

# BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

FOR UMDNJ-RWJMS  
RESEARCH LABORATORIES

CAMDEN CAMPUS

Adapted from the Employer Guide and Model Exposure  
Control Plan, Bloodborne Pathogens Standard 29 CFR Part 1910.1030  
by the New Jersey Department of Health Public Employees  
Occupational Safety and Health Program

Environmental & Occupational  
Health & Safety Services (EOHSS)

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## **Introduction**

Human Immunodeficiency Virus (HIV) which causes Acquired Immune Deficiency Syndrome (AIDS), Hepatitis C, and Hepatitis B warrant serious concern for personnel occupationally exposed to blood and certain other body fluids that could be contaminated with bloodborne pathogens. It is estimated nationally that more than 5.6 million in health care and public safety occupations are potentially exposed. In recognition of these potential hazards, the New Jersey Public Employees Occupational Safety and Health Act has adopted the Occupational Safety and Health Administration (OSHA) regulation [Bloodborne Pathogens 29 Code of Federal Regulations (CFR) 1910.1030] to help protect New Jersey public workers from these health hazards.

The major intent of this regulation is to prevent the transmission of bloodborne diseases within potentially exposed workplace occupations. The standard is expected to reduce and prevent employee exposure to the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and other bloodborne diseases. The Occupational Safety and Health Administration (OSHA) estimates the standard could prevent more than 200 deaths and about 9,000 infections per year from HBV alone. The standard requires that employers follow universal precautions, which means that all blood or other potentially infectious materials must be treated as being infectious for HIV and HBV. Each employer must determine the application of universal precautions by performing an employee exposure evaluation. If employee exposure is recognized, as defined by the standard, then the standard mandates a number of requirements. One of the major requirements is the development of an Exposure Control Plan (ECP), which mandates engineering controls, work practices, personal protective equipment, HBV vaccinations and training. The standard also mandates practices and procedures for housekeeping, medical evaluations, hazard communication, and recordkeeping.

### **Using this Exposure Control Plan**

Through out this document you will find blank spaces where laboratory-specific information must be provided. Until this information is provided and all laboratory personnel are familiar with the specifics, the Plan can not in either a legal or practical sense serve as a sufficiently detailed infection control guide. It is strongly recommended that once the Plan is “completed”, the Principal Investigator conduct a brief laboratory specific review of the Plan. This should be feasible over the course of a lunch break.

If your laboratory is already working under a safety plan that includes the same information as this Plan, simply attach this document to it and continue to use your existing safety plan. Alternatively, you can amend your current plan by adding the completed “filled-in blanks” to your existing plan. A laboratory’s final Exposure Control Plan version must, at a minimum, cover the same details as this Plan.

## Policy

In accordance with the UMDNJ Bloodborne Pathogens Policy (00-01-45-50:00) [http://www.umdnj.edu/oppmweb/Policies/HTML/HealthSafety/00-01-45-50\\_00.html](http://www.umdnj.edu/oppmweb/Policies/HTML/HealthSafety/00-01-45-50_00.html), UMDNJ laboratories are committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following Exposure Control Plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with the OSHA Bloodborne Pathogens Standard, Title 29 Code of Federal Regulations 1910.1030. The Exposure Control Plan is a key document to assist clinics, laboratories and departments in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- I. Employee exposure determination
- II. Procedures for evaluating the circumstances surrounding an exposure incident, and
- III. Schedule and method for implementing the specific sections of the standard, including:
  - C Methods of compliance
  - C Hepatitis B vaccination and post-exposure follow-up
  - C Training and communication of hazards to employees
  - C Recordkeeping

## Program Administration

Either the names or job titles of the individuals responsible for each of the areas listed below should be inserted in the spaces. If practical, the responsibilities for the complete program may also be held by one individual.

- C (PI and/or designee - name[s]) \_\_\_\_\_ is (are) responsible for the implementation and completion (providing information in the blank spaces) of the ECP. (He/she/they) \_\_\_\_\_ will maintain and update the written ECP at least annually and whenever necessary to include new or modified tasks and procedures.
- C Employees covered by the Bloodborne Pathogens Standard will receive an explanation of this ECP during their initial training session. It will also be reviewed during annual refresher training. A copy of the Plan will be kept in the laboratory in the same binder as the Laboratory Safety Plan.
- C Those employees who are reasonably anticipated to have contact with or exposure to blood or other potentially infected materials listed on page 4 are required to comply with the procedures and work practices outlined in this ECP.
- C (PI and/or designee) \_\_\_\_\_ will be responsible for completing the “Employee Exposure Determination” (page 5) and the “Cleaning Schedule (page 18), ensuring that effective disinfectants are used.
- C **The Dean of Research, or the Department Chairman** for each clinical department will be responsible for ensuring that all medical actions required are performed and that appropriate medical records are maintained.
- C The Principal Investigator in conjunction with Environmental and Occupational Health and Safety Services (EOHSS) will be responsible for training, documentation of training, and making the written ECP available to employees, and PEOSH representatives.
- C The Principal Investigator/Environmental Services will maintain and provide adequate supplies of all necessary personal protective equipment, engineering controls (i.e., sharps containers, etc.), labels, and red bags as required by the standard.

## Materials which are Covered under this Plan

Bloodborne Pathogens are defined as pathogenic micro-organisms that are present in human blood and can infect and cause disease in humans. These pathogens include, but are not limited to, Hepatitis B virus (HBV), and Human Immunodeficiency Virus (HIV).

The following materials have been implicated in the occupational transmission of bloodborne pathogens and are covered under this Plan.

- a. Any unfixed tissue or organ (other than intact skin) from a human (living or dead);
- b. HIV-containing cells or tissue cultures, organ cultures, and HIV or HBV-containing cultures medium or other solutions; and
- c. Blood, organs, or other tissue from experimental animals infected with HIV or HBV.
- d. Other Potentially Infectious Materials (OPIM), including the following human body fluids:
  1. semen
  2. vaginal secretions
  3. cerebrospinal fluid
  4. synovial fluid
  5. pleural fluid
  6. pericardial fluid
  7. peritoneal fluid
  8. amniotic fluid
  9. saliva in dental procedures
  10. any body fluid visibly contaminated with blood
  11. all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- e. Human Cell Lines: Biosafety Level and Bloodborne Pathogen Program applicability

Human cell lines and human cell strains from primary explants are handled at Biosafety Level 2 (BSL2). Human cell lines obtained from commercial sources, even when they have been screened for bloodborne pathogens may become contaminated with adventitious agents while they are in use in the laboratory. Cell lines obtained from non-commercial sources (colleagues passing along an interesting clinical specimen) undergo even less screening. Therefore, all cell cultures should be handled at BSL2 and contaminated materials must be autoclaved before disposal in Regulated Medical Waste containers. Conducting operations at BSL 2 will also reduce the chances of the culture contamination. A checklist of BSL2 facility and work practice requirements is available at: <http://www2.umdnj.edu/eohssweb/publications/BL2.htm>

Laboratories using primary explants and human cell strains (non-transformed cells) and cell lines propagated from primary explants must also comply with the provisions of the Bloodborne Pathogens standard unless the strains have been characterized\* to be free of bloodborne pathogens.

