Stanford University
Bloodborne Pathogens Local Exposure Control Plan and Guidance

This Local Exposure Control Plan is specific to the laboratory indicated below and is supplemental to the institutional requirements outlined in the Stanford University Institutional Bloodborne Exposure Control Plan

Principal Investigator/ Supervisor:
Phone:
Email:
Department:
Building:
Room(s):

Overview

This document introduces the PI/Supervisor to the purpose and use of the Stanford University Bloodborne Pathogens Local Exposure Control Plan (Local ECP). Included are guidance and instructions on how to complete the Local ECP, including forms required to be completed.

Keep the completed Local ECP, along with updates and training records, in a location available for reference by personnel and regulators.

Stanford University - Bloodborne Pathogens Local Exposure Control Plan

i. Purpose, Regulatory Driver and Scope

The California Occupational Safety and Health Administration (Cal-OSHA) Bloodborne Pathogens Standard (8 CCR • 5193) requires employers to establish an Exposure Control Plan (ECP), which provides methods and procedures to eliminate or minimize potential exposures of employees to human blood/bloodborne pathogens (BBP), or other potentially infectious materials (OPIM) or blood. Principal Investigators (PIs) and supervisors should refer to the Stanford University Institutional Exposure Control Plan as a resource for exposure control background, issues and regulatory procedures.

Stanford University Local Bloodborne Pathogen Exposure Control Plan:

The Stanford University Bloodborne Pathogens Local Exposure Control Plan supplements the Stanford University Institutional Exposure Control Plan for areas overseen by a PI/Supervisor, who is responsible for the health and safety of their supervised personnel. **The Local ECP addresses health and safety issues specific to the materials and procedures being used by research personnel and constitutes a Tier III training for these topics.**

PIs/supervisors with employees who may be exposed to human Bloodborne Pathogens (BBPs)/Other Potentially Infectious Materials (OPIM)/Blood must ensure personnel complete a Local ECP. Working with employees, use this document to:

- Guide identification of procedures and materials in the laboratory that have the possibility of exposing personnel to BBPs/OPIM
- Review methods of compliance to ensure a safe work environment
- Determine appropriate engineering and work practice controls
- Review requirements for reporting and documenting sharps injuries
- Ensure participation in the Stanford University Medical Surveillance Program

The Local ECP shall be completed and reviewed by the PI/Supervisor and personnel annually and/or as needed by job changes. The completed Local ECP shall be located in the laboratory (as a hard copy or on computer) for reference and documentation of compliance.

Elements of the Local ECP to be completed by the PI/Supervisor in collaboration with employees include:

1. PI/Supervisor to review ECP fundamentals with employees using the material presented in the Local ECP as a guide.
2. Laboratory Specific Information
    a. Exposure Determination – identification of materials, job categories, tasks and procedures (Appendix A, provided at the end of Local ECP)
    b. Methods of Compliance – training documentation, local ECP completion and reviews (Appendix B, provided at the end of Local ECP)
3. Reporting and Documentation of Injuries
    a. Documentation of use of non-compliant sharps (Appendix C, provided at the end of Local ECP)
    b. Incident reporting of sharps accidents
4. Medical Surveillance Program
    a. Hepatitis B Declaration
    b. Incident reporting of potential exposures

ii. Responsibilities

Principal Investigator/Supervisor Responsibilities

The PI/Supervisor has responsibility for the health and safety of laboratory personnel doing work in his/her laboratory. The PI/ Supervisor 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.

What to do	How to do it
1. Identify use of BBPs or Other Potentially Infectious Materials (OPIM) in lab, implement and enforce safety procedures.	See Biosafety **Website** (Safety/Medical Monitoring, BBP) for more information, complete Appendix A.
2. Complete local Exposure Control Plan with personnel.	Complete this document.
3. Obtain Administrative Panel on Biosafety (APB) approval if needed.	See Biosafety **website** (APB) for more information.
4. Train personnel to work with BBP/OPIM, maintain training records.	PI/Supervisor to provide Tier III training; complete Appendix B, refer to Stanford University Biosafety Manual (Chapter 5)
5. Report BBP/OPIM exposure and sharps injuries.	See Biosafety **website** (Emergency Procedures/ Accidental Exposures) for more information.
6. Discuss Hepatitis B Virus exposure and vaccination; submit completed Hep B Vaccine Declaration Form to SUOHC within 10 working days.	See Stanford University Hepatitis B Vaccine Declaration Form.
7. Explain medical surveillance, consultation, examination available for personnel.	Refer to Stanford University Biosafety Manual (Chapter 6).
8. Provide and maintain Personal Protective Equipment (PPE), engineering controls and safety equipment.	See Biosafety **website** (General Laboratory Safety) for more information, complete Appendix C as needed.
9. Communicate potential hazards to laboratory visitors.	Refer to Stanford University Biosafety Manual (Chapter 7)
10. Have Local ECP available to personnel and regulators.	Keep completed copy, along with annual updates and training records, available for reference. Include copy of Stanford University Institutional Exposure Control Plan, or know where to obtain one as needed.

