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University of California, Merced
Environmental Health and Safety

Bloodborne Pathogens
Exposure Control Plan
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Bloodborne Pathogens Exposure Control Plan

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Bloodborne Pathogens Standard:
Title 8, CCR, Section 5193

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1.1 INTRODUCTION

The California Occupational Safety and Health Administration (Cal/OSHA) issued its Bloodborne Pathogens Standard effective January 11, 1993. The Standard requires all employers with employees who may have occupational exposure to blood or other potentially infectious materials (OPIM), as defined by the Standard, to prepare, implement and maintain an Exposure Control Plan. An Exposure Control Plan is a document which sets forth procedures, control measures and equipment designed to eliminate or minimize employee risk from exposure to Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), and other bloodborne pathogens.

The office of Environment, Health & Safety, has prepared this Exposure Control Plan to inform and guide those employees at UC Merced who work with or come in contact with Bloodborne Pathogens.

In order to meet Cal/OSHA requirements, a written Exposure Control Plan should include as a minimum the following elements:

- a) A Policy Statement regarding the intent of the Plan;
- b) The requirements and responsibility for Evaluation and Review of the Plan;
- c) An Exposure Determination to establish which job classifications place employees "at risk";
- d) A description of the different Methods of Compliance that will be used, such as Universal Precautions, engineering and work practice controls, personal protective equipment, etc.;
- e) Procedures for Hepatitis B Vaccination, Post-Exposure Evaluation and Follow-Up;
- f) Training and education of employees through Hazard Communication;
- g) Medical and training Recordkeeping requirements; and
- h) Special requirements for research laboratories which use HIV, HBV, and HCV.

Each of the above elements is presented and discussed in this Plan. Employers must make Exposure Control Plans specific for their worksites and the tasks performed therein. Site specific information is provided in Section 11, titled Site Specific Information for The Exposure Control Plan.

2.1 POLICY STATEMENT

It is the policy of UC Merced to ensure the safety of all its employees. To this end, the following Exposure Control Plan has been developed for the purpose of:

- a) Protecting employees by eliminating or minimizing their occupational exposure to blood or certain other body fluids; and
- b) Complying with the Cal/OSHA Bloodborne Pathogens Standard (Title 8, Code of California Regulations, Section 5193).

In order to eliminate or minimize employee risk from occupational exposure the employees must:

- a) Learn what tasks may result in exposure;
- b) Follow the work routine established by this Plan; and
- c) Report any incidents involving exposure.

3.1 EVALUATION AND REVIEW

This Plan will be reviewed and updated:

- a) At least annually;
- b) Whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure;
- c) To identify new or revised job classifications, that involve occupational exposure; and
- d) To review the exposure incidents that occurred since the previous update.

4.1 EXPOSURE DETERMINATION

Each supervisor must evaluate all employees job functions to determine which of their employees may be "at risk" of occupational exposure to blood or Other Potentially Infectious Materials (OPIM). The following examples can be used as a guide when determining whether there is a risk of occupational exposure to HBV, HCV, HIV, and other bloodborne pathogens.

Does the employee ever:

- a) Work with animals, such as primates that are infected with Hepatitis B, HIV, or other bloodborne pathogens OR perform tasks where such animals are housed?
- b) Work with HBV, HIV or other bloodborne pathogens or with preparations, such as liquid solutions or powders containing the HBV or HIV?
- c) Handle human blood products such as whole blood, plasma, serum, platelets, or white cells?
- d) Handle human body fluids such as semen, cerebrospinal fluid, vaginal secretions, joint fluid, pleural fluid, peritoneal fluid, pericardial fluid, or amniotic fluid?
- e) Handle unfixed human tissue or organs? (Tissues and organs soaked in chemical preservatives such as alcohol or formaldehyde are “fixed”)
- f) Handle blood, blood products, body fluids or unfixed tissues or organs of animals infected with the HBV, HCV, HIV or other bloodborne pathogens?
- g) Handle sharp instruments such as knives, needles, scalpels, or scissors which have been used by others working with human blood or other potentially infectious materials to include human organs, tissues or body fluids OR used by others working with similar body parts and fluids from animals infected with the HBV, HCV, HIV or other bloodborne pathogens?
- h) Enter areas where other individuals work with human or animal blood, body fluid, tissues, or organs which are infected with the HBV, HIV or other bloodborne pathogens AND perform tasks where any of the aforementioned body substances may come in contact with the laboratory worker’s skin, broken skin, or mucus membranes?
- i) Perform tasks which may potentially result in the workers exposed skin or mucous membranes coming in contact with human or animal blood, body fluids, organs, or tissues which are infected with the Hepatitis B Virus, Hepatitis C Virus, HIV or other bloodborne pathogens?
- j) Clean clinical areas or equipment?
- k) Dispose of medical waste or soiled laundry?
- l) Perform first aid where exposure to human blood or OPIM is possible?
- m) Clean up spills of human blood or OPIM?

If the answer to any of the above questions is “yes,” then the employee is considered to be at risk to occupational exposure to HIV, HBV, HCV, or other bloodborne pathogens.

