

UNIVERSITY OF NORTH FLORIDA
BLOODBORNE PATHOGEN PROGRAM
EXPOSURE CONTROL PLAN

I. Introduction

In December of 1991 the Occupational Safety and Health Administration (OSHA) promulgated the Bloodborne Pathogens Standard, 29 CFR 1910.1030. This standard was developed to minimize the potential for work-related transmission of infectious diseases via human blood, body fluids and other materials. The standard requires impacted employers to develop a strategy aimed at reducing the potential for infection. The following document is the Exposure Control Plan for the University of North Florida and is one in a series of documents developed to ensure employee health and safety at UNF.

II. Responsibility

It is the responsibility of department chairpersons or directors to ensure that individual departments and groups are in compliance with the Bloodborne Pathogen Standard.

It is the responsibility of principal investigators or departmental supervisors to ensure the requirements and procedures outlined in this Exposure Control Plan that are appropriate to the individual work areas are carried out.

Employees are responsible for reporting exposures to their supervisors and complying with all components of this Exposure Control Plan.

Student Health Services (SHS) will be responsible for providing immunizations, post-exposure follow-up and keeping medical records for students only. Employee care is limited to hepatitis B vaccination and emergency treatment. Requisite training as outlined in this Plan is provided on a scheduled basis only. Prophylaxis, other immunization and post-exposure follow-up must be arranged through a private physician. Several area hospitals and clinics provide these services. Please contact the Department of Human Resources for further information on care providers.

Environmental Health & Safety (EH&S) is responsible for reviewing and overseeing this Exposure Control Plan. This includes coordinating compliance efforts, acting as a consultant for departments regarding implementation and enforcement, evaluating work practices and personal protective equipment, providing educational materials, tracking employee training and medical monitoring.

II. Definitions

A. Blood

Blood refers to human blood, human blood components and products made from human blood.

B. Bloodborne Pathogens

Bloodborne Pathogens are 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 and human immunodeficiency virus (HIV).

C. Decontamination

Decontamination is the use of physical or chemical means to remove, inactivate or destroy microorganisms 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.

D. Engineering Controls

Engineering controls are those controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the biological hazard from the workplace.

E. Exposure Incident

An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or other potentially infectious material (OPIM) that results from the performance of an employee's duties.

F. Occupational Exposure

Occupational exposure means reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or OPIM that results from the performance of an employee's duties. Section III identifies UNF personnel with the potential for occupational exposure.

G. Other Potentially Infectious Materials (OPIM)

Materials other than human blood that are potentially infectious for bloodborne pathogens.

These include: (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 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; (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); (3) HIV-containing cell or tissue cultures, organ cultures, culture medium or other solutions; and (4) blood, organs or other tissues from experimental animals infected with zoonotic diseases.

H. Parenteral

Parenteral means piercing mucous membranes or the skin barrier through such events as needle sticks, human or animal bites, cuts or abrasions.

I. Personal Protective Equipment

Personal protective equipment (PPE) is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) are not intended to protect against hazards and are therefore not considered PPE.

J. Universal Precautions

Universal Precautions are 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.

K. Work Practice Controls

Work Practice Controls are those practices that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g. prohibiting recapping of needles).

III. Exposure Determination

Employees who may be exposed to human blood and OPIM during the course of their employment must have their job classifications evaluated for the likelihood of such exposure. These evaluations are made without regard to the use of PPE. The following categories have been developed according to the tasks performed:

Category 1- Those job classifications in which all employees have occupational exposure. Tasks include providing first aid, inoculations and medical examinations.

Appropriate PPE and infection control measures are required for all employees in this category.

Category 2- Those job classifications in which some, but not all employees have occupational exposure. Tasks include clinical instruction refuse collection, biowaste collection, housekeeping and plumbing maintenance. Appropriate PPE and infection control procedures are readily available and used as procedures or tasks demand.

Category 1

Student Health Services Director
Student Health Services Coordinator
Student Health Services Nurse
Aquatics Center Coordinator
Aquatics Center Head Guard
Aquatics Center Lifeguards
UPD Law Enforcement Officers
Athletics Head Trainer
Athletics Assistant Trainer

Category 2

Physical Therapy Instructors
PT Assistant Professors
PT Associate Professors
Health Science Clinical Educators
Nursing Instructors
Nursing Assistant Professors
Nursing Associate Professors
Physical Facilities Custodial Workers
PF Sr. Custodial Workers
PF Maintenance Support Workers
PF Custodial Supervisors
PF Recycle Clerk
PF Maintenance Mechanics

Companies who are in compliance with the OSHA Bloodborne Pathogens Standard shall provide contractor services that fall within either of the above categories. This includes the training, vaccination and recordkeeping components of the Standard.