Laboratory Personnel Responsibilities

Laboratory personnel who work with Blood/BBP/OPIM have the responsibilities listed below. Consult with your PI/Laboratory Supervisor as you implement your responsibilities.

What to do	How to do it
1. Complete Local Exposure Control Plan with PI/Supervisor.	Complete this document. See Stanford University Institutional Exposure Control Plan for additional information as needed.
2. Review and understand blood/BBP/OPIM hazards and hazards of laboratory procedures prior to conducting work.	See Biosafety **website** (Safety/Medical Monitoring, BBP) for more information, complete Appendix A.
3. Complete all required health and safety training.	Complete Tier I (general laboratory safety), Tier II (BBP training) and Tier III (lab specific training by PI/Supervisor) and Appendix B. In addition, refer to Stanford University Biosafety Manual (Chapter 5).
4. Use PPE, engineering controls and safety equipment.	See Biosafety **website** (General Laboratory Safety) for more information, complete Appendix C as needed.
5. Confirm PI has APB approval for use of non-exempt biohazardous materials (if being used) and appropriate personnel are listed.	See Biosafety **website** (APB) for more information.
6. If required by job responsibilities, participate in medical surveillance program.	Refer to Stanford University Biosafety Manual (Chapter 6).
7. Promptly report accidents and unsafe conditions to PI/ Supervisor.	See Biosafety **website** (Emergency Procedures/Accidental Exposures) for more information.

Environmental Health & Safety Responsibilities

1. Medical Services	EH&S will make provisions for all appropriate required medical services.
2. General laboratory safety training	EH&S provides general laboratory safety Tier I training; see http://www.stanford.edu/dept/EHS/prod/training/index.html for additional information.
3. Blood Borne Pathogen training	EH&S provides Tier II BBP training via a web based format, with mandatory annual updates (https://axess.stanford.edu/)
4. Personal Protective Equipment	EH&S provides consultation or advice on PPE
5. Sharps Injury Log	EH&S will maintain the OSHA Sharps Injury Log and carry out annual reviews of the Log; any identified trends or concerns will be reviewed at the University level by a group comprising of representation from EH&S, Stanford University Occupational Health & Safety, researchers and clinical users, as appropriate. Review will include, but not be limited to the following: 1. Area/Department involved 2. Type/model/brand of sharp 3. Task or procedure performed 4. Description of incident 5. Training

This section provides direction for the following items:

- Guide identification of procedures and materials in the laboratory that have the possibility of exposing personnel to BBPs
- Review methods of compliance to ensure a safe work environment
- Determine appropriate engineering and work practice controls
- Review requirements for reporting and documenting sharps injuries
- Ensure participation in the Stanford University Medical Surveillance Program

Universal Precautions:

"Universal Precautions" is an approach to infection control whereby all human/primate blood and other human/primate body fluids, tissues and cells are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens (BBP's).

Important definitions:

1. **Blood** means *human blood, human blood components, and products* made from human blood.

2. **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 (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

3. **"Other Potentially Infectious Materials"** (OPIM) are:

    A. The following *human* body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

    B. Any *unfixed tissue (including primary cells and tissue culture cells lines) or organ* (other than intact skin) from a human (living or dead).

    C. Any of the following, if known or reasonably likely to contain or be infected with bloodborne pathogens (including but not limited to HIV, HBV or HCV):

        - Cells, tissue, or organ cultures from humans or experimental animals (cell cultures)
        - Blood, organs, or other tissues from experimental animals (primary cells)
        - Culture medium or other solutions

Engineering, Work Practice Controls and PPE:

Engineering, work practice controls and PPE must be used to eliminate or minimize exposure to individuals.

Engineering and Work Practices

1) Hand washing
Personnel must wash their hands immediately upon removal of gloves and upon any contact with potential BBP materials.

2) Mouth pipetting

Mouth pipetting is prohibited.