## **Materials Excluded From the Bloodborne Pathogen Program**

Established human cell lines which are characterized\* to be free of contamination are not covered by the Bloodborne Pathogen Standard as long as documentation that such cell lines do not contain bloodborne pathogens is available and is kept in the laboratory.

For example, in order to handle human HeLa cells, without having to comply with the requirements of the bloodborne pathogens standard (BPS), human HeLa cells should be documented to be pure HeLa cells and shown to be free of bloodborne pathogens by testing.

\*Characterization of human cell lines for inclusion or exclusion from compliance with the BPS, would include screening of the cells lines or "strains" for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses or EBV, if the cells are capable of propagating such viruses. Most cell lines are screened for human mycoplasmas and are free of bacterial and mycotic contaminants. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology (polymerase chain reaction or nucleic acid hybridization) to identify latent viruses capable of infecting humans such as Herpes viruses(e.g., EBV), or papilloma members of the Papovavirus group, etc. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the bloodborne pathogen program.

Source: OSHA Clarification Letter

[http://www.osha-slc.gov/OshDoc/Interp\\_data/I19940621.html](http://www.osha-slc.gov/OshDoc/Interp_data/I19940621.html)

ATCC information on their testing of cell lines for bloodborne pathogens is available at: <http://www.atcc.org/SearchCatalogs/faqCellBiology.cfm#Q53>.

## Employee Exposure Determination

Note: You are not required to complete both sections that follow; you may complete one or both sections, depending on the applicable situation.

- A. As part of the exposure determination section of our ECP, the following is a list of all job titles in this laboratory in which all employees have occupational exposure. Refer to the “definitions” listed in Appendix B, to define “occupational exposure”.

_____	_____
_____	_____
_____	_____

- B. The following is a list of job classifications or job titles in which some employees have occupational exposure. Included are a list of tasks and procedures in which occupational exposure may occur for these individuals.

Job Classification	Tasks and Procedures
_____	_____
_____	_____
_____	_____

All exposure determinations for A and B were made without regard to the use of Personal Protective Equipment (PPE).

Note: Category B would include, for example, specific Research Teaching Specialists who handle human blood or other potentially infectious materials (even sporadically) while other RTSs handle only formalin-fixed material in another area of the laboratory. Outside Contractors or vendors (i.e., plumbing contractor, etc.) must be notified of potential contact with blood or other potentially infectious materials so they can take appropriate precautions.

Note: "Good Samaritan" acts which result in exposure to blood or other potentially infectious materials from assisting a fellow employee (i.e., assisting a co-worker with nosebleed, giving CPR or first aid) are not covered by the Bloodborne Pathogens Standard. However, Post-Exposure Evaluation and Follow-up should be provided in such cases.

## Substitution & Engineering Controls

Engineering controls remove or isolate a hazard with a minimum of worker effort. For example, sharps containers reduce the risk of accidental injury from discarded needles, slides, and other sharp objects.

Sharps are any material capable of piercing skin, including but not limited to needles, razor blades, Pasteur pipettes, and capillary tubes. Percutaneous injuries, most frequently the result of needle sticks, have caused the majority of the documented occupationally acquired HIV infections

In 2000, the OSHA BBP standard was revised to require use of safety sharps (safety sharps are engineered to protect the user from needlesticks or other sharps injuries) in the presence of blood or other potentially infectious material. This requirement is enforced by NJ PEOSH for all NJ state institutions. EOHSS has posted a factsheet on this law at: <http://www2.umdnj.edu/eohssweb/publications/safemedicaldevice.htm>. Laboratories are not exempt from this requirement.

Responsible Investigators (faculty members with assigned laboratory rooms) must decide whether there is a safety sharp alternative for each blood or OPIM procedure and, whenever possible, must switch to using only the safety sharp for that procedure. EOHSS will periodically inform Responsible Investigators of new devices as they become commercially available. The Responsible Investigator must ensure that personnel receive adequate training in the use of the new devices and must get input from users about whether the new devices make the job safer. EOHSS is available to provide guidance on these issues.

Use of sharps containers is required, even when safety sharps are utilized. They must be easily accessible to personnel and must be located at or near the immediate area where sharps are used. Sharps containers in research (not clinical) labs must be autoclaved before disposal if they were used with blood, OPIM, or BL2 or higher materials.

Another type of substitution, easily implemented, is the replacement of glass items with plastic ones, whenever possible.

Examples of engineering controls include, but are not limited to:

C	Self-sheathing needles	C	Mechanical needle recapping devices
C	Biological Safety Cabinets* (*Must be certified at least annually if used with BL2 materials)	C	Centrifuge Safety Devices (safety cups, sealed rotors)
C	Spill Trays	C	Specimen Transport Bags
C	Chemical Disinfectant Traps*	C	Vacuum Line Filters*
C	Safety Scalpels		

\* See Appendix C for “Effective Use of Biological Safety Cabinets”.

The specific engineering controls used in this laboratory are listed below (delete or add items as necessary):

- |  |                              |
|--|------------------------------|
| Biological Safety Cabinets                   | Sharps Containers            |
| Spill pans and trays                         | Autoclaves                   |
| Centrifuge Safety Devices                    | Secondary containers         |
| Specimen transports                          | Bags                         |
| Splash Guards                                | Mechanical Pipetting Devices |
| "Bench-Kote" or other work surface coverings |                              |

OTHERS (Specify):

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## Work Practice Controls

All employees will utilize Universal Precautions. Universal Precautions is an infection control method which requires employees to assume that all human blood and specified human body fluids are infectious for HIV, HBV, HCV and other bloodborne pathogens.

Other Work Practice Controls include, but are not limited to:

- C Washing hands immediately or as soon as feasible after removal of gloves.
  - C Washing body parts as soon as possible after skin contact with blood or other potentially infectious materials occurs.
  - C Prohibiting the recapping, shearing, breaking, or bending of needles.
  - C Posting labels and signs in accordance with the Standard's provisions..
  - C Equipment and work surface decontamination.
  - C Prohibiting eating, drinking, food and beverage storage, smoking, application of cosmetics, and handling contact lenses in work areas, and refrigerators or freezers where blood or other potentially infectious materials are present.
  - C Performing all procedures involving blood or other potentially infectious materials in such a manner as to minimize splashing, splattering, and generation of droplets of these substances.
  - C Placing specimens of blood or other potentially infectious materials in a container which prevents leakage during collection, handling, processing, storage, transport or shipping.
  - C Using secondary containers (sturdy containers, specimen transport bags) for the prolonged storage or transports of blood or other potentially infectious material.
  - C Ensuring that equipment which may have become contaminated with blood or other potentially infectious materials are decontaminated prior to servicing or shipping. Items not completely decontaminated will be labeled per section (g)(1)(I)(H) of the Standard.
  - C Using mechanical pipetting devices only.
  - C Adhering to established procedures for housekeeping and decontamination.
  - C Other Work Practice Controls used in this laboratory include:
- 
-

## Personal Protective Equipment

Personal Protective Equipment (PPE) must be provided at no cost to affected personnel, be easily accessible, and used whenever the potential for occupational exposure remains after engineering and work practice controls have been instituted, or if these controls are not feasible. In addition to understanding the appropriate uses of various types of PPE, it is equally important to realize that all PPE items have certain limitations that should be considered in making a selection.