IV. Training

A. Scope

1. All employees with reasonably anticipated exposure to bloodborne pathogens or OPIM will receive annual training regarding the prevention and control of bloodborne pathogens.
2. New employees with reasonably anticipated exposure to bloodborne pathogens and OPIM will receive training within 30 days of employment.
3. Additional training shall be provided to employees as their job duties change. This will be monitored by individual supervisors in consultation with EH&S.

B. Record-Keeping

1. The dates of the training sessions, content outline, attendees list and presenters list shall be maintained by the individual departments for three (3) years.
2. Departmental compliance with the training requirement will be monitored by EH&S. A list of persons trained shall be submitted to EH&S annually by each department.

C. Content

1. The training program shall contain the following elements:
 - a. An accessible copy of the bloodborne pathogen standard.
 - b. A general explanation of the epidemiology and symptoms of bloodborne diseases.
 - c. An explanation of modes of transmission of bloodborne pathogens.
 - d. A review of the exposure control plan.
 - e. An explanation of the appropriate methods for recognizing procedures and other activities that may involve exposure to blood and OPIM.
 - f. An explanation of the use and limitations of practices that will prevent or reduce the likelihood of exposure. This includes the appropriate use of PPE and proper work practices.
 - g. Information on the types, proper use, location, removal, handling, decontamination and/or disposal of PPE.
 - h. An explanation of the rationale for selecting PPE.
 - i. Information on the hepatitis B vaccine, including information on its efficacy, safety and the benefits of being protected against hepatitis B.
 - j. An explanation of the post-exposure evaluation in the event of an exposure including reporting mechanisms, time frame for reporting and the medical management that is available.

- k. Information on the management of emergencies associated with bloodborne pathogens including persons to contact and precautions.
- l. Review of signs, labeling and bagging procedures associated with prevention and control of bloodborne pathogens.

V. Hepatitis B Vaccination

The vaccine for hepatitis B shall be offered at no cost to employees identified in Section III.

Vaccine refusal shall be documented by the employee signing the Hepatitis B Vaccine Declination statement (see Attachment A). The statement shall be maintained in the employee's medical record.

Refusal of the vaccine is not final and the employee may request vaccination at any future time.

VI. Medical Recordkeeping

Employee medical records shall be maintained in the employee's permanent file by the Human Resources Department for the duration of employment, plus thirty (30) years.

VII. Exposure Prevention

A. Universal Precautions

Universal Precautions shall be practiced to prevent employee exposure to blood and OPIM (see Attachment B).

B. Engineering and Work Practice Controls

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. PPE shall be used when occupational exposure may occur even though the engineering and work practice controls are in place.

Engineering controls shall be examined and maintained or replaced on a regular schedule.

1. Hand washing facilities shall be provided and maintained with adequate supplies.
2. Hand washing shall be performed after removal of gloves and after contact

- with blood or OPIM.
3. Employees who have exudative lesions or weeping dermatitis shall refrain from handling blood or OPIM until the condition resolves.
 4. Contaminated sharps and needles shall not be bent, recapped or sheared.
 5. Contaminated sharps and needles shall be disposed of in puncture resistant, color-coded or labeled, leak-proof containers.
 6. Eating, drinking, smoking, handling contact lenses and applying cosmetics are prohibited in work areas where there is a potential for blood or OPIM exposure.
 7. Food and drink are prohibited in work areas where there is a potential for blood or OPIM exposure.
 8. All procedures involving blood and OPIM shall be performed in such a manner to minimize splashing, spraying, spattering, generation of droplets or aerosolization of these substances.
 9. Mouth pipetting and suctioning are not allowed.
 10. Resuscitation devices including mouthpieces or resuscitation bags shall be available for use in areas where the need for resuscitation is predictable (University Police Department, Student Health Services, Aquatic Center, etc.).
 11. All specimens of blood or OPIM shall be placed in closable, leak-proof containers prior to transport. If contamination of the outside of the primary container is likely, then a second container such as a plastic bag should be placed over the primary container to prevent contamination and/or leakage during handling, storage or transport.

C. Personal Protective Equipment (PPE)

PPE, including gloves, gowns, laboratory coats, face shields, face masks, eye protection, foot coverings, resuscitation bags and other items shall be provided to employees, as appropriate, to prevent exposure to blood or OPIM. These items shall be worn as needed for the task involved. PPE shall be considered "appropriate" if it does not permit the passage of blood or OPIM through to an employee's skin, mucous membranes or street clothes.