3) No eating, drinking

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are not permitted in work areas. Food and drink are not to be placed or stored in areas (refrigerators, microwaves, etc.) where potential BBP/OPIM are kept or may be present.

4) Needles, sharps, and broken glass

Used needles and other sharps are not to be sheared, bent, broken, recapped, or resheathed by hand. Used needles are not to be removed from disposable syringes. Disposable sharps must not be reused. All sharps, contaminated or not, shall be disposed of in a puncture-resistant hard sided, labeled sharps container.

Broken glassware must not be directly handled with a gloved or bare hand. Use a mechanical tool (tongs, dustpan and broom) to collect the pieces into a hard-sided container labeled 'Broken glass' (non-contaminated). Contaminated broken glass must be placed in a puncture-resistant hard-sided container and disposed of as biohazardous waste (see Stanford Bio/Medical Waste Guidelines).

A) Safety Sharps

The Cal-OSHA BBP Standard requires any laboratory using human or primate blood, blood products, cell lines, tissues or other potentially infectious materials to use **Needleless Systems/and or engineered sharps ('safety sharps').**

B) Documentation of use of non-safety sharps (Appendix C)

A sharps device without safety feature(s) may only be used if:

- Alternative products are not market-available
- Alternative products do not clearly improve safety
- Available product(s) jeopardize(s) patient safety

The evaluation process for the use of a **non-safety sharp** must be documented; any use of non-safety sharps must be re-evaluated and documented annually. Record the process using Appendix C and retain the document with the Local ECP (Appendix C provided at end of Local ECP).

5) Minimization of aerosols

Biological safety cabinets (Class I or II (A1, A2, B1, B2)) or other physical containment devices must be used whenever possible while performing operations capable of creating aerosols. If a biological safety cabinet cannot be used, the most effective means of minimizing exposure to aerosols is to contain them by using closed containers (sealed centrifuge rotors, capped test tubes, etc.).

6) Disinfection of work area and spill cleanups

The work area must be disinfected before and after handling BBP/OPIM. Non-laboratory personnel should not handle equipment that has been used with potential BBP's until it has been decontaminated. All spills must be cleaned up immediately and disinfected with a germicide by appropriate decontamination procedures determined by the laboratory supervisor. The laboratory supervisor or other laboratory personnel must immediately report laboratory accidents (major spills, injuries, illnesses) to EH&S (650.723.0448). For additional information see Spills under Reference information on the biosafety web page (http://www.stanford.edu/dept/EHS/prod/researchlab/bio/) then Safety/Medical Monitoring Exposure Control Plan.

7) Labeling and Communication

A biohazard warning sign incorporating the universal biohazard symbol  shall be posted on the access door to the laboratory work area. All BBP/OPIM must be stored in containers labeled with a biohazard symbol. Equipment where potentially infectious materials are stored or handled must also be labeled with the biohazard symbol. Placards are available from EH&S.

8) Limited Access

Access to a laboratory is limited or restricted by the laboratory supervisor when work is in progress. When work with blood or blood products is being performed, non-laboratory personnel (maintenance, administrative personnel) and non-authorized should be discouraged from entering. If they must enter a facility, the hazards of the work being performed must be fully explained.

9) Transportation on Campus

Specimens of blood or other potentially infectious materials shall be placed in a primary container that prevents leakage (capped test tube, centrifuge tube, etc.) during collection, handling, and storage. If the specimens are transported through hallways, the primary containers must be placed in a secondary container (bucket, non-breakable tube or container, cooler, etc.) which would contain the contents if the primary container if it were to leak or break.

10) Shipping of Samples

In compliance with the Department of Transportation regulations (Biosafety - under Shipping), personnel involved with shipping of biohazardous agents or potential BBPs **must have** documented training prior to shipping. Shipping training can be done online with "EHS-2700: DOT: Shipping Biological Goods or Dry Ice" available online at axess.stanford.edu.

11) Blood Collection

All human blood collection shall be performed in accordance with established phlebotomy procedures.

12) Biological Waste Disposal

Specific procedures for the disposal of biological materials are available from are found on the Medical Waste Poster (Medical Waste Guide) and can also be found in the Stanford University Biosafety Manual and on the Biosafety website.

13) HIV, HBV and HCV Research Laboratories

If PI/Supervisor cannot verify personnel experience and proficiency, they shall ensure personnel are provided necessary training prior to assigning work potentially involving HIV, HBV or HCV.

This section applies, in addition to the above requirements, to research laboratories engaged in the culture, production, concentration, experimentation, and manipulation of HIV, HBV and HCV.