Use the blank spaces on page 11 to list the PPE to be used for each task conducted in the laboratory. The type of PPE for a given task will depend on the risk entailed in a particular operation which in turn can be assessed by, for example, addressing the following questions:

What is the volume of infectious material in use?

What is titer of the material in use? (The viral titer of tissue culture supernatants may be several orders of magnitude higher than the titer in clinical specimens.)

When the identity of the infectious agent is known, what is its natural route of infection?

How hazardous is the agent, both in terms of transmissibility and severity of illness?

What are chances of accidental exposure for different types of activities? That is, will one liter flasks of liquid growth media be manipulated outside of a Biological Safety Cabinet or will the activity be streaking plates from a microfuge tube inside a Cabinet?

**Gloves** -Always inspect for holes and tears before donning. They are subject to losing their “barrier protection” quality with prolonged use or as the result of exposure to laboratory chemicals; therefore gloves must be changed frequently during prolonged operations and as soon as possible if they become torn, punctured, or contaminated with blood or other infectious material. They do not provide protection against percutaneous injury.

***Glove selection*** - There are certain occasions where a glove designed for barrier protection is not the appropriate choice. For example, gloves designed for barrier protection against infectious materials offer limited resistance to significant amounts of hazardous chemicals. In a clinical setting, it may be inappropriate to use a barrier glove or any glove at all for taking a patient’s blood pressure or pulse. EOHSS can provide assistance in glove use and selection for these occasions.

***Latex allergies*** - Until recently, latex gloves were considered the “gold standard” for the provision of barrier protection, but because of their availability and low cost, it became routine to use them for every task. A significant number of wearers have become sensitized to latex rubber proteins or the chemicals used in manufacturing the gloves. EOHSS can provide information on substitutes for latex gloves that provide the same level of barrier protection against infectious materials as latex without putting the wearer at risk for sensitization. Always use non-powdered gloves regardless of the glove material used.

**Laboratory coats** - Coats that fasten in the rear offer greater protection than front-buttoning ones. If the potential exists for large amounts of splashing, a water-proof plasticized apron should be worn over a rear-fastened laboratory coat. Laboratory coats are not to be worn outside of the laboratory if they have been used while working with bloodborne pathogens or any other pathogenic organism. Frankly contaminated laboratory coats should either be discarded as regulated medical waste or decontaminated by the wearer. Further information on the handling of contaminated PPE can be found in the “Laundry” section on page 20.

**Eye protection**-Safety glasses with side shields are the minimum level of eye protection for handling blood or other potentially infectious materials. They do not protect the eyes from large splashes.

Splash-proof goggles, by virtue of their tighter fit around the eyes, are required for activities with an elevated risk of splash exposure.

Face shields should be worn to supplement, not replace goggles in the highest splash-risk situations.

Contact lenses will inhibit the ability of any eye washing to flush infectious organisms or hazardous chemicals from the eyes. Their use in the laboratory is not recommended.

**Masks** - provide protection against droplet/splash exposure of the nose and mouth. They do not provide a barrier to organisms transmitted by inhalation (e.g., tuberculosis).

**Head and shoe covers** - These are appropriate in high exposure situations where a large degree of splashing can be anticipated.

Appropriate personal protective equipment is required for the following tasks; the specific protective equipment to be used is listed after the task:

Task	Personal Protective Equipment
_____	_____
_____	_____
_____	_____
_____	_____

First aid responders must have quick access to kits containing impervious gloves, resuscitation bags or mouthpieces, eye protection, aprons, disinfectant towelettes for hand washing, and red bags or biohazard-labeled bags.

All employees using personal protective equipment must observe the following precautions:

- C Wash hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.
- C Remove protective equipment before leaving the work area and after a garment becomes contaminated.
- C Place used protective equipment in appropriately designated areas or containers when being stored, washed, decontaminated, or discarded.
- C Wear appropriate gloves when it can be reasonably anticipated that you may have contact with blood or other potentially infectious materials and when handling or touching contaminated items or surfaces. Replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- C Double-gloving should be employed for work with high titer and/or highly infectious materials; consideration should be given to the effect of the resultant loss of dexterity.
- C Following any contact of body areas with blood or any other infectious materials, wash hands and any other exposed skin with soap and water as soon as possible. Employees must also flush exposed mucous membranes (eyes, mouth, etc.) with water.
- C Utility gloves may be decontaminated for reuse if their integrity is not compromised. Discard them if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- C Never wash or attempt to decontaminate disposable gloves for reuse.
- C Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or other potentially infectious materials pose a potential hazard to the eye, nose, or mouth.
- C If a garment(s) is contaminated by blood or other potentially infectious materials, it must be removed immediately or as soon as feasible. If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should be trained to remove the pull-over scrub in such a way as to avoid contact with the outer surface; e.g., rolling up the garment as it is pulled toward the head for removal. However, if the amount of blood exposure is such that the blood penetrates the scrub and contaminates the inner surface, not only is it impossible to remove the scrub without exposure to blood, but the penetration itself constitutes exposure. Employees shall be trained to cut such a contaminated scrub to aid removal and prevent exposure to the face.

## **Training**

All employees who have or are reasonably anticipated to have occupational exposure to bloodborne pathogens will receive training conducted by EOHSS or Department or laboratory-based trainers. (All trainers must attend a Trainer's Training which is provided by EOHSS). The training program will cover, at a minimum, the following elements:

1. An explanation of the requirements of the OSHA Bloodborne Pathogens Standard;
2. An explanation of the epidemiology, transmission, and symptoms of bloodborne diseases;
3. A review of the Exposure Control Plan;
4. An explanation of the appropriate methods that can be used to recognize and evaluate tasks and activities with potential exposure;
5. An explanation of the use and limitations of the different methods of control, including, but not limited to, engineering controls, work practices and personal protective equipment;
6. Information on the appropriate actions and procedures to follow if an exposure occurs;
7. Information on the Hepatitis B vaccine, including efficacy, safety, and that the vaccine will be free of charge to employees;
8. An explanation of the signs and labels required by the standard;
9. An opportunity for interactive questions and answers; and
10. Additional training for employees in HIV and HBV research laboratories which is specific to the practices and operations of the laboratory.

An attendance sheet will be signed by each employee upon completion of training. This document will be kept with the employee's records at EOHSS. Departmental- or laboratory-based trainers are responsible for the forwarding of attendance sheets to EOHSS.

## Hepatitis B Vaccination

Hepatitis B vaccines currently in use (as opposed to the first ones licensed) contain no human source material. The immunization series involves three intramuscular injections with the second injection given one month after the first and the third one administered five months after the second. The vaccine is effective > 95% of the time when all three doses are given and immunity is thought to last at least fifteen years after documented proof of immunity. It may be contraindicated for those with allergies to yeast (the immunogenic antigen is cultivated in cells of *S. cerevesiae*); pregnant women should consult their physician before receiving the vaccine, as should those who are immunocompromised.