1. Gloves

- a. Disposable, single use gloves shall be worn when it is reasonably anticipated that the employee will have hand contact with blood or OPIM. The gloves shall be replaced when worn, torn or contaminated. They shall not be washed or decontaminated for re-use.
- b. Utility gloves may be decontaminated and re-used if not punctured.

2. Masks, eye protection, face shields:

Masks in combination with eye protection devices shall be worn when there is a reasonably anticipated chance of exposure to blood or OPIM through splashes, sprays, spatters or droplets.

3. Gowns, gloves, aprons and other protective coverings:

These shall be worn depending upon the task and the degree of exposure anticipated.

4. Surgical caps, hoods or boots:

These shall be worn when gross contamination is reasonably anticipated.

There shall be a designated area in each work setting for the dispensing, storage, cleaning and disposal of PPE. Contaminated PPE that is not immediately decontaminated shall be clearly designated and treated as biohazardous material.

D. Housekeeping

1. Cleaning, Disinfection and Sterilization Practices

- a. All environmental and work surfaces shall be properly cleaned and disinfected on a regular schedule and after contamination with blood or OPIM (see Attachment C).
- b. Appropriate personal protective equipment (e.g. gloves) shall be worn to clean and disinfect blood and OPIM spills.
- c. Cleaning, disinfection and sterilization of equipment shall be performed, as appropriate, after contamination with blood and OPIM (see Attachment C).

2. All linens used in UNF Student Health Services patient facilities shall be considered contaminated and shall be handled using Universal Precautions.
3. All infectious wastes shall be managed according to UNF Biohazardous Waste Disposal Policy (see Attachment D).
 - a. Gloves shall be worn by employees who have direct contact with contaminated waste.
 - b. All biohazardous and/or biomedical waste designated for removal and incineration off-site shall be labeled according to Florida Statutes.

E. Labels

1. Warning labels as specified by the bloodborne pathogen standard shall be used. Red bags or red containers may be substituted for labels.
2. The labels shall include the biohazard symbol and be fluorescent orange or orange red.
3. Warning labels shall be placed on containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials. Other containers used to store, transport or ship blood and OPIM shall also be labeled.
4. Warning labels should be affixed to contaminated equipment and state which portions of the equipment are contaminated.

VIII. Exposure Management

Exposure management including post exposure prophylaxis shall be done in compliance with OSHA standard 1919.1030 and Florida Statutes.

UNF employees who have been determined to be at risk shall receive education regarding the management of exposures to bloodborne pathogens that shall include the following:

1. Wound and skin exposures shall be immediately washed with soap and water.
2. Exposures shall be reported to the supervisor.
3. Exposed individuals shall go as soon as possible (within 1 to 24 hours) to

their personal physician or local hospital emergency room for follow-up evaluation and treatment.

A confidential medical evaluation and follow-up should be conducted for all exposure events to employees. The follow-up should include these components:

1. The route and circumstances of the exposure shall be documented.
2. The identification of the source individual shall be documented unless it is unfeasible or prohibited by State law.
3. The source individual shall be tested for HIV or HBV according to Florida Statutes. Retesting is not necessary when the source individual is known to be positive for HIV or HBV. Those results shall be disclosed to the employee according to Florida Statutes.
4. Serologic testing of the exposed employee shall be offered within the provisions of Florida Statutes for HIV. If the employee consents to baseline blood collection, but chooses not to be tested for HIV at that time, the sample shall be held for 90 days after the incident enabling the employee to have HIV testing within the 90 days.

The evaluation and follow-up protocols are based upon U. S. Public Health Service recommendations. A written follow-up letter shall be provided to the exposed employee within 15 days of the completion of the evaluation. The letter shall document:

1. That the employee has been informed of the results of the evaluation.
2. That the employee has been informed about any medical conditions resulting from exposure to blood or other potentially infectious materials which require any further evaluations or treatment.
3. The hepatitis B immunization status and the need for immunization.
4. The letter shall not include any confidential material.

The medical personnel responsible for evaluation of exposures shall be knowledgeable about the OSHA Bloodborne Pathogen Standard 1910.1030 and Florida Statutes. Information regarding the results of the source individual's blood testing and the immunization status shall be provided to the medical evaluator. A description of the exposed employee's duties as they relate to the incident shall also be given to the evaluator.