Once it has been determined that a particular job classification is at risk of potential exposure, the job needs to be categorized as either category I, (all employees in the job classification are at risk) or category II (some of the employees in the job classification are at risk to exposure). For job classifications, in which only some personnel are at risk of potential exposure (category II), a list of all tasks and procedures or groups of closely related tasks and procedures which may involve possible exposure to blood or OPIM must be made.

This exposure determination shall be made without regard to the use of personal protective equipment (PPE).

5.00 METHODS OF COMPLIANCE

5.1 Universal Precautions

It is recognized that the most effective mechanism for prevention of infection with bloodborne pathogens is to minimize occupational exposure by minimizing potential contact with contaminated materials. As mandated by the Standard, Universal Precautions shall be practiced at UC Merced at all times to prevent contact with blood or OPIM by those persons designated to be "at-risk".

Universal Precautions apply to human

- a) Blood;
- b) Tissues and organs (prior to fixation) body fluids containing visible blood;
- c) OPIM fluids regardless of visible blood contamination, e.g., semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal, pericardial, amniotic, saliva in dental procedures

Typically Universal Precautions do not apply to the following body substances unless they contain visible blood:

»Feces » Nasal secretions » Sputum » Sweat » Tears » Urine » Vomit »Saliva »Breast Milk

NOTE: There are cases when bloodborne pathogens may be present in these materials, even without evidence of visible blood. Special precautions may be advisable.

5.2 Engineering and Work Practice Controls

Supervisory personnel will evaluate all tasks for exposure potential and will institute the use of engineering and work practice controls whenever possible to eliminate or minimize employee exposure. If there is a reasonable expectation of occupational exposure after initiation of these controls, then the facility will provide and assure that its employees use appropriate personal protective equipment (PPE) as supplemental protection.

5.2.1 Engineering Controls

Engineering controls that are used to reduce or eliminate potential exposures shall be inspected by supervisors on a regular basis. Supervisors will maintain a written record of the maintenance schedule, the results of inspections and corrective action taken. Maintenance will be performed when recommended by the manufacturer, and when examination indicates the need. Engineering controls will be replaced/ modified as necessary to maintain safe working conditions.

Engineering controls include but are not limited to:

- Self-sheathing needles;
- Biological safety cabinets (Class II);
- Splashguards;
- Sharps disposal containers;
- Mechanical pipetting devices;
- Contained centrifuge enclosures; and
- Screw top centrifuge bottles or tubes.

NOTE: Biological safety cabinets used to prevent harmful exposure from biohazard agents or biohazardous materials must be certified when installed, annually, and whenever they are moved or undergo major servicing (HEPA filter replacement, motor repairs, etc.) Records of tests performed must be retained for at least 5 years.

5.2.2 Work Practice Controls

Work practice controls are meant to reduce the likelihood of exposure through alteration of the manner in which a task is performed. Therefore, supervisors will be responsible for documenting and instituting work practices or laboratory procedures that will minimize potential exposure and will be responsible also for evaluating these on a regular basis to ensure their effectiveness. Appropriate work practices will be reviewed with each employee, and the employee will be expected to follow the designated work practice controls.

The engineering and work practice controls listed below must be followed:

Employee Personal Actions

- a) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure;
- b) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or benchtops where blood or OPIM are present;
- c) All procedures involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances; and
- d) Mouth pipetting/suctioning of blood or OPIM is prohibited.

Hand washing

- a) Hand washing facilities must be readily accessible to employees

- b) When provision of hand washing facilities is not feasible, either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes shall be provided. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible
- c) Employees shall wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment
- d) Employees shall wash their hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or OPIM

Handling of Disposable Needles and Other Sharp Instruments

- a) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed. Shearing or breaking of contaminated needles is prohibited
- b) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer demonstrates that no alternative is feasible or that such action is required by a specific medical or dental procedure. Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique

Handling of Reusable Sharp Instruments (e.g., lancets, scalpels, etc.)

- a) Contaminated reusable sharps shall be placed in appropriate containers immediately or as soon as possible after use until properly reprocessed. These containers shall be puncture resistant, properly labeled "Biohazard", leak proof on the sides and bottom
- b) Reusable sharps that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed

Handling of Specimens:

Specimens of blood or OPIM shall be placed in a properly labeled, closed container which prevents leakage during collection, handling, processing, storage, transport or shipping. If the specimen could puncture the primary container, the primary container shall be placed within a properly labeled, leak proof, puncture-resistant secondary container

Handling of Contaminated Equipment

- a) Equipment contaminated with blood or OPIM shall be decontaminated as necessary before servicing or shipping unless decontamination of the equipment or portions of it is not feasible
- b) A readily observable label shall be attached to the equipment stating which portions remain contaminated
- c) This information shall be conveyed to all affected employees, servicing representative and/or manufacturer, as appropriate, prior to handling, servicing or shipping so that appropriate precautions will be taken

5.3 Personal Protective Equipment (PPE)

5.3.1 Provision

Supervisors will determine and document the requirement for specific personal protective equipment for their employees based on anticipated employee exposure to blood or OPIM. Personnel will be provided, at no cost to them, with appropriate PPE for performing tasks which may result in exposure. The protective equipment will be considered appropriate only if it does not permit blood or OPIM to pass through or reach the employees clothing, skin, eyes, mouth or other mucous membranes under the normal conditions of use and for the duration of time which the protective equipment will be used. Personal protective equipment includes but is not limited to: masks, gloves, lab coats, face shields, eye protection, mouthpieces, resuscitation bags, pocket masks, or other ventilation devices.