A. Laboratory doors shall be kept closed when work involving HIV, HBV or HCV is in progress.

B. Access to the work area shall be limited to authorized persons.

C. All activities involving OPIM shall be conducted in biological safety cabinets or other physical-containment devices within the containment module.

D. Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from animals and diaphragm bottles. All sharps (needles, blades, etc.) must have engineered sharps protection.

E. **Written biosafety procedures shall be prepared and adopted into the local Exposure Control Plan; a copy of the approved APB protocol can be used for this purpose.** Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

F. Personnel shall have prior experience in the handling of human pathogens or tissue culture.

Personal Protective Equipment

Personnel must wear gloves, lab coat, and safety glasses whenever handling blood/BBPs/OPIM. In addition to above items, personnel must wear any additional PPE (booties, face shield, etc.) that is needed to prevent blood or other potentially infectious material from contaminating their street clothes, skin, eyes, mouth, or other mucous membranes under normal conditions. All PPE shall be removed prior to leaving the work place and placed in appropriate designated areas.

Personal protective equipment (PPE) will be provided without cost to all individuals who are at risk of occupational exposure to bloodborne pathogens**.** The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the individual's clothing, skin, eyes, mouth, or other mucous membranes during use. Consultation or advice on PPE is provided by Stanford University EH&S.

1) **Eye protection**
   Protective eye wear must be worn in the laboratory when it is reasonably anticipated that blood or other potentially infected material may make contact with the mucous membranes of the eye. Face shields may be required in addition to protective eyewear if there is a potential for splashes, sprays, or aerosols.

2) **Lab coats and protective clothing**
   Laboratory coats, gowns, smocks, etc. must be worn while in the laboratory. Protective clothing must be removed and left in the laboratory before leaving the lab. Wear appropriate street clothing (i.e. long pants, closed-toed shoes) in addition to PPE. Personnel are not permitted to take home any PPE, including lab coats, for laundering or cleaning.

3) **Gloves**
   All personnel engaged in activities that may involve skin contact with potentially infectious fluids or tissues must wear gloves. Gloves are also required for laboratory workers with dermatitis or other lesions on the hands who may have direct or indirect contact with potentially infectious materials. Gloves must be replaced frequently and immediately if they become contaminated or damaged in any way. Gloves should be removed before touching common equipment (phone, computer, appropriate laboratory equipment) to prevent contamination.

Reporting and Documenting Incidents and Sharps Injuries

All incidents and sharps related injuries shall be reported immediately by completing a Stanford University Incident Investigation Report (SU-17) and a Sharps Injury Report (within 24 hours of the injury).

All incidents and sharps related injuries shall be reported immediately by completing a Stanford University Incident Investigation Report (SU-17)and a Sharps Injury Report (within 24 hours of the injury) both forms are additionally available on the Biosafety web site). Medical information will not be discussed or revealed to supervisors, personnel representatives, or other health care professionals who do not need the information.

Medical Surveillance Program

The PI/Supervisor, working with the employee, will explain medical surveillance participation and services available for personnel. EH&S provides required medical services and emergency service oversight. Any communication between the medical provider and the PI/Supervisor will be carried out in a manner that does not breach medical confidentiality

1) **Hepatitis B Vaccination**

All personnel covered by the Local ECP must complete the "Stanford University Hepatitis B Vaccine Declaration Form" and submit to the Stanford University Occupational Health Center (SUOHC) within 10 working days from start of potential exposure.

Hepatitis B Vaccine: A safe and effective vaccine is available for protection from Hepatitis B. While Stanford University strongly encourages employees to be vaccinated, accepting vaccination is not a condition of employment. Immunization requires three injections of vaccine over a six-month period. This vaccine is available at no cost to all personnel that are potentially exposed to blood/OPIM. Post-vaccination serological testing to ensure that protective antibodies to Hepatitis B have developed is also provided at no cost following completion of the vaccination series or as medically indicated.

The PI/Supervisor will ensure that all personnel with potential for occupational exposure to BBP are offered the Hepatitis B (HBV) vaccination in a timely manner (within ten working days of initial assignment). The HBV vaccination will be offered to personnel as a prophylactic treatment or made available post-exposure. Hepatitis B immune globin is also offered as a prophylactic within 24 hours of an occupational exposure.

HBV-related information, FAQs, and the declaration form are available online at: www.stanford.edu/dept/EHS/prod/researchlab/medsurv/.