IX. HIV and HBV Research and/or Production Laboratories

There are special requirements for research laboratories and production facilities engaged in the culture, production, concentration, experimentation and manipulation of HIV and HBV (see Attachment E). These requirements DO NOT apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissue or organs. These requirements apply in addition to the other requirements of this rule.

XI. Assessment: Monitoring, Review and Update

A. Monitoring

1. Each department chairperson or director shall be responsible for monitoring his or her department's or group's compliance with the Bloodborne Pathogen Standard.
2. EH&S shall assist departments in monitoring compliance with the Bloodborne Pathogen Standard.

B. Review and Update

EH&S shall review and assess the Exposure Control Plan annually. Input from the departments and from campus-wide monitoring will be used to update this plan as needed.

UNIVERSITY OF NORTH FLORIDA
HEPATITIS B VACCINE DECLINATION

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

SIGNATURE

PRINTED OR TYPED NAME

DEPARTMENT

DATE

UNIVERSITY OF NORTH FLORIDA
UNIVERSAL PRECAUTIONS POLICY

Universal Precautions

According to the concept of Universal Precautions, all human blood, human blood components, products made by human blood and certain other materials are treated and handled as if known to be infectious for HIV, HBV and other blood borne pathogens.

The other potentially infectious materials (OPIM) which require Universal Precautions include: (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 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; (2) any unfixed tissue organ (other than intact skin) from a human (living or dead); (3) HIV – containing cell or tissue cultures, organ cultures and HIV – containing culture medium or other solutions; and (4) blood, organs or other tissues from experimental animals infected with HIV or HBV.

The following shall be observed:

1. **PPE:** Personal protective equipment shall be used to prevent skin and mucous membrane contact with blood OPIM. These may include the use of gloves, masks, protective eyewear or face shields and gowns or aprons as appropriate for the task.
2. **Handwashing:** Hands and other skin surfaces shall be washed immediately after contact with blood or OPIM. Hands shall be washed each time gloves are removed.
3. **Prevent Puncture Wounds:** All sharps (needles, scalpels, and razor blades) shall be disposed of in labeled, leak proof, puncture proof sharp containers. Needles shall not be bent, sheared or recapped. Sharps containers shall be available in the area where sharps are being used.
4. **Dermatitis:** Employees who have exudative lesions or weeping dermatitis shall refrain from handling blood or OPIM until the condition resolves.
5. **Biological Safety Cabinets (BSC):** BSC are required for procedures that may generate an aerosol (vortexing, grinding, blending, etc.)

UNIVERSITY OF NORTH FLORIDA
BLOODBORNE PATHOGEN PROGRAM

GERMICIDE/DISINFECTANTS/STERILIZERS

This section contains guidelines for the use of sterilants, disinfectants and germicides.

Environmental Cleaning

All blood and OPIM spills must be decontaminated with a 1:10 dilution of sodium hypochlorite (bleach) and water or with a 2% aqueous solution of glutaraldehyde.

Recommendations for Chemical Disinfection and Sterilization of Instruments and Equipment

Decontamination and Cleaning

All the objects to be disinfected or sterilized should be thoroughly cleaned to remove blood, tissue, food, and other residue. If necessary, they should be decontaminated before or during cleaning.

Indications for Sterilization of High-Level Disinfection

Steam sterilization is the optimum way to achieve disinfection. If the item may be damaged by heat, pressure or moisture or if it is otherwise not amenable to steam sterilization, gas sterilization may be used.

Environmental surfaces contaminated with blood or OPIM should be cleaned using a 1:10 dilution of chlorine bleach solution that is prepared daily. The contaminated area should be flooded with the bleach solution and then cleaned up using paper towels. Ten minutes of the exposure is required for disinfection. Gloves should be worn during clean up procedures. Chlorine bleach can corrode metal and should be rinsed thoroughly. Other high-level disinfectants (i.e., 2% glutaraldehyde) may be used according to Table 1.