5.3.2 Use

The supervisor shall ensure that employees use appropriate PPE as necessitated by their work tasks. However, under rare and extraordinary circumstances, employees may decline to use PPE if, in their professional opinion, its use would prevent the delivery of health care or would pose an increased safety hazard to themselves or to their co-workers. Should this happen, then the employer shall investigate and document all of the circumstances involved in order to determine if changes can be made to avoid future recurrence.

5.3.3 Accessibility

The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powder-free gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

5.3.4 Cleaning, Laundering and Disposal

The employer must clean/laundry, repair, replace or dispose of any PPE when necessary without cost to the employee.

All garments penetrated by blood or OPIM shall be removed immediately or as soon as possible.

PPE is to be worn only when needed for protection and is to be removed prior to leaving the work area. When PPE is removed, it is to be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

5.3.5 Gloves

Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, and other non-intact skin; when handling or touching contaminated items or surfaces; and when performing vascular access procedures, except for phlebotomies in a volunteer blood donation center when the employer judges that routine gloving for all phlebotomies is not necessary. In this case the employer shall periodically reevaluate this policy; make gloves available to all employees who wish to use them for phlebotomy; not discourage the use of gloves and require that gloves be used in the following circumstances: when the employee has cuts, scratches, or other breaks in his or her skin; when the employee judges that hand contamination with blood may occur (e.g. when performing phlebotomy on an uncooperative individual); and when the employee is receiving training in phlebotomy.

Disposable gloves will not be washed or decontaminated for re-use and will be replaced when they become contaminated, or if they are damaged in any way that compromises their ability to function as a barrier.

Utility gloves may be decontaminated for re-use unless they show any signs of deterioration or when their ability to function as a barrier has been compromised, (cracked, peeling, torn, punctured) in which case they must be discarded.

5.3.6 Masks, Eye Protection and Face Shields

Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

NOTE: Although surgical masks may be considered PPE for protection of mucous membranes from potential splash of infectious agents or OPIM, they are not considered by the Standard to be respiratory protection.

5.3.7 Gowns, Aprons and Other Protective Body Clothing

Appropriate protective clothing (such as, but not limited to, gowns, aprons, lab coats, clinic jackets or similar outer garments) shall be worn in exposure situations. The specific type will depend upon the task and degree of exposure anticipated. When gross contamination can be reasonably anticipated, (such as autopsies and orthopedic surgery), surgical caps or hoods and/or shoe covers or boots shall be worn in addition.

5.4 Housekeeping

UC Merced supervisors are responsible for ensuring that:

Their worksites are maintained in a clean and sanitary condition;

- The supervisor of a worksite determines, implements and maintains an appropriate written schedule for cleaning and method of decontamination based upon the location within the worksite, type of surface, type of soil present, and tasks or procedures performed in the area;
- All equipment, environmental and working surfaces are cleaned and decontaminated after contact with blood or OPIM as soon as feasible using an appropriate disinfectant; whenever there is overt contamination; after any spill of blood or OPIM; and at the end of the work shift if the surface may have become contaminated since the last cleaning;
- Any protective coverings (such as plastic wrap, aluminum foil, or imperviously-backed sorbant paper) used to cover equipment, environmental and working surfaces are removed and replaced as soon as feasible when contaminated;

- All bins, pails, cans and similar receptacles intended for reuse which may be contaminated are inspected and decontaminated on a regularly scheduled basis;
- Broken glassware which may be contaminated is picked up using mechanical means (brush, dust pan, tongs or forceps) and not by hand; and
- Employees do not reach into containers by hand to retrieve reusable contaminated sharps.

5.5 Laundry Procedures

The following provisions are specified by the Standard in order to minimize exposures when handling contaminated laundry

- Supervisors must ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate PPE. Contaminated laundry must be handled as little as possible and with a minimum of agitation;
- Contaminated laundry must be bagged or containerized at the location where it was used; do not sort or rinse it in the location of use;
- Contaminated laundry must be placed and transported in appropriately labeled or color-coded bags or containers; and
- Contaminated laundry that is wet and will soak through the bag or cause leakage from the bag or container must be placed and transported in bags or containers that prevent soak through or leakage.

NOTE: If your area uses Universal Precautions in handling all contaminated laundry, then alternative labeling or color-coding is sufficient if it permits employees to recognize the containers as requiring compliance with Universal Precautions. However, if your area ships contaminated laundry off-site where Universal Precautions are not used, then your area must employ the required labeling or a color-coding system.

