

6.0 CHAPTER 6 –BLOOD-BORNE PATHOGENS, UNIVERSAL PRECAUTIONS, HUMAN TISSUE and CELL CULTURE

6.1 Definitions

Bloodborne pathogens (BBP) are pathogenic microorganisms that are present in human "blood" and "other potentially infectious material." These pathogens include hepatitis B virus (HBV), Hepatitis C (HCV) and human immunodeficiency virus (HIV), syphilis, malaria and many others.

"Blood" means human blood, human blood components and products made from human blood.

"Other Potentially Infectious Materials" means:

- 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 and all undifferentiated body fluids in emergency response situations.
- Any unfixed tissue or organ (other than intact skin) from a human.
- HIV-containing cell or tissue cultures, organ cultures and HIV, HBV, or HCV-containing culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV, HBV, or HCV.

"Universal Precautions" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids/tissues/cell lines are treated as if known to be infectious for HIV, HBV, HCV and other blood-borne pathogens.

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

6.2 Exposure Control Plan

If there is any possibility an employee may be exposed to BBP's during the course of their work, the Principal Investigator must do the following:

- A. Implement a written Exposure Control Plan (see Chapter 7) which adopts BSL-2 or higher containment practices and procedures.
- B. Perform and document the following:
 1. Exposure determination
 2. Procedure for the evaluation of exposure incidents
 3. Hepatitis B vaccination and follow up

4. Training
5. Record keeping

6.3 Methods of Compliance

6.3.1 Universal Precautions

UCSB observes the concept of Universal Precautions which is an approach to infection control whereby all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV and other BBP's. Follow BSL-2 practices and procedures for all teaching, clinical, research or other work with human blood, tissues, cells and fluids.

All laboratory coats and contaminated items should be decontaminated (i.e., steam autoclaved) prior to cleaning and laundry.

6.3.2 Engineering & Work Practice Controls

The term "Engineering Controls" refers to controls (e.g., sharps disposal containers, needle-less systems and self-sheathing needles) that isolate or remove the hazard of blood-borne pathogens from the workplace and, therefore, reduce the potential for employee exposure. Other devices include biosafety cabinets and uni-directional airflow from areas of lower to areas of higher hazards.

Work practice controls include frequent handwashing; proper handling and disposal of contaminated needles; no eating, drinking, smoking, application of cosmetics or contact lenses in the lab; and no mouth pipetting.

Food and drink must not be stored in the same refrigerator or on the same shelves, countertops or benchtops where BBP's are placed. Containers used for storage, transport or shipping of blood-borne pathogens must be labeled properly (see Shipping Chapter).

6.3.3 Engineered Sharps Injury Protection

Sharps with engineering controls must be 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 a physical attribute built into any other type of needle device, or into a non-needle sharp.

CAL/OSHA Needleless Systems and Needles with Engineered Sharps Injury Protection List

<http://www.dhs.cahwnet.gov/ohb/SHARPS/disclaim.htm>

6.3.4 Personal Protective Equipment (PPE)

In addition to engineering controls, personal protective equipment must also be used. For research involving potential exposure to BBP the minimum required PPE includes gloves, lab coats, eye protection or face shields. Additional PPE such as gowns and masks may be used as appropriate.

6.3.5 Housekeeping

A generally clean and sanitary laboratory environment must be maintained. There must be a regular and proper decontamination of all work surfaces, equipment, bins, cans and other similar receptacles intended for reuse. Regulated waste must be separated into contaminated sharps and other wastes, then stored and disposed of in proper containers.

6.4 HIV, HBV or HCV Research Laboratories

Unless otherwise permitted by the IBC, laboratories working specifically with HIV, HBV or HCV must follow standard BSL-2 for handling clinical material, and BSL-3 practices and procedures for growing and concentrating virus particles. See Chapter 3, *Biosafety Level Practices Chart*, for further details.

6.5 HBV Vaccination & Post-exposure

6.5.1 General

The university (by means of funding provided by the department or PI) must make the hepatitis B vaccination available to those employees who have the potential for occupational exposure. Post-exposure evaluation and follow up must be provided to those employees who have had an exposure incident. This must be done at no cost to the employees and at a reasonable time and place. It must be done by or under the supervision of a licensed physician, or by or under the supervision of another licensed health care professional.