The hepatitis B vaccination series must be made available at no cost within 10 days of initial assignment to employees who have occupational exposure to blood or other potentially infectious materials, unless:

- C the employee demonstrates immunity (due to previous infection or immunization); or
- C medical reasons prevent taking the vaccination

Volunteers with potential exposure must also have documentation of immunity or must obtain the vaccine series.

Each PI must make arrangements with his/her department for employees to get the hepatitis B vaccines and/or antibody testing.

Hepatitis B vaccines (and antibody testing) are currently being given to Camden campus employees at the RWJMS Employee Health Services (732-445-0123 x2), to Cooper employees at Cooper Occupational Health Services 856-342-2990, or for students, through Cooper Department of Medicine (342-2990).

\*Student vaccinations are provided through Cooper Department of Medicine; they should be consulted for their policy on the provision and cost of HBV vaccinations.

As required by the University Policy on HIV, HBV and HCV 00-01-45-52:00 at [http://www.umdnj.edu/oppmweb/Policies/HTML/HealthSafety/00-01-45-52\\_00.html](http://www.umdnj.edu/oppmweb/Policies/HTML/HealthSafety/00-01-45-52_00.html) , all house staff, faculty and staff who have direct patient contact, (as defined in the University Policy on HIV, HBV and HCV), or who have contact with potentially infectious body fluids or laboratory materials must be immunized against hepatitis B or be able to demonstrate immunity. Hepatitis B vaccination booster doses must be made available if recommended by the United States Public Health Service.

## Post Exposure Evaluation

The UMDNJ University Policy, Appendix E, "Chemoprophylaxis After Potential Occupational/Educational HIV Exposure" (00-01-40-40:10) addresses post exposure evaluation and follow-up procedures. It was recently revised (9/24/96) to incorporate the CDC's recommended addition of protease inhibitors to the anti-HIV regimen to attempt to prevent HIV infection in the event of exposure. Treatment with chemoprophylactic drugs is voluntary.

Should an exposure incident occur, decontamination should immediately be performed at the nearest sink, eyewash, or safety shower. Exposed individuals should then notify their supervisor or Principal Investigator and medical personnel as follows:

UMDNJ Employees: Report directly to the Cooper Emergency Department who will provide treatment and medications as necessary, or refer the employee to Cooper Occupational Health Services (depending upon the time of occurrence).

Cooper Employees  
and Medical Residents: Report directly to Cooper Occupational Health Services (phone 856-342-2990 (Monday - Friday, 8:00 am - 4:30 pm) or to Cooper Emergency department after-hours. Regardless of the location of initial treatment, all follow-up care will occur at Cooper Occupational Health Services.

UMDNJ-RWJMS  
Students Report directly to the Cooper Emergency Room and follow-up by contacting Cooper Department of Medicine.

Note: Based on the current CDC recommendations, if chemoprophylaxis is indicated it should be initiated within 1 to 2 hours post exposure. Therefore, medical attention should be obtained as quickly as possible.

For exposures of UMDNJ students or personnel, UMDNJ Risk and Claims should then be notified of the incident as soon as possible by calling (973) 972-6277. Once notified, they will provide the exposed individual with specific follow-up instructions. Each exposure must also be documented on a UMDNJ Incident Report form.

If indicated, testing on a voluntary basis, for anti-HIV and anti-HCV antibodies will be conducted at: baseline, six weeks, 12 weeks, six months, and twelve months. HBV antibody testing, or vaccine, booster, or immunoglobulin will be administered as appropriate.

**The Principal Investigator, Department Chair and EOHSS** will review the circumstances of the exposure incident to determine if procedures, protocols and/or training need to be revised to prevent a reoccurrence of the incident.

## **SUMMARY: POST EXPOSURE EVALUATION**

- C Documentation of exposure routes and how exposure incident occurred;
- C Identification and documentation of source individual's infectivity, if possible;
- C Collection and testing of employee's blood for HBV and HIV serological status (employee's consent required);
- C Post-exposure prophylaxis when medically indicated;
- C Counseling; and
- C Evaluation of reported illnesses.

## **Healthcare Professionals**

Healthcare professionals responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up must have a copy of the OSHA Bloodborne Pathogens Standard which is available at: <http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html>.

The Principal Investigator or designee in conjunction with the exposed person will also ensure that the health care professional evaluating an employee after an exposure incident receives the following:

- C description of the employee's job duties relevant to the exposure incident;
- C route(s) and circumstances of exposure;
- C if possible, results of the source individual's blood test; and
- C relevant employee medical records, including vaccination status.

### **Healthcare Professional's Written Opinion**

The Principal Investigator or supervisor shall ensure that the affected person is provided with a copy of the evaluating healthcare professional's written opinion within 15 days after completion of the evaluation.

For hepatitis B vaccinations, the healthcare professional's written opinion will be limited to whether the employee requires or has received the hepatitis B vaccination.

The written opinion for post-exposure evaluation and follow-up will be limited to whether or not the employee has been informed of the results of the medical evaluation and any medical conditions which may require further evaluation and treatment.

All other diagnoses must remain confidential and not be included in the written report to the employee's PI/supervisor.

## Housekeeping/Cleaning/Disinfection

The Principal Investigator's designee and the laboratory staff are required by the Standard to develop and implement a written schedule for cleaning and decontaminating work surfaces. A pre-existing Cleaning Schedule can be substituted for this one provided that it includes the same details, regardless of the format.

### CLEANING SCHEDULE

Area (Bench top, centri- fuge, safety cabinet)	Scheduled Cleaning Times*	Cleaners & Disinfectants Used	Specific Instructions
	completion of procedures after overt contamination end of work shift, if needed AND:		
	completion of procedures after overt contamination end of work shift, if needed AND:		
	completion of procedures after overt contamination end of work shift, if needed AND:		
	completion of procedures after overt contamination end of work shift, if needed AND:		

Note: A list of approved sterilants and disinfectants\* can be obtained from the Environmental Protection Agency (EPA) website at: <http://www.epa.gov/oppad001/chemregindex.htm>.

\* Approved refers to a manufacturer's right to use terms such as "disinfectant", "tuberculocidal", "sporicidal", etc. on the product label. It is based on demonstrated anti-microbial activity in specified testing protocols. In addition, a 10% solution of household bleach, prepared fresh weekly, will provide effective decontamination for routine housekeeping and routine spill response.

Decontaminate work surfaces with an appropriate disinfectant after completion of procedures, immediately when overtly contaminated, after any spill of blood or other potentially infectious materials, and at the end of the work shift when surfaces have become contaminated since the last cleaning.

Remove and replace protective coverings such as plastic wrap and aluminum foil when contaminated.

Inspect and decontaminate, on a regular basis, reusable receptacles such as bins, pails, and cans that have a likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as feasible.

Always use mechanical means such as tongs, forceps, or a brush and a dust pan to pick up contaminated broken glassware; never pick up with hands even if gloves are worn.

Store or process reusable sharps in a way that ensures safe handling.

Place regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that are constructed to prevent leakage.

When discarding contaminated sharps, place them in containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leak-proof on the sides and bottom.