TABLE 1: Recommended procedures for Disinfection and Sterilization

| | Sterilization | | Disinfection | |
|---|---|------------------------------|--|---------------------------------|
| | | High-Level | | Low-Level |
| contact membranes intact | Will enter tissue or vascular system or blood will flow through | | Will come in contact with mucous membrane but not enter tissue or vascular system. | |
| | Procedure | Procedure Exposure Time (hr) | Exposure Time (10-30min) ^a | Procedure Exposure Time (10min) |
| Smooth Hard surface | A | mfr. Rec. | C | K |
| | B | mfr. Rec. | D | L |
| | C | | E | M |
| | D | | F | N |
| | E | | G | P |
| Rubber Tubing & catheters ¹ | A | mfr. Rec. | C | |
| | B | mfr. Rec. | E | |
| | E | 6 | F | |
| | | | H | |
| | | | I | |
| Polyethylene Tubing & Catheters 1,2, 3 | A | mfr. Rec. | C | |
| | B | mfr. Rec. | D | |
| | C | 10 | E | |
| | D | 18 | F | |
| | E | 6 | H | |
| | | | I | |
| | | | J | |
| Lensed instruments ³ arthroscopes ⁴ | B | mfr. Rec. | C | |
| | C | 10 | E | |
| | E | 6 | | |
| Hinged Instruments | A | mfr. Rec. | | |
| | B | mfr. Rec. | | |
| | C | 10 | | |
| | E | 6 | | |

NOTE: Key on following page.

- 1 Tubing must be completely filled for disinfection.
- 2 Thermo stability should be investigated when indicated
- 3 Instruments or catheters that enter tissue or the vascular system should be sterilized.
- 4 Arthroscopes may be processed in glutaraldehyde between patients and gassed at the end of the day. Arthroscopes used on infected and/or isolated patients will be gassed after use.

Manufacturer's Recommendations will be followed in the use of disinfectants and sterilizers.

UNF BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

ATTACHMENT C

Key to Table 1

| | |
|---|---|
| A | Heat sterilization including steam or hot air (see manufacturer's recommendations.) |
| B | Ethylene oxide gas (for time, see manufacturer's recommendations) |
| C | Glutaraldehyde (2%) |
| D | Formaldehyde (8%) – alcohol (70%) solution (corrosion inhibitor*needed if formulated in hospital |
| E | 6% stabilized hydrogen peroxide (will corrode copper, zinc and brass). |
| F | Wet pasteurization at 75 degrees C for 30 minutes after detergent cleaning. |
| G | Sodium hypochlorite (1000 ppm available chlorine) (will corrode metal instruments) |
| H | Phenolic solutions (3% aqueous solution of concentrate) |
| I | Iodophor. Use only a product approved for disinfection by the EPA, and follow the product label for use dilution. |
| J | Ethyl or isopropyl alcohol (70% - 90%) |
| K | Ethyl alcohol (70% - 90%) |
| L | Sodium hypochlorite (100 ppm available chlorine) |
| M | Phenolic germicidal detergent solution |
| N | Iodophor germicidal detergent |
| P | Quaternary ammonium germicidal detergent solution |

- a. The longer the exposure to a disinfectant, the more likely it is that all bacteria will be eliminated. Ten minutes exposure may not be adequate to disinfect many objects, especially those that are difficult to clean because they have narrow channels or other areas that can harbor organic material or bacteria.

UNIVERSITY OF NORTH FLORIDA
BIOLOGICAL WASTE DISPOSAL POLICY

All biohazardous waste must be inactivated prior to disposal. The preferred method is steam sterilization (autoclaving) although chemical inactivation or incineration may be appropriate in some cases. Liquid waste that has been chemically inactivated may be poured down the drain for discharge into the sanitary sewer.

CATEGORIES**1. Biohazardous Waste**

Any liquid or solid waste contaminated with:

- a. human or animal pathogens that are considered BSK-2 or above
- b. plant pathogens if regulated by APHIS or DPI
- c. all recombinant nucleic acid materials

In addition, Florida Statute 10D-104 requires the following items to be treated as biohazards:

- a. all human disease causing agents
- b. human and non-human primate blood, blood products or other human body fluids
- c. human and non-human primate tissue and body parts
- d. any medical device (tubing, etc.) contaminated with a, b, or c, which represents a significant risk of infection.

2. Non-Infectious Clinical Waste

This category of waste refers to waste that has been generated in a clinical health care setting and which is not contaminated with biohazardous or infectious human disease causing agents.

Clinical waste includes non-infectious waste from Student Health Services.

This material need not be inactivated prior to disposal. It must be disposed of in red or orange colored biohazard bags, biohazard boxes or sharp disposal containers that are clearly marked as biohazard.

Final disposition of these bags and boxes shall be in the appropriate biomedical waste receptacle.

3. Sharps

Sharp objects (needles, scalpels, razor blades and pipettes) shall be placed in puncture-proof containers with the appropriate color-coding biohazard labeling. Sharps that are contaminated must be inactivated prior to disposal.