5.6 Regulated Waste Disposal

At UC Merced the handling and disposal of regulated medical waste will be as follows (Detailed in UC Merced Biosafety Manual)

5.6.1 Disposal of Contaminated Sharps:

- Contaminated sharps shall be discarded as soon as possible into sharps containers that are labeled with the words “Biohazardous Waste” or with the international biohazard symbol and the word “Biohazard” and are puncture resistant, leak proof and closeable to assure containment;
- In addition all containers must be labeled with “University of California, Merced,” address of facility, PI’s name, and building and room number where waste was generated;
- Such containers shall be easily accessible to personnel and shall be located as close as possible to the immediate area where sharps are being used or can be reasonably anticipated to be found;
- Sharps containers shall be kept upright when being used, they will not be overfilled, and containers replaced routinely;
- Sharps containers shall be closed immediately prior to their removal from the area of use or replacement to prevent spillage or protrusion of contents during handling, storage, transport or shipping;
- A secondary container shall be used if leakage of the primary container is possible. The secondary container shall be properly labeled, closeable, leak proof and constructed to contain all contents during handling, storage, transport or shipping; and
- Reusable containers shall not be opened, emptied or cleaned manually or in any other manner which would expose personnel to the risk of percutaneous injury.

5.6.2 Other Regulated Medical Waste

- Other regulated waste shall be placed in containers/bags which are closeable, constructed to contain all contents and prevent leakage during handling, storage, transport and shipping;
- Waste bags or containers must be labeled “Biohazardous Waste” or with the international biohazard symbol and the word “BIOHAZARD” and color coded red. In addition all containers must be labeled with “University of California, Merced,” address of facility, PI’s name, and building and room number where the waste was generated;
- Prior to removal, waste bags or containers shall be closed to prevent spillage or protrusion of contents during handling, storage, transport or shipping; and
- If outside contamination occurs or is likely, the waste bags/containers must be placed in a second container that is closeable, leak proof, labeled and color coded.

NOTE: Disposal of all regulated waste shall be in accordance with applicable State (see Medical Waste Management Act, California Health & Safety Code, Division 20, Chapter 6.1 and part14) and local regulations.

6.1 HEPATITIS B VACCINATION

The hepatitis B vaccine and vaccination series will be made available to all employees who may have occupational exposure. Pre-exposure vaccine will be offered free of charge to employees after they have received training in occupational exposure and within 10 working days of initial assignment, unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, the vaccine is contraindicated for medical reasons or satisfy the “exception” defined below. Participation in a prescreening program is not a prerequisite for hepatitis B vaccination.

Employees who decline to take the vaccine will be required to sign a Cal/OSHA required waiver indicating their refusal (see Appendix A). However, employees who refuse the initial vaccine may change their decision and receive the vaccine at any time as long as they are still considered to be at risk.

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

The Hepatitis B vaccine and vaccination series is available to all UC Merced employees who have occupational exposure and post-exposure follow-up to employees who have been involved in or had an exposure incident. Typically the involved departments and/or labs are responsible for any costs incurred.

The **Patients First Medical Center** is the administrator for the Hepatitis B vaccination program and shall ensure that all medical evaluations and procedures including the Hepatitis B vaccine and vaccination series and post-exposure follow-up, including prophylaxis are:

- Made available at no cost to the employees;
- Made available to the employee at a reasonable time and place;
- Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional; and
- Provided according to the recommendations of the U.S. Public Health Service

Exceptions:

First aid providers are not required to be offered pre-exposure hepatitis B vaccine if:

- The primary job assignment is not the rendering of first aid;
- Any first aid rendered is only as a collateral duty responding solely to injuries resulting from workplace incidents, generally at a location where the incident occurred; and
- They follow the “Additional Requirements for First Aid Incidents” outlined in 7.00 when first aid assistance is actually provided.

NOTE: *This exception does not apply to designated first aid providers who render assistance on a regular basis, e.g. at a first aid station, clinic, dispensary, or other location where injured employees routinely go for assistance, and emergency or public safety personnel who are expected to render first aid in the course of their work.*

7.1 POST-EXPOSURE EVALUATION AND FOLLOW UP

Post-exposure evaluation with follow-up is available to all employees who have been involved in an exposure incident. (See “Additional Requirements for First Aid Incidents” below.)

Any exposure incident will be reported immediately to the supervisor and to the person responsible for investigation of exposure incidents. This person will investigate the circumstances of the exposure incident and will make a written, detailed report of these circumstances and document the route(s) of exposure to the employer. The goal of the investigation is to identify and correct any problems in order to prevent recurrence of similar incidents.

Following a report of an exposure incident, the employer will make immediately available to the exposed employee, at no cost, a confidential medical evaluation and follow-up that must include at least the following elements:

- Documentation of exposure route(s) and circumstances of occurrence;
- Identification and documentation of source individual, unless infeasible or prohibited by law;
- Source HBV and HIV testing after consent is obtained;
- Make results of source individual's testing available to exposed employee, but stress the absolute necessity for the employee to understand and abide by all local, state, and federal regulations regarding the confidentiality of the information provided;
- Collection and testing of exposed employee's blood for HBV and HIV serological status after consent is obtained; the employee may refuse to have their blood tested at this time, but may elect to have the blood tested anytime within 90 days of its collection;
- Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;
- Counseling; and
- Evaluation of reported illnesses

A confidential post-exposure medical evaluation and follow-up will be offered free to any employee who incurs an exposure incident. UC Merced will ensure that the health care professional responsible for the employee's HBV vaccination and evaluation after an exposure incident is provided with specific information about the exposure incident.