Ensure that sharps containers are easily accessible to personnel and located as close as feasible to the immediate area where sharps are used or can be reasonably anticipated to be found. Sharps containers also must be kept upright throughout use, replaced routinely, closed when moved, and not allowed to overfill.

Never manually open, empty, or clean reusable contaminated sharps disposal containers.

Discard all regulated waste according to Appendix I of the 2003 Laboratory Safety Plan.

## Laundry

The following contaminated articles will be laundered:

- C \_\_\_\_\_
- C \_\_\_\_\_
- C \_\_\_\_\_

**Note:** Employers responsible for the cost of providing, cleaning, laundering, and disposal of any personal protective equipment required to protect employees from bloodborne pathogens. Employees must not take home items for laundering.

Laboratory coats and other reusable PPE that are grossly contaminated with Bloodborne Pathogens or other infectious materials must be autoclaved or otherwise decontaminated by laboratory personnel knowledgeable of the hazard before being sent to be laundered.

Otherwise, all generators of laundry must have determined if the receiving facility uses universal precautions. If Universal Precautions are not used, then clearly mark laundry sent off-site with orange biohazard labels or use red bags.

**Note:** Disposable protective clothing can be used to eliminate or greatly reduce the need for laundering.

## Labels and Signs

### *Labels*

Warning labels must be affixed to the following items:

- |   |  |   |  |
|---|--|---|--|
| C | containers of regulated waste  | C | other containers used to store, transport, or ship blood or other potentially infectious materials |
| C | sharps disposal containers   |   |  |
| C | refrigerators and freezers containing blood and other potentially infectious materials | C | contaminated equipment awaiting repair (note the area contaminated)                                |
|   |  | C | laundry bags and containers  |

The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word "BIOHAZARD" in a contrasting color, and be attached to each object by string, wire, adhesive, or other method to prevent loss or unintentional removal of the label.

These labels are not required when:

- C red bags or red containers are used
- C individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, shipment or disposal
- C containers of blood, blood components, or blood products are labeled with their contents and have been released for transfusion or other clinical use

### *Signs*

All laboratories covered by the Bloodborne Pathogens Standard and those working at Biological Safety Level-2 or higher must display a sign at the entrance to the work area incorporating the features required for "Labels" as well as:

- C the biohazard symbol
- C special requirements for entering the area
- C the name and phone number of the Principal investigator or other responsible person.

## **Recordkeeping**

### **Medical Records**

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.20.

RWJMS Employee Health Services (EHS), Cooper Occupational Health Services, and the Cooper Department of Medicine are responsible for maintenance of the required records. EHS is located in the EOHSI Clinic, Frelinghuysen Avenue, Piscataway Campus; and Cooper Occupational Health Services and Department of Medicine are located within Cooper Medical Center, Camden, NJ.

In addition to the requirements of 29 CFR 1910.20, the medical record will include:

- C The name and social security number of employee;
- C A copy of the employee's hepatitis B vaccinations and any medical record relative to the employee's ability to receive vaccination;
- C A copy of all results of examinations, medical testing, and follow-up procedures as required by the standard;
- C A copy of all healthcare professional's written opinion(s) as required by the standard

The UMDNJ-SOM Department of Family Medicine located in the Primary Care Center, Suite 219, will be the custodian of hepatitis B immunization records for laboratory personnel vaccinated by Family Medicine. Such records will include hepatitis B vaccination status and any other medical record relative to the employee's ability to receive vaccination.

All employee medical records will be kept confidential and will not be disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by the standard or as may be required by law.

Employee medical records shall be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

Employee medical record shall be provided upon request of the employee or to anyone having written consent of the employee within 15 working days.

### **Training Records**

Bloodborne pathogen training records will be maintained by EOHSS. The training record shall include the dates of the training sessions; contents or a summary of the sessions; names and qualifications of persons conducting the training; and names and job titles of all persons attending the training sessions. Training records will be maintained for a minimum of three (3) years from the date on which the training occurred.

Employee training records will be provided upon request to the employee or the employee's authorized representative within 15 working days.

### **Transfer of Records**

If \_\_\_\_\_ (insert name of your department) is ever dismantled and there is no successive department which will receive and retain the records for the prescribed period, the school or unit will be responsible for ensuring that the records are maintained as required by the standard. The Dean's Office will be responsible for the maintenance or assignment of the records in this situation.

**APPENDIX A OF THE BBP PLAN**  
**OSHA Bloodborne Pathogens Standard: 29 CFR Part 1910.1030**

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1910.1030(a)

Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

1910.1030(b)

Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

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

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means 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.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

- (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;
- (2) The administration of medication or fluids; or
- (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means (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); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means 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.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means 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 clinic 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 means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means 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).

1910.1030(c)

Exposure Control --

1910.1030(c)(1)

Exposure Control Plan.

1910.1030(c)(1)(i)

Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

1910.1030(c)(1)(ii)

The Exposure Control Plan shall contain at least the following elements:

1910.1030(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2),

..1910.1030(c)(1)(ii)(B)

1910.1030(c)(1)(ii)(B)

The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

1910.1030(c)(1)(ii)(C)

The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

1910.1030(c)(1)(iii)

Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

1910.1030(c)(1)(iv)

The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)

Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)

An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)

The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

1910.1030(c)(2)

Exposure Determination.

1910.1030(c)(2)(i)

Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1910.1030(c)(2)(i)(A)

A list of all job classifications in which all employees in those job classifications have occupational exposure;

..1910.1030(c)(2)(i)(B)

1910.1030(c)(2)(i)(B)

A list of job classifications in which some employees have occupational exposure, and

1910.1030(c)(2)(i)(C)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

1910.1030(c)(2)(ii)

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

1910.1030(d)

Methods of Compliance --

1910.1030(d)(1)

General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

1910.1030(d)(2)

Engineering and Work Practice Controls.

1910.1030(d)(2)(i)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

..1910.1030(d)(2)(ii)

1910.1030(d)(2)(ii)

Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

1910.1030(d)(2)(iii)

Employers shall provide handwashing facilities which are readily accessible to employees.

1910.1030(d)(2)(iv)

When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

1910.1030(d)(2)(v)

Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

1910.1030(d)(2)(vi)

Employers shall ensure that employees wash 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 other potentially infectious materials.

1910.1030(d)(2)(vii)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

..1910.1030(d)(2)(vii)(A)

1910.1030(d)(2)(vii)(A)

Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

1910.1030(d)(2)(vii)(B)

Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

1910.1030(d)(2)(viii)

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

1910.1030(d)(2)(viii)(A)

Puncture resistant;

1910.1030(d)(2)(viii)(B)

Labeled or color-coded in accordance with this standard;

1910.1030(d)(2)(viii)(C)

Leakproof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)

In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

1910.1030(d)(2)(ix)

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.