Transport

The transport of biohazardous waste outside of the laboratory (i.e. to an autoclave or incinerator) must be in closed, leak proof containers that are labeled as biohazards. Labeling may be accomplished by use of red or orange biohazard bags or by affixing the universal biohazard symbol.

Storage

Storage of non-inactivated biohazardous waste is restricted to within the generating laboratory. It may not be store for longer than 24 hours prior to inactivation.

Landfill Policy

Local landfills will not accept any biological waste. This material should be carried to the appropriate biomedical waste collection site for disposal. It shall not be disposed of in the regular trash.

Biohazard Bags

All biohazard bags used for waste disposal must meet impact resistance (165 grams) and tearing resistance (480 grams) requirements. Written documents (bag quality test report) from the manufacturer must be kept on file.

Please note that it is the responsibility of the supervisor, department head or chairperson to ensure compliance with this policy.

UNIVERSITY OF NORTH FLORIDA
BLOODBORNE PATHOGEN PROGRAM
REQUIREMENTS FOR
HIV AND HBV RESEARCH LABORATORIES
AND PRODUCTION FACILITIES

This section applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation and manipulation of HIV and HBV. It does NOT apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissue or organs. The requirements listed here apply in addition to other requirements of the Blood borne Pathogen Program Exposure Control Plan.

Research laboratories and production facilities shall meet the following criteria:

1. Standard microbiological practices are used. All infectious waste will be inactivated prior to disposal.
2. Special practices include:
 - a. Laboratory doors will be kept closed when work involving HIV or HBV is in progress.
 - b. Contaminated materials that are to be transported are carried in a durable leak-proof, labeled or color coded container that is closed prior to being removed from the work area.
 - c. Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any special requirements and who comply with all entry and exit procedures will be allowed in the work area.
 - d. Biohazard signs (see Exposure Control Plan for description) shall be posted on all access doors when work involving OPIM or infected animals is in progress.
 - e. All activities involving OPIM shall be conducted in biological safety cabinets or other physical containment devices within the containment module. No work with OPIM shall be conducted on the open bench.
 - f. Laboratory coats, gowns, smocks, uniforms or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.
 - g. Special care shall be taken to avoid skin contact with OPIM. Gloves shall be worn

when handling infected animals and OPIM.

- h. All waste from work areas will be inactivated prior to disposal.
 - i. Vacuum lines shall be protected with liquid disinfectant traps and HEPA filters that are routinely maintained and replaced as necessary.
 - j. Hypodermic needles and syringes shall be used only for parental injection and aspirations of fluids from laboratory animals and diaphragm bottles. Extreme caution shall be used when handling needles and syringes. Needles should not be bent, sheared or recapped. Needles shall be placed in an appropriate sharps container and inactivated (by steam sterilization or chemically) prior to disposal.
 - k. All spills shall be immediately contained and cleaned up by the appropriate professional staff or personnel trained to work with OPIM.
 - l. A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or supervisor.
 - m. A Biosafety Manual shall be prepared and updated at least annually. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures and shall be required to follow them.
2. Containment Equipment
- a. Certified Biological Safety Cabinets (BSC) or other appropriate combinations of PPE and physical containment devices shall be used with all activities involving OPIM that pose a threat of exposure to droplets, aerosols, or spills.
 - b. BSC shall be certified when installed, whenever moved and at least annually.

HIV and HBV research laboratories shall meet the following criteria:

- 1. Each laboratory shall contain a facility for hand washing and an eye wash facility.
- 2. An autoclave shall be available for decontamination of waste and other materials in proximity to the lab area.

HIV and HBV production facilities shall meet the following criteria:

- 1. The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be a basic requirement for entry into

the work area from access corridors or other contiguous areas. Physical separation of the high containment work area from access corridors or to other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock or other access facility that requires passing through two sets of doors before entering the work area.

2. The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these areas shall be sealed or capable of being sealed to facilitate decontamination
3. Each work area shall contain a sink for washing hands and an eye wash facility. The sink shall be foot, elbow or automatically operated and located near the exit door.
4. access doors to the work area or containment module shall be self-closing.
5. an autoclave for decontamination of regulated waste or other materials shall be located within or very near the work area.
6. a ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

Training requirements for HIV and HBV research laboratories and production facilities:

The following additional training requirements are required for employees in HIV and HBV research laboratories and production facilities:

1. The employer shall ensure that the employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility prior to being allowed to work with HIV or HBV.
2. the employer shall ensure that employees have prior experience in the handling of human pathogens or tissue cultures prior to working with HIV or HBV.
3. the employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall ensure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.