UC Merced will ensure that the health care professional evaluating an employee after an exposure incident is provided with the following:

- A copy of the Standard;
- A description of the exposed employee's duties as they relate to the exposure incident; documentation of the route(s) of exposure and circumstances under which the exposure occurred;
- Results of the source individual's blood testing, if available; and
- All medical records relevant to the appropriate treatment of the employee, including vaccination records

The evaluating health care professional must submit a written opinion to the employer following the evaluation. The employer must obtain and provide the employee with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation for HBV vaccination and for post exposure follow-up.

The health care professional's written opinion for HBV vaccination and post exposure follow-up shall be limited to the following information:

For HBV Vaccination:

- Whether vaccination is indicated for the employee and if the employee has received such vaccination

For Post Exposure Evaluation and Follow-Up:

- A statement that the employee has been informed of the evaluation, and a statement that the employee has been told about any medical conditions resulting from exposure to blood and OPIM which require further evaluation or treatment.

NOTE: All other personal medical information shall remain confidential and shall not be included in the written report to the employer.

Additional Requirements for First Aid Incidents:

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

The report must include:

- The names of all first aid providers who rendered assistance, regardless of whether PPE was used;
- A description of the first aid incident; time, and date; and a determination of whether or not, in addition to the presence of blood or OPIM, an exposure incident occurred. This determination is necessary in order to ensure that proper post-exposure evaluation, prophylaxis and follow-up procedures are made available immediately if there has been an exposure incident,
- The report must be recorded on a list of such first aid incidents. It will be readily available to all employees and shall be provided upon request to the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations; and
- Provision for the full hepatitis B vaccination series will be made available as soon as possible, but in no event later than 24 hours, to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM regardless of whether or not a specific exposure incident has occurred.

8.00 HAZARD COMMUNICATION

8.1 Labels and Signs

The Standard requires that warning labels be affixed to containers of regulated waste, refrigerators and freezers and other containers which are used to store, transport or ship blood or OPIM. Required labels shall be fluorescent orange or orange-red in color with the international biohazard symbol with the legend BIOHAZARD in a contrasting color. To be consistent with the California Medical Waste Management Act, the Standard requires that regulated waste be labeled even if red bags or containers are used.

Labels must be an integral part of the container or must be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents the loss or unintentional removal.

Labels required for contaminated equipment must be in accordance with this section and must also state which portions of the equipment remain contaminated.

Containers of blood, blood components or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from these labeling requirements.

Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary, provided the containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding is required when such specimens/containers leave the facility.

Regulated medical waste shall be placed in red bags. Contaminated sharps shall be placed in sharps containers. **Red** bags and sharps containers shall be labeled with the words "Biohazardous Waste" or with the international biohazard symbol and the word "Biohazard". In addition all bags and sharps containers must be labeled with "University of California, Merced," address of facility, PI's name, and building and room number where waste was generated.



Signs must be posted at the entrance to work areas for HIV, HBV, or HCV research laboratories. These signs must bear the international biohazard symbol with the legend BIOHAZARD and must include the name of the infectious agent, special requirements for entering the area, name, telephone number of the laboratory director or other responsible person. These signs must be fluorescent orange-red or predominantly so with lettering and symbols in a contrasting color. Biohazard signs shall be used to signify the actual or potential presence of a biohazard and to identify equipment, containers, rooms, material, experimental animals, or combinations thereof, which contain or are contaminated with viable hazardous agents. "Biohazard" includes only those infectious agents presenting a risk or potential risk to the well-being of man.

8.2 Information and Training

All at risk employees will be provided with training in accordance with the requirements of the Standard. This training will be provided to the employee at the time of initial assignment to tasks that may result in potential exposure and at least annually thereafter. Training will be given during working hours and at no cost to the employee. Training shall be conducted in person by

an individual who is knowledgeable in the subject matter being presented. Training material presented must be appropriate in content and vocabulary to the educational level, literacy and language of employees. Modifications of any potentially hazardous tasks will require re-training of employees assigned to those tasks. Training must include at a minimum the following elements:

- Where copies of the Standard are available.
- A review/explanation of the contents of the Standard.
- A general discussion on bloodborne diseases and their modes of transmission.
- An explanation of the facility's exposure control plan and its availability.
- Methods for recognizing tasks and other activities that may involve exposure to blood and OPIM.
- A discussion of the use and limitations of engineering and work practice controls and personal protective equipment.
- Information on types, selection, proper use, location, removal, handling, decontamination and disposal of personal protective equipment.
- Hepatitis B vaccine information (efficacy, safety, benefits, method of administration, free of charge).
- Emergency response procedures involving blood or OPIM.
- Information on how to handle exposure incidents.
- An explanation of the post-exposure evaluation and follow-up program.
- An explanation of signs, labels and/or color coding.