1910.1030(d)(2)(x)

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

..1910.1030(d)(2)(xi)

1910.1030(d)(2)(xi)

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

1910.1030(d)(2)(xii)

Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

1910.1030(d)(2)(xiii)

Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

1910.1030(d)(2)(xiii)(A)

The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

1910.1030(d)(2)(xiii)(B)

If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

..1910.1030(d)(2)(xiii)(C)

1910.1030(d)(2)(xiii)(C)

If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

1910.1030(d)(2)(xiv)

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)

A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)

The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

1910.1030(d)(3)

Personal Protective Equipment --

1910.1030(d)(3)(i)

Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective

equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)

Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

1910.1030(d)(3)(iii)

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, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)

Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

..1910.1030(d)(3)(v)

1910.1030(d)(3)(v)

Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)

If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)

When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

1910.1030(d)(3)(ix)

Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items

or surfaces.

1910.1030(d)(3)(ix)(A)

Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

..1910.1030(d)(3)(ix)(B)

1910.1030(d)(3)(ix)(B)

Disposable (single use) gloves shall not be washed or decontaminated for re-use.

1910.1030(d)(3)(ix)(C)

Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(D)

If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

1910.1030(d)(3)(ix)(D)(1)

Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)

Make gloves available to all employees who wish to use them for phlebotomy;

1910.1030(d)(3)(ix)(D)(3)

Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)

Require that gloves be used for phlebotomy in the following circumstances:

1910.1030(d)(3)(ix)(D)(4)(i)

When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)

When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)

When the employee is receiving training in phlebotomy.

..1910.1030(d)(3)(x)

1910.1030(d)(3)(x)

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 other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

1910.1030(d)(3)(xi)

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 occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)

Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

1910.1030(d)(4)

Housekeeping --

1910.1030(d)(4)(i)

General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

1910.1030(d)(4)(ii)

All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

..1910.1030(d)(4)(ii)(A)

1910.1030(d)(4)(ii)(A)

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

1910.1030(d)(4)(ii)(B)

Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

1910.1030(d)(4)(ii)(C)

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

1910.1030(d)(4)(ii)(D)

Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)

Reusable sharps that are contaminated with blood or other potentially infectious materials 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.

1910.1030(d)(4)(iii)

Regulated Waste --

..1910.1030(d)(4)(iii)(A)

1910.1030(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

1910.1030(d)(4)(iii)(A)(1)(i)

Closable;

1910.1030(d)(4)(iii)(A)(1)(ii)

Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and

1910.1030(d)(4)(iii)(A)(1)(iv)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:

1910.1030(d)(4)(iii)(A)(2)(i)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can

be reasonably anticipated to be found (e.g., laundries);

1910.1030(d)(4)(iii)(A)(2)(ii)

Maintained upright throughout use; and

1910.1030(d)(4)(iii)(A)(2)(iii)

Replaced routinely and not be allowed to overfill.

1910.1030(d)(4)(iii)(A)(3)

When moving containers of contaminated sharps from the area of use, the containers shall be:

1910.1030(d)(4)(iii)(A)(3)(i)

Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

1910.1030(d)(4)(iii)(A)(3)(ii)

Placed in a secondary container if leakage is possible. The second container shall be:

1910.1030(d)(4)(iii)(A)(3)(ii)(A)

Closable;

1910.1030(d)(4)(iii)(A)(3)(ii)(B)

Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

1910.1030(d)(4)(iii)(A)(3)(ii)(C)

Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(4)

Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

1910.1030(d)(4)(iii)(B)

Other Regulated Waste Containment --

1910.1030(d)(4)(iii)(B)(1)

Regulated waste shall be placed in containers which are:

1910.1030(d)(4)(iii)(B)(1)(i)

Closable;

1910.1030(d)(4)(iii)(B)(1)(ii)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(1)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

1910.1030(d)(4)(iii)(B)(1)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(B)(2)

If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

1910.1030(d)(4)(iii)(B)(2)(i)

Closable;

1910.1030(d)(4)(iii)(B)(2)(ii)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(2)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

1910.1030(d)(4)(iii)(B)(2)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

..1910.1030(d)(4)(iv)

1910.1030(d)(4)(iv)

Laundry.

1910.1030(d)(4)(iv)(A)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

1910.1030(d)(4)(iv)(A)(3)

Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

1910.1030(d)(4)(iv)(B)

The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

..1910.1030(d)(4)(iv)(C)

1910.1030(d)(4)(iv)(C)

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

1910.1030(e)

HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)

This paragraph 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, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)

Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)

Special Practices.

1910.1030(e)(2)(ii)(A)

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

..1910.1030(e)(2)(ii)(B)

1910.1030(e)(2)(ii)(B)

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(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 specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

1910.1030(e)(2)(ii)(D)

When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

1910.1030(e)(2)(ii)(E)

All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

1910.1030(e)(2)(ii)(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.

..1910.1030(e)(2)(ii)(G)

1910.1030(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)

Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath

or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

..1910.1030(e)(2)(ii)(L)

1910.1030(e)(2)(ii)(L)

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

1910.1030(e)(2)(ii)(M)

A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)

Containment Equipment.

1910.1030(e)(2)(iii)(A)

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

..1910.1030(e)(3)(i)

1910.1030(e)(3)(i)

Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

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 the 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 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.

1910.1030(e)(4)(ii)

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 surfaces shall be sealed or capable of being sealed to facilitate decontamination.

..1910.1030(e)(4)(iii)

1910.1030(e)(4)(iii)

Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)

An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)

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).

1910.1030(e)(5)

Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

1910.1030(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

..1910.1030(f)(1)

1910.1030(f)(1)

General.

1910.1030(f)(1)(i)

The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

1910.1030(f)(1)(ii)

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)

Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)

Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii)

The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

..1910.1030(f)(2)

1910.1030(f)(2)

Hepatitis B Vaccination.

1910.1030(f)(2)(i)

Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure 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.

1910.1030(f)(2)(ii)

The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

1910.1030(f)(2)(v)

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 in accordance with section (f)(1)(ii).

1910.1030(f)(3)

Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)

Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

..1910.1030(f)(3)(ii)

1910.1030(f)(3)(ii)

Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

..1910.1030(f)(3)(iii)(B)

1910.1030(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)

Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)

Documentation of the route(s) of exposure and circumstances under which exposure occurred;

..1910.1030(f)(4)(ii)(D)

1910.1030(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)

The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)

That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

..1910.1030(f)(5)(iii)

1910.1030(f)(5)(iii)

All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6)

Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)

Communication of Hazards to Employees --

1910.1030(g)(1)

Labels and Signs --

1910.1030(g)(1)(i)

Labels.

1910.1030(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:

1910.1030(g)(1)(i)(C)

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(1)(i)(D)

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

..1910.1030(g)(1)(i)(E)

1910.1030(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)

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 the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)

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

1910.1030(g)(1)(i)(H)

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

1910.1030(g)(1)(i)(I)

Regulated waste that has been decontaminated need not be labeled or color-coded.

1910.1030(g)(1)(ii)

Signs.

1910.1030(g)(1)(ii)(A)

The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

(Name of the Infectious Agent)  
(Special requirements for entering the area)  
(Name, telephone number of the laboratory director or other responsible person.)

..1910.1030(g)(1)(ii)(B)

1910.1030(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)

Information and Training.

1910.1030(g)(2)(i)

Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)

At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)

Within 90 days after the effective date of the standard; and

1910.1030(g)(2)(ii)(C)

At least annually thereafter.

1910.1030(g)(2)(iii)

For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

1910.1030(g)(2)(iv)

Annual training for all employees shall be provided within one year of their previous training.