6.5.2 Hepatitis B Vaccination

This must be available to the employee within 10 working days of initial assignment to work involving occupational exposure. Employees may decline to receive the vaccination. Those who decline must sign a declination form. This signed form should be kept as a confidential record by the laboratory. Should an employee (still covered under the Standard) who had previously declined decide at a later date to receive the vaccination, it must be made available to him or her at no cost.

<http://www.ehs.ucsb.edu/programs/occhlth/bbpxpose.pdf>

6.5.3 Post-exposure Evaluation & Follow Up

Following a report of an exposure incident, the PI must make available to the exposed employee a confidential evaluation and follow up. This must include documentation of the route(s) and circumstances of the exposure incident; a testing* of the source individual's blood sample for HBV, HCV and HIV (unless these are already known to be present in the source individual). Results of the source individual's blood sample test must be made available to the exposed employee, who must be informed of applicable laws.

** Testing of a person's blood must be done in conformance with current California state laws and guidelines.*

6.5.4 Information to Health Care Provider

For an employee who is simply being vaccinated, the responsible health care professional must be provided a copy of the BBP Standard. For an employee who is being followed up after an exposure incident, the responsible health care professional must be provided with the BBP Standard, a description of the exposed employee's duties, documentation of circumstances and route(s) of exposure, results of source individual's blood testing and all pertinent medical records.

6.5.6 Health Care Provider's Written Opinion

Written opinion for routine vaccination must be limited to whether the hepatitis B vaccination is indicated and whether the employee has received it. Written opinion for post-exposure evaluation and follow up, on the other hand, must be limited (for the purposes of patient confidentiality) to the following information:

- That the employee has been informed of the results of the evaluation; and
- that the employee has been told about medical consequences of exposure which might require further evaluation or treatment.

6.6 Hazard Communication

6.6.1 Labels and Signs

Fluorescent orange-red labels displaying the international biohazard symbol and the legend "biohazard" in contrasting colors are attached to containers of biohazardous materials.

Labeled red bags or labeled red containers are used for biohazardous waste and sharp containers.

Fluorescent orange-red signs with lettering and symbols in contrasting colors are

posted at entrances to work areas. Such signs specify name of infectious agent, special requirements for entering, name and telephone number of PI or other responsible person(s).

6.6.2 Information and Training

Training must be conducted during working hours and at no cost to the employee. The training must be conducted at the time of initial assignment of employee and annually thereafter, where annually means within one year of previous training.

The training material must be tailored to match the educational level of the employees.

Elements of the training include:

- Access to copies of the Blood-Borne Pathogen Standard
- Epidemiology and clinical features of blood-borne diseases
- Explanation of Exposure Control Plan
- How to recognize tasks that carry risk of occupational exposure
- Explanation of engineering controls, work practices and personal protective equipment
- Basis for Personal Protective Equipment selection
- Information on and explanation of emergency procedures
- Information on signs, labels and color-coding
- Opportunity for interactive questions and answers session with the trainer

6.7 Record Keeping

6.7.1 Medical Records

Medical records must be established and maintained by the Occupational Health and should include:

- Name and social security number of employee
- Hepatitis vaccination status
- Copy of information provided to health professional
- Copy of health exam results
- Copy of health care professional's written opinion

Records must be confidential and may not be disclosed without the employee's written consent. Records must be kept for the duration of employment, and for at least 30 years after the last date of employment.

6.7.2 Training Records

Training records must be established and maintained. These records should include date of training; contents or summary of training; names, qualifications and signature of trainer(s); names, job titles and signatures of trainees; and a signed statement by trainees that they understand and agree to conduct their work in accordance with the training precepts. This record must be maintained for a minimum of three years from the date of training. (See Appendix 4 for template.)

6.7.3 Availability of Records

Upon request, all records must be made available to the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations, NIOSH or a designated representative for examination and copying. In addition, training records must be made available to employees or employee's representative. Upon request, medical records may only be made available to the employee or to someone who has the employee's signed consent.