The employees must be given the opportunity for interactive questions and answers with the training facilitator.

EH&S shall ensure that general training is provided. Each facility will be responsible for site specific training.

9.00 RECORDKEEPING

9.1 Medical Records

These records shall be kept for employees with occupational exposure. They shall be confidential and shall not be disclosed without the employee's written permission. Records must be maintained for the duration of employment plus 30 years and shall include:

- Employee's name and social security number;
- Hepatitis B vaccination status, including dates, of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination;
- Results of any examinations, medical testing, and follow-up procedures;
- A copy of the information provided to the health care professional; and
- A confidential copy of the health care professional's written opinion.

EH&S is responsible for maintaining medical records related to occupational exposure as required by the Standard.

9.2 Training Records

Required training records shall be maintained for 3 years and shall contain the following information:

- Dates and contents of training;
- Name and qualifications of trainer; and
- Names and job titles of all employees attending training sessions.

General training records will be maintained at Environmental Health and Safety. Site specific records will be maintained at each facility.

9.3 Equipment Records

Biological safety cabinets that are used to prevent harmful exposure from biohazard agents or biohazardous materials must be certified when installed, annually and whenever they are moved or undergo major servicing (HEPA filter replacement, motor repairs, etc.) Records of tests performed must be retained for 5 years.

9.4 Availability of Records

- All records required to be maintained shall be made available upon request to the subject employee, the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations or designated representative and the Director of the National Institute for Occupational Safety and Health (NIOSH), U. S. Department of Health and Human Services or a designated representative for examination and copying;
- Employee training records required by this Standard shall be provided upon request for examination and copying to employees, to employee representatives, to the Chief and to NIOSH; and
- Employee medical records required by this Standard shall be provided upon request for examination and copying to the subject employee; to anyone having written consent of the subject employee, to the Chief, and to NIOSH.

9.5 Transfer of Records

- The employer shall comply with the requirements involving transfer of records; and
- If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify NIOSH at least three (3) months prior to their disposal and transmit them to NIOSH, if required to do so, within that three (3) month period.

10.00 HIV, HBV, and HCV RESEARCH LABORATORIES

All UC Merced laboratories engaged in the culture, production, concentration, experimentation, and manipulation of HIV, HBV, HCV are required to comply with the following special provisions in addition to the other requirements contained in this Plan and guidelines established by the National Institutes of Health and the Centers for Disease Control (refer to Biosafety Level 3 facility and practices, or Biosafety Level 2 facility with Biosafety Level 3 practices as printed in the NIH/CDC Guidelines titled "Biosafety in Microbiological and Biomedical Laboratories"). These special provisions do not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissue or organs.

10.1 Special Practices

- Supervisory personnel shall be responsible for preparing, implementing, reviewing and updating written biosafety procedures for their work site. This manual will be required reading for all personnel and will be adopted into the Site Specific Exposure Control Plan. Personnel shall be advised of potential hazards and shall be required to follow the written practices and procedures;
- Personnel must be advised of potential hazards, must read instructions on practices and procedures, and must follow them;
- Laboratory doors must be kept closed when work with HIV, HBV, and HCV is in progress;
- Access to the work area must be limited to authorized persons;
- Written policies and procedures must be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (vaccination, PPE, etc., if required), and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms;
- When OPIM (with the potential of HIV, HBV, and HCV contamination) or infected animals are present in the work place, hazard warning signs must be posted on all access doors, and all doors must be kept closed while work is in progress. Such warning signs must comply with the following requirements: Signs shall be florescent orange-red or predominantly so and bear the biohazard symbol and the word "BIOHAZARD" in contrasting color along with the following legend:
 1. Name of the Infectious Agent;
 2. Special requirements for entering the area; and
 3. Name, telephone number of the laboratory director or other responsible person
- All regulated waste must be incinerated or decontaminated by a method known to effectively destroy bloodborne pathogens (e.g., autoclaving). Such methods are further specified in California Health and Safety Code, Chapter 6.1 and Part 14;
- Contaminated materials must be placed in durable, leak proof, labeled or color-coded containers that are closed before being removed from the work area for decontamination;

- Before disposal, all waste from work areas and from animal rooms must be incinerated or decontaminated;
- No work with OPIM (with the potential of HIV or HBV contamination), HIV or HBV is to be conducted on an open bench. Use biological safety cabinets or other physical containment devices for manipulations;
- Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing must be used in the work areas and animal rooms;
- PPE must not be worn outside of the work area and must be decontaminated before being laundered;
- Avoid skin contact with OPIM (with the potential of HIV, HBV, or HVC contamination), HIV, HBV, or HVC. Gloves must be worn when handling infected animals and when making hand contact with OPIM is unavoidable;
- Vacuum lines must be protected with liquid disinfectant traps and HEPA filters or similar quality filters. Check traps and filters routinely. Replace as necessary;
- Extreme caution must be used when handling needles and syringes;
- Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to syringe) shall be used for injecting or aspirating OPIM. Hypodermic needles and syringes are to be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles;
- Do not bend, shear, replace in the sheath or guard, or remove needles from syringes after use;
- After use, needles and syringes must be placed promptly in puncture-resistant containers and autoclaved or decontaminated before reuse or disposal;
- All spills must be immediately contained and cleaned up by properly trained and equipped personnel; and
- A spill or accident that results in an exposure incident must be reported immediately to the laboratory director (Principal Investigator) or other responsible supervisor.