To schedule a vaccination or a medical consult concerning exposure risk, and the risks and benefits of the vaccination, Stanford University students and employees can go to the:

Stanford University Occupational Health Center (SUOHC)
Environmental Safety Facility (ESF)
480 Oak Road, Room B15
Stanford, CA 94305-8007

Phone: (650) 725-5308
Fax: (650) 725-9218

If an at-risk employee declines the vaccination, the employee must sign a declination form. Employees who declined vaccination may request and obtain the vaccination at a later date at no cost.

2) Post-Exposure Evaluation and Follow-up

Any exposure (e.g. spill, needlestick, ingestion) resulting in direct, unprotected contact with human or primate blood, fluids, or tissue gives the employee the right to prompt medical evaluation and treatment with a qualified physician. These services will be provided at no cost to the employee.

What to do post-exposure: After any direct exposure to BBP, **immediately wash the affected area with soap and water.**

In the event that a Stanford University employee or student is accidentally exposed to human blood or blood products, **students and employees** should report to the Stanford University Occupational Health Center (SUOHC) (650.725.5308) at 480 Oak Road, Stanford, CA, 94305 or to **Stanford Hospital Emergency Room if it is an emergency or after normal business hours and weekends,** where an established medical protocol will be followed. This protocol is designed to provide the individual with the most appropriate medical procedures, consultation and supportive therapy. The exposed employee or student will be provided with a written opinion that will include:

- HBV vaccination status and recommendation
- Results of the post-exposure evaluation and follow-up discussion of any medical conditions resulting from exposure to blood or other potentially infectious materials which requires further evaluation or treatment
- All other findings or diagnoses shall remain confidential and will 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.

Exposure to animal bites and scratches: It is important to report all bite wounds and scratches. Wounds must be cleansed immediately in your work area. Instructions for the proper cleaning of wounds will be given to you by your supervisor. **After you have cleansed the wound, go immediately to the Stanford University Occupational Health Center** (650.725.5308) or **to the Stanford Emergency Room after hours and on weekends.**

Instructions

The PI/Supervisor shall review the Local ECP with input from employees covered by BBP. After review, complete Appendixes A and B. A separate Appendix A can be used for each person, or attach a list of personnel that are determined to come under the same exposure determinations and procedures. Fill out Appendix C as needed. Keep completed appendixes with the Local ECP.

Review the completed Local ECP annually and/or when job descriptions or processes change.

Local Exposure Control Plan: The Local ECP will comprise of the following:

- Completed and updated Appendixes A (Exposure Determination), B (Training Documentation), and C (Non-compliant Sharps)
- An available copy of the Local ECP Guidance document

HIV, HBV and HCV Research Laboratories and Production Facilities shall include:

- Written biosafety procedures in the Exposure Control Plan (reference the appropriate approved protocol from the Stanford University Administrative Panel on Biosafety)

In addition, personnel should know where to access the Stanford University Institutional Exposure Control Plan.

The PI/Supervisor will file the Local ECP in a central location within the laboratory or workplace. The PI/Supervisor, together with employees covered by the Local ECP, will review and revise the Local ECP annually and/or whenever changes in procedure or personnel occur. Documentation shall be maintained by PI/Supervisor for three (3) years.

Reviews: Annual and as needed

The following items shall be included in the review process:

- New or revised employee positions, new or modified tasks and procedures which affect occupational exposure
- Changes in technology that eliminate or reduce exposure to BBP (needleless systems, engineered sharps)
- Review and evaluate exposure incidents which occurred since previous update
- Review and respond to information indicating that the Local ECP is deficient in any area

To Complete Local ECP

For convenience an Excel spread sheet (Local ECP Check Sheet) is provided to assist in recording and documenting personnel names, positions, dates and information during completion of required ECP segments. Attach completed Check Sheet to appendixes. The use of this sheet is optional.

1. Appendix A: Exposure Determination

The PI/Supervisor must identify procedures and materials in the laboratory that have the possibility of exposing personnel to BBPs (**Appendix A**). Note that this evaluation will not take into consideration the use of personal protective equipment (PPE).

2. Appendix B: Training Documentation

Laboratory personnel must receive general and laboratory-specific information and training at the time of initial assignment to the laboratory, and prior to assignments involving new exposure situations. Training must be documented and maintained by PI/Supervisor for three years.