..1910.1030(g)(2)(v)

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)

The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)

An accessible copy of the regulatory text of this standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

..1910.1030(g)(2)(vii)(F)

1910.1030(g)(2)(vii)(F)

An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

1910.1030(g)(2)(vii)(G)

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)

Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)

Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

1910.1030(g)(2)(vii)(K)

An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

1910.1030(g)(2)(vii)(L)

Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

..1910.1030(g)(2)(vii)(M)

1910.1030(g)(2)(vii)(M)

An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

1910.1030(g)(2)(vii)(N)

An opportunity for interactive questions and answers with the person conducting the training session.

1910.1030(g)(2)(viii)

The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)

The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

..1910.1030(g)(2)(ix)(C)

1910.1030(g)(2)(ix)(C)

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 assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

1910.1030(h)

Recordkeeping --

1910.1030(h)(1)

Medical Records.

1910.1030(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)

This record shall include:

1910.1030(h)(1)(ii)(A)

The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)

A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)

A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

1910.1030(h)(1)(ii)(D)

The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

..1910.1030(h)(1)(ii)(E)

1910.1030(h)(1)(ii)(E)

A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

1910.1030(h)(1)(iii)

Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

1910.1030(h)(1)(iii)(A)

Kept confidential; and

1910.1030(h)(1)(iii)(B)

Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)

The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)

Training Records.

1910.1030(h)(2)(i)

Training records shall include the following information:

1910.1030(h)(2)(i)(A)

The dates of the training sessions;

1910.1030(h)(2)(i)(B)

The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

..1910.1030(h)(2)(i)(D)

1910.1030(h)(2)(i)(D)

The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)

Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)

Availability.

1910.1030(h)(3)(i)

The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

1910.1030(h)(3)(ii)

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

1910.1030(h)(3)(iii)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant

Secretary in accordance with 29 CFR 1910.1020.

..1910.1030(h)(4)

1910.1030(h)(4)

Transfer of Records.

1910.1030(h)(4)(i)

The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

1910.1030(h)(4)(ii)

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 the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

1910.1030(h)(5)

Sharps injury log.

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

1910.1030(i)

Dates --

1910.1030(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

1910.1030(i)(2)

The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)

Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

1910.1030(i)(4)

Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]

## **APPENDIX B OF THE BBP PLAN DEFINITIONS**

**Biosafety Level (BL):** One of four combinations of laboratory practices and techniques, safety equipment, and laboratory facilities recommended by the Centers for Disease Control and the National Institutes of Health in "Biosafety in Microbiological and Biomedical Laboratories", as being appropriate for minimizing the risk of infectious disease when microorganisms are worked with. BL-1 applies to agents that do not ordinarily cause human disease. BL-2 is appropriate for agents that can cause human disease, but whose potential for transmission is limited. BL-3 applies to agents that may be transmitted by the respiratory route, which can cause serious infection. BL-4 is used for the diagnosis of exotic agents that pose a high risk of life-threatening disease, which may be transmitted by the aerosol route and for which there is no vaccine or therapy..

**BMBL:** The CDC-NIH publication, "Biosafety in Microbiological and Biomedical Laboratories, 4th edition" lists the appropriate biosafety levels for numerous microorganisms, and the work practices that should be implemented

**Blood** - human blood, human blood components, and products made from human blood.

**Bloodborne Pathogens** - pathogenic micro-organisms that are present in human blood and can infect and cause disease in humans. These pathogens include, but are not limited to, Hepatitis B virus (HBV), and Human Immunodeficiency Virus (HIV).

**Contaminated** - the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

**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.

**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.

**Other Potentially Infectious Materials (OPIM)** - Materials which have been implicated in the occupational transmission of bloodborne pathogens.

1. The following human body fluids:

- a. semen
  - b. vaginal secretions
  - c. cerebrospinal fluid
  - d. synovial fluid
  - e. pleural fluid
  - f. pericardial fluid
  - g. peritoneal fluid
  - h. amniotic fluid
  - i. saliva in dental procedures
  - j. any body fluid visibly contaminated with blood
  - k. 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 cells or tissue cultures, organ cultures, and HIV or HBV-containing cultures medium or other solutions; and
  4. Blood, organs, or other tissue from experimental animals infected with HIV or HBV.

**Regulated Waste -**

1. Liquid or semi-liquid blood or OPIM;
2. Contaminated items that would release blood or other potentially infectious material in a liquid or semi-liquid state if compressed;
3. Items that are caked with dried blood or other potentially infectious material and are capable of releasing these materials during handling;
4. Contaminated sharps; and
5. Pathological and microbiological wastes containing blood or other potentially infectious material.

**Universal Precautions** - an approach to infection control whereby all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

## **APPENDIX C OF THE BBP PLAN**

### **Effective Use of Biological Safety Cabinets**

Allow cabinet to run for five minutes before starting in order to purge ambient air. Wipe down cabinet interior with 70% ethanol.

Place all items required for the procedure inside cabinet before starting work. In the event of a spill, include a container of disinfectant (10% “Clorox”)\*. Allow appropriate contact time and allow cabinet air to circulate for five minutes before resuming work.

Cover work surface with an absorbent, plastic-lined bench pad, but be sure not to block the front or rear grill; this will interrupt the integrity of the protective air-flow “curtain”.

Arrange materials so that contaminated items do not pass over clean items.

Perform work four to six inches in back of front intake grill; move arms slowly.

Excess heat will cause turbulence and damage HEPA filters. If a Bunsen burner must be used, a model with a easily adjustable pilot light should be used. Alternatively, a “micro incinerator” can be used.

Protect the building vacuum system by placing a cartridge filter between vacuum trap and valve. (See diagram below).

Upon completion of work, wipe the interior with 70% alcohol.

BSCs are not chemical fume hoods. Unless one designed for 100% exhaust is used, vapors will be continually recirculated within the cabinet and exhausted into the laboratory.

**Always shut off UV light when working in the BSC.**

Cabinets must be certified annually to not only protect against infectious disease hazards but to also maintain the cabinet’s ability to prevent the contamination of research material.

See <http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm> for more information.

**APPENDIX D OF THE BBP PLAN**  
**UMDNJ Policy: Chemoprophylaxis After Potential**  
**Occupational/Educational HIV Exposure**

**For current version, please see:**

[http://www.umdnj.edu/oppmweb/Policies/HTML/HealthServ/00-01-40-40\\_10](http://www.umdnj.edu/oppmweb/Policies/HTML/HealthServ/00-01-40-40_10)

1. HEALTH SERVICES      **TITLE:** MANAGEMENT OF OCCUPATIONAL/  
**SUBJECT:** EDUCATIONAL EXPOSURES TO HIV,  
HBV AND HCV

**CODING:** 00-01-40-40:10      **ADOPTED:** 12/01/90      **AMENDED:** 10/18/02

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I. PURPOSE

The purpose of this policy is to outline the procedure under which postexposure prophylaxis will be made available to the University's health-care personnel, including students, housestaff, faculty, staff and postdoctoral fellows who in the course of their studies and/or occupational activities are exposed to blood, tissue or other body or laboratory fluids that may contain human immunodeficiency virus (HIV), hepatitis B virus (HBV) and/or hepatitis C virus (HCV). This policy is based upon the available scientific data and Public Health Service recommendations for postexposure management of health-care personnel who have occupational exposure that may place them at risk of acquiring HIV, HBV and/or HCV.