10.2 Containment Equipment

- Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices (e.g., special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) shall be used for all activities with OPIM (with the potential of HIV, HBV, or HVC contamination), HIV, HBV, HCV that pose a threat of exposure to droplets, splashes, spills or aerosols.
- Biological safety cabinets shall be certified when installed, annually, and whenever they are moved or undergo major servicing (HEPA filter replacement, motor repairs, etc.). Records of tests performed must be retained for at least 5 years.

10.3 Other HIV, HBV, and HCV Research Laboratory Requirements

- Each laboratory must include hand washing and eye wash facilities which are readily available within the work area; and
- An autoclave for decontamination of regulated waste shall be available.

10.4 Additional Training Requirements

Laboratory Principal Investigators/Supervisors must ensure that prior to working with HBV, HCV or HIV, employees will:

- Demonstrate proficiency in standard microbiological practices and techniques, and in those practices and operations specific to their work site;
- Be experienced in handling human pathogens or tissue culture; and
- Demonstrate proficiency in techniques in a progression of work activities, but without handling infectious agents, if there is no prior experience in human pathogen handling. Employees will be allowed to participate in work activities involving infectious agents only after proficiency has been demonstrated.

11.00 SITE SPECIFIC INFORMATION FOR THE EXPOSURE CONTROL PLAN

11.1 Facility Information

School: _____

Supervisor: _____

Location (Building/Room) _____

Phone Number: _____

Date of Preparation of Plan: _____

Emergency Phone: _____

EH&S: (209) 228-4639 (Biosafety Officer); (209) 228-7864 (Chemical Hygiene Officer); (209)228-4234 (EHS Director)

Emergency, UC Merced Police: (209) 228-2677 or Dial 9-911

Contact one or more of the following for further assistance:

Patients First Medical Center. 394 E Yosemite Avenue, Merced, CA 95340. P: 209-383-3990

_____ is responsible, for preparing, implementing and maintaining the Plan and also for performing the annual Plan review, updates to plan, procedures, and reviews of work practice controls.

Copies of the Plan may be obtained from _____ (name/position)

at _____ (location).

11.2 Exposure Determination (See 4.00 for details)

Following a review of work practices, without regard to the use of personal protective equipment (PPE), it has been determined that the following employees or tasks have a risk of exposure to bloodborne pathogens (BBP) and/or other potentially infectious materials (OPIM):

Employees:

Tasks:

11.3 Methods of Compliance

11.3.1 Engineering and Work Practice Controls (See 5.02 for details). In this facility the following engineering and work practice controls will be used:

_____ is responsible for ensuring that biological safety cabinets are certified as required. These records must be maintained for 5 years.

b. This work site will be cleaned and decontaminated according to the following schedule:

Area	Schedule	Procedure and Cleaner/Sanitizer Used

11.4 Hepatitis B Vaccination (See 6.00 for details)

The hepatitis B vaccine and vaccination series will be offered to all employees who have occupational exposure.

_____ will ensure that all employees in their facility who have occupational exposure are offered the vaccination series unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons. Employees who decline to take the vaccine will be required to sign a Cal/OSHA required waiver indicating their refusal (see Appendix A).

11.5 Post Exposure Evaluation and Follow Up (See 7.00 for details)

All exposure incidents shall be reported, investigated and documented. When an employee incurs an exposure incident, it shall be reported to the employee’s supervisor and EH&S.

Post-exposure evaluation and follow-ups will be performed by

Patients First Medical Center. 394 E Yosemite Avenue, Merced, CA 95340. P: 209-383-3990

EH&S shall ensure that the health care professional evaluating an employee after an exposure incident is provided with the following:

- A description of the exposed employee's duties as they relate to the exposure incident;
- A copy of the Standard;
- A description of the exposed employee's duties as they relate to the exposure incident
- Documentation of the route(s) of exposure and circumstances under which the exposure occurred;
- Results of the source individual's blood testing, if available; and
- All medical records relevant to the appropriate treatment of the employee, including vaccination records

EH&S shall obtain and provide the employee with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation.

11.6 Hazard Communication

11.6.1 Labels and Signs (See 8.01 for details)

_____ shall ensure that biohazard labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM, and other containers used to store, transport or ship blood or OPIM.

11.6.2 Information and Training (See 8.02 for details)

Environmental Health and Safety shall ensure that general training is provided. Each facility will be responsible for site specific training.

_____ shall ensure that training is provided to employees at the time of initial assignment to tasks where occupational exposure may occur, when any modifications to any potentially hazardous tasks are made, and that it shall be repeated within twelve months of the previous training.

