 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

⁵ http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/MedicalWasteManagementAct.pdf

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:

- 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)