All personnel with potential for occupational exposure to blood, BBP or OPIM must complete the following online training in the Stanford Training and Registration System (STARS) (available through axess.stanford.edu):

- EHS-1500 or EHS-4875: Biosafety (Initial)
- EHS-1600: Bloodborne Pathogens (EHS-1601 for annual updates)

To complete Bloodborne Pathogen training, the following must be done:

- Local Exposure Control Plan (after initial completion, review Local ECP annually or as required by job change)
- Specific Tier III training will be provided by the PI/Supervisor and includes specific safety training for each person's duties, specific equipment usage and procedures (**Appendix B**).

3. Appendix C: Non-compliant Sharp Documentation

The evaluation process for the use of a non-safety sharp must be documented (**Appendix C**); retain the document with the Local ECP. Any use of non-safety sharps must be re-evaluated and documented annually.

Appendix A Exposure Determination

PI/Supervisor name _____

Location(s) (room, building) _____

Date _____

Instructions: Complete the following sections as they relate to employees covered by the local ECP and the nature of the work being carried out in your facility. Use a separate Information sheet for each combination of Exposure Determination, Job Categories, and Tasks and Procedures.

Employee Name (enter name(s) or use the Local ECP Check Sheet): _____

_____

I. Exposure Determination – identification of materials, job categories, tasks and procedures

A. Identify all materials that may apply:

☐	Human tissues/cells/tissues/tissue culture cells	☐	Human fluids
☐	Non human primate cells/tissues/tissue culture cells	☐	Non human primate fluids
☐	Blood borne biological agents	☐	Human blood

List agents: _____

2. Methods of Compliance – training documentation, local Exposure Control Plan completion and reviews

A. Job Categories in which personnel may reasonably have contact with BBP's (check off all that might apply).

☐	Principal Investigator	☐	Graduate Student
☐	Researcher	☐	Undergraduate Student
☐	LSRA/Technician	☐	Laboratory Worker
☐	Post-Doctoral Fellow	☐	Clinician
☐	Phlebotomist	☐	Nurse

☐ Other List jobs: _____

_____

Appendix A (continued) Exposure Determination

B. Tasks and Procedures: Identify which procedures used in the work place that may create a risk of BBP exposure (check off all that might apply).

- ☐ 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, cutting, or other
- ☐ 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
- ☐ Others

List procedures (use additional space as needed): _____

Appendix B Training Documentation

Laboratory - specific training shall be provided by the PI/Supervisor and will include specific safety training for each person's duties, including specific equipment usage and procedures.

Training Provided: Identify the specific trainings completed/provided by the PI/Supervisor to the individual listed above.

☐ Laboratory-specific agent/material training (Tier III) by PI/Supervisor (Local Exposure Control Plan)

Review Provided: Confirm the following items were reviewed by you and the PI/Supervisor

☐ New or revised employee positions, new or modified tasks and procedures which affect occupational exposure

☐ Changes in technology that eliminate or reduce exposure to BBP (needleless systems, engineered sharps)

☐ Review and evaluate exposure incidents which occurred since previous update

☐ Review and respond to information indicating that the local ECP is deficient in any area

For employees responsible for direct patient care/donors (in addition to above):

☐ PI/Supervisor shall solicit input from non-managerial employees responsible for direct patient care/donors that are potentially exposed to BBP; include identification, evaluation and selection of effective engineering and work practice controls

By signing below, you indicate that you have:

- **Reviewed/updated the completed the Local Exposure Control Plan with your PI/ Supervisor and understand the potential BBP hazards associated with your work.**
- **Reviewed any sharps exposures that had occurred within your work environment during the past year.**

PI/Supervisor signature _____ Date _____

Signatures of personnel involved in training/review (add additional page if necessary)

_____ _____

_____ _____

_____ _____

_____ _____

Appendix C Non-compliant Sharps Documentation

If the PI/Supervisor decides that a non-compliant sharp is necessary for a certain procedure, the reason must be documented; keep documentation with the completed Local ECP. Review annually.

The following exceptions apply to the required engineering controls (re Bloodborne Pathogens Standard (1910.1030 (d)(3)(A)1.-3):

- Market Availability: The engineering control is not available in the marketplace.
- Patient Safety: The engineering control is not required if a licensed healthcare professional directly involved in a patient's care determines that use of the engineering control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient.
- Safety Performance: The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.
- Availability of Safety Performance Information: The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace.

Complete the below information if non-compliant sharps are in use (add additional pages as necessary).

Devise Information	Reason(s) for Exception	Name	Date (Initial Use and Annual Re-evaluation)
Example			
25g X 1" needle	***Specific size needed for research use. Not available on market.***	***Leland Stanford Jr.***	***April 1, 2011***