11.07 Recordkeeping

11.07.1 Training Records (See 9.02 for details)

General training records will be maintained at Environmental Health & Safety. Site specific records will be maintained at each facility.

_____ is responsible for maintaining the training records in accordance with the requirements of the Standard. These records shall be maintained for 3 years.

11.8 HIV, HBV and HCV Research Laboratories

11.8.1 Special Practices (See 10.01 for details)

_____ is responsible for writing and maintaining written biosafety procedures for this facility and shall ensure that all laboratory personnel who are required to do so have read these procedures.

Attach the written biosafety procedures (i.e., biosafety manual) that are specific for the work site.

11.8.2 Containment Equipment (See 10.02 for details)

_____ is responsible for ensuring that laboratory employees use appropriate containment equipment (e.g., biosafety cabinets) and adhere to proper laboratory procedures while carrying out their work tasks at this site.

11.8.3 Additional Training Requirements (See 10.04 for details)

_____ is responsible for training and documentation of the special training required in labs where workers are at risk of HIV, HBV, or HCV exposure.

GLOSSARY

Blood: Human blood, human blood components, and products made from human blood.

Bloodborne Pathogens (BBP): 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).

Biological Safety Cabinet: 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 safety cabinets are classified as:

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

Contaminated: 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: Laundry which has been soiled with blood or other potentially infectious materials, or may contain sharps

Contaminated Sharps: Any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontaminate: 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.

Engineering Controls: Controls (e.g., Biosafety cabinets, sharps disposal containers, self-sheathing needles) that isolate or minimize the bloodborne pathogens hazard in the workplace.

Exposure Incident: 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.

HBV: Hepatitis B virus.

HCV: Hepatitis C virus

HIV: Human immunodeficiency virus.

Medical Waste: The definition of medical waste as stated in the regulations is complex. In most of the situations encountered at UC Merced the definition can be summarized as follows: Medical waste is waste that includes fluid blood or material of a biological origin with known or suspected infectious components.

According to the regulations, Medical Waste must meet both of the following requirements:

1. The waste is generated or produced as a result of any of the following actions:
 - a. Diagnosis, treatment, or immunization of human beings or animals.
 - b. Research pertaining to the diagnosis, treatment, or immunization of human beings or animals.
 - c. The production or testing of biologicals.
2. The waste is either of the following:
 - a. Biohazardous waste.
 - b. Sharps waste.

Occupational Exposure: 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.

OPIM: Other Potentially Infectious Materials

1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is visibly contaminated with blood such as saliva or vomit, 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. 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.

Parenteral: Piercing mucus membranes or the skin barrier through such events as needle sticks, human bites, cuts and abrasions.

Personal Protective Equipment (PPE): 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.

Regulated Waste: Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. Regulated Waste includes "medical waste" regulated by Health and Safety Code Chapter 6.1 and Part 14.

Source Individual: Any individual, living or dead, whose blood or other potentially infectious materials 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.

Sterilize: The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores. Sterilization includes procedures regulated by Health and Safety Code Section 25090.

Universal Precautions: 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 HIV, HBV, and other bloodborne pathogens.

Work Practice Controls: Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

REFERENCES and Additional Information:

1. Biosafety in Microbiological and Biomedical Laboratories, Third Edition, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), U. S. Department of Health and Human Services, Public Health Service, May 1993.
2. Barclays California Code of Regulations, Title 8 §5193, p 844.10 – 884.12(f), Register 2001, No 31; 03 August 2001
3. Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), U. S. Department of Health and Human Services, Public Health Service, HHS Publication No (CDC) 21-1112, December, 2009.

Signature Page

Date First Approved: _____

Principal Investigator: _____ Bldg: _____ Room No: _____

Student/Staff Signatures (indicating knowledge & understanding of this Plan):

X _____	Date _____	X _____	Date _____
X _____	Date _____	X _____	Date _____
X _____	Date _____	X _____	Date _____
X _____	Date _____	X _____	Date _____
X _____	Date _____	X _____	Date _____
X _____	Date _____	X _____	Date _____
X _____	Date _____	X _____	Date _____

NOTE: Pursuant to OSHA, the Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures that affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

a) Annual Review: _____ Date	PI: _____ Signature
b) Annual Review: _____ Date	PI: _____ Signature
c) Annual Review: _____ Date	PI: _____ Signature
d) Annual Review: _____ Date	PI: _____ Signature
e) Annual Review: _____ Date	PI: _____ Signature
f) Annual Review: _____ Date	PI: _____ Signature
g) Annual Review: _____ Date	PI: _____ Signature

Appendix A



Hepatitis B Vaccine Declination

The Bloodborne Pathogen Standards, CCR Title 8 5193, issued by the Occupational Health Administration require the employer to ensure that employees who decline to accept the Hepatitis B vaccination sign the following statement.

I understand that due to my occupational exposure to blood or other potentially infectious materials that I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with the Hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis B vaccination at this time. I understand that by declining this vaccine, I could be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious material and I want to be vaccinated with the Hepatitis B vaccine, I can receive the vaccination series at no charge to me.

California Labor Code § 142.3

Sign

Print Name

Date

UCMerced email