6.8 Working with Human Tissues

All human blood, blood products, body fluids and tissues are listed as potentially infectious Materials. Established human cell lines must be treated as if they are potentially infected with Bloodborne Pathogens and laboratories working with these materials must have annual Bloodborne Pathogens training.

Under no circumstance shall anyone work with cells derived from themselves or from first-degree relatives since the host immune systems may not provide adequate protection.

Biosafety Level 2 practices and procedures must be followed when handling human blood, blood products, body fluids and tissues because of the infectious agents they may contain, including established human cell lines.

Biosafety Level 2 practices and procedures are consistent with the concept known as "Universal Precautions" which requires all specimens of human blood, blood products, body fluids and tissues to be treated as if they are infectious. In 1991, Cal/OSHA promulgated a standard to eliminate or minimize occupational exposure to Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) and other blood-borne pathogens. This regulation embraces the federal regulation, [Occupational Exposure to Bloodborne Pathogens](#), and mandates a combination of engineering and work practice controls, training and Hepatitis B vaccination. Other provisions are included to help control the health risk to employees resulting from occupational exposure to

human blood and other potentially infectious materials which may contain these or other specified agents.

Hepatitis B vaccination is available to all occupationally at-risk university employees through UCSB Student Health Services. Mandatory training, which provides information on protection from occupational exposure to blood-borne pathogens, is provided by EH&S on an annual basis. For more information on registration for Hepatitis B vaccine, call UCSB Student Health Services.

Investigators using human blood, blood products, body fluids or tissues must complete a laboratory-specific Exposure Control Plan. The completed plan must be readily available in the laboratory for all workers.

Laboratory personnel (faculty and staff) in HIV, HCV or HBV research laboratories must fulfill additional requirements as follows:

- A. The employee must attend general biosafety training offered by EH&S.
 - B. The employee must have prior experience in the handling of human pathogens or tissue cultures before working with HIV, HCV or HBV.
 - C. Before being allowed to work with HIV, HCV or HBV, the employee must demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the laboratory to the satisfaction of the Principal Investigator/laboratory supervisor.
- C. An employee with no prior experience in handling human pathogens must be trained in the laboratory prior to handling infectious materials. Initial work activities shall not include handling of infectious agents. A progression of work activities will be assigned as techniques are learned and proficiency is developed. Participation in work activities involving infectious agents will be allowed only after proficiency has been demonstrated to the satisfaction of the Principal Investigator/laboratory supervisor.

6.8.1 Cell Culture

When cell cultures are known to contain an etiologic agent, an oncogenic virus or amphotropic packaging system the cell line must be classified at the same level as that recommended for the agent.

Furthermore, the following must be handled at Biosafety Level 2 or higher containment level:

- All cell lines of human/primate origin

- Any cell lines derived from lymphoid or tumor tissue
- All cell lines exposed to or transformed by any oncogenic virus
- All cell lines exposed to or transformed by amphotropic packaging systems
- All clinical material (e.g., samples of human tissues and fluids obtained after surgical resection or autopsy)
- All cell lines new to the laboratory (until proven to be free of all adventitious agents)
- All mycoplasma-containing cell lines

6.9 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).

Aspects of Universal Precautions include frequent handwashing; proper handling and disposal of contaminated needles; no eating, drinking, smoking or application of cosmetics or contact lenses in the lab; and no mouth pipetting. Food and drink must not be stored in the same refrigerator, nor on the same shelves, countertops or benchtops where BBP's are placed. Eating and drinking is allowed only in designated "Clean Areas" within BSL-1 and BSL-2 laboratories.

The container for storage, transport or shipping of BBPs must be labeled properly.

Engineering controls (biosafety cabinets, ventilation, closed top centrifuge rotors, etc.) are the primary methods to control exposures. Personal Protective Equipment (PPE) should also be used to protect personnel from exposures. Personal Protective Equipment (e.g., gloves, lab coats, gowns, face shields, masks) should be selected and used as appropriate.

All work with human blood, tissues, cells and other body fluids must be conducted using BSL-2 containment practices, procedures and facilities.