II. ACCOUNTABILITY

Under the direction of the President, the Senior Vice President for Academic Affairs, and the Presidents/CEOs of the Healthcare Units shall ensure compliance with this policy. The Deans, Vice Presidents, Director of Risk and Claims Management, Directors of Student Health Services and Directors of Occupational Medicine Services shall implement this policy.

III. REFERENCES

1. Centers for Disease Control and Prevention, Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(RR11).

2. Centers for Disease Control and Prevention, Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients during Exposure-prone Invasive Procedures. MMWR 1991;40(RR8).
3. Centers for Disease Control and Prevention, Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR 1998;47(RR19).
4. Student Immunizations & Health Requirements (University policy [#00-01-25-40:00](#))
5. Housestaff Immunizations and Health Requirements (University policy [#00-01-40-45:00](#))
6. Bloodborne Pathogens (University policy [#00-01-45-50:00](#))
7. HIV, HBV and HCV (University policy [#00-01-45-52:00](#))

#### IV. POLICY

1. Avoiding occupational/educational exposures is the primary way to prevent transmission of HIV, HBV and HCV in health-care settings (see Reference 6). However, hepatitis B immunization and postexposure management are integral components of a complete program to prevent infection following bloodborne pathogen exposure and are important elements of workplace safety.
2. In an attempt to prevent HIV, HBV and/or HCV infection due to occupational/educational exposures, UMDNJ shall make postexposure prophylaxis available at no expense to the students, housestaff, faculty, staff and postdoctoral fellows of the University who have exposures in the course of their educational and/or professional activities at the University's facilities or affiliated institutions which may place them at risk of acquiring HIV, HBV and/or HCV infection. See Reference 1 for the CDC's guidelines for management of exposures and recommendations for postexposure prophylaxis.
3. The Deans, Presidents/CEOs of the Healthcare Units and Vice Presidents shall oversee the development of written detailed protocols which must be strictly adhered to following an exposure, and the dissemination of this information to all appropriate individuals on each Campus of the University. Those individuals, services or offices responsible for carrying out these protocols shall be identified and their names published on each Campus. The procedures developed to implement this policy shall ensure timely (within hours of exposure) availability of medical attention and counseling, and of postexposure prophylaxis if requested, 24 hours a day. The goal of these procedures is preparedness to begin postexposure prophylaxis as soon as possible, ideally within hours, following exposure. These protocols and lists of responsible individuals or offices shall be reviewed and updated on a regular basis as often as required. This policy, its attachment and the references from the Centers for Disease Control and Prevention listed in section IV

containing information on postexposure prophylaxis should be used as guidelines for the Campus protocols.

4. Exposed individuals shall be counseled concerning: the risks of their exposure to HIV, HBV and HCV (including considerations of infectivity of exposure source and type of exposure); the known scientific facts, known and unknown risks and potential benefits of postexposure prophylaxis; the need for follow-up medical evaluations whether or not postexposure prophylaxis is elected; the necessity of precautions to prevent transmission of potential HIV, HBV and HCV infection during the follow-up period; and other relevant issues. Such counseling shall continue to be available throughout the medication period if postexposure prophylaxis is requested and during the follow-up period whether or not postexposure prophylaxis is requested.

5. Individuals may accept or decline postexposure prophylaxis on a purely voluntary basis and will not be subject to any discrimination in their studies or job duties as a result of their decision. Exposed individuals shall receive follow-up counseling, postexposure testing and medical evaluation regardless of whether they receive postexposure prophylaxis. Those who become HIV seropositive, whether or not postexposure prophylaxis was taken, HBV seropositive or HCV seropositive should be evaluated, in discussions with appropriate HIV counselors and/or infectious disease experts according to published recommendations for HIV-infected, HBV-infected and HCV-infected, health-care personnel (see Reference 2). All individuals who develop occupation/education related infections must be referred to the Office of Risk and Claims Management.

6. A signed informed consent/waiver form shall be required in all instances before initiation of postexposure prophylaxis (see EXHIBIT).

7. Individuals electing to receive HIV postexposure prophylaxis who meet all criteria and have signed the required form shall receive medication and follow-up evaluations by health-care providers, health services or offices identified in advance on each campus and available 24 hours a day. At least the first one to three days' supply of medications shall be available in all identified sites where individuals are instructed to report after an exposure so that prophylaxis can be started as soon as possible.

8. Upon report of an exposure, date and time, source, and details of the exposure shall be recorded. These details must include type of procedure being performed, type and brand of device involved, department or work area where the exposure occurred, how the exposure occurred, amount and type of fluid or material, depth of injury and whether fluid was injected, duration and extent of skin or mucous membrane contact, condition of skin, and details about the exposure source (such as HIV/HBV/HCV status and/or risk for these infections). The course of counseling, medical care and medication received shall be documented in writing. A summary of the experience on each campus with occupational/educational exposures, postexposure prophylaxis, and the outcome with or without postexposure prophylaxis shall be sent to the Senior Vice President for Academic

Affairs annually by the Schools, Directors of Student Health Services and Directors of Occupational Medicine Services on all Campuses. The summary shall not identify exposed individuals or source persons by name.

9. Confidentiality will be maintained to the extent possible and permitted by law.

10. If the HIV, HBV and HCV status of the source person is not known, the source person should be informed of the incident and every effort made to obtain this information through appropriate testing. In most cases, this will be the responsibility of the source person's health-care provider. Initiation of postexposure prophylaxis, if elected by the exposed individual, shall begin as soon as possible following exposure regardless of the availability of information about the source person's HIV, HBV and HCV status. However, the results of source-person testing and/or information about the source persons's symptoms and risk factors may contribute to the decision to continue postexposure prophylaxis.

11. As part of job orientation and ongoing job training, all UMDNJ health-care faculty and staff shall be educated concerning the risk for and prevention of bloodborne infections, including the need to be vaccinated against hepatitis B, and to report exposures immediately after they occur, and shall be familiarized with the principles of postexposure management and with their Campus's, School's or Unit's specific procedures for obtaining postexposure care. This shall be the responsibility of the Vice President for Human Resources, the President/CEOs of the Healthcare Units and the Deans. All students and housestaff shall receive similar education and information prior to clinical or laboratory studies or duties. The Deans shall ensure that their students and housestaff are so educated and shall assign the direct responsibility for this to appropriate individuals at each School.

12. For UMDNJ housestaff at non-UMDNJ clinical facilities, the pertinent School shall make arrangements concerning immediate care and shall determine cost responsibility in consultation with the affiliated institution. For UMDNJ students at non-UMDNJ clinical sites, the pertinent School shall make arrangements concerning immediate care and shall bear costs of any care charged by non-UMDNJ institutions. UMDNJ housestaff and students working/studying at non-UMDNJ clinical sites and who are exposed may receive medical care, including postexposure prophylaxis and follow up, at UMDNJ facilities designated to carry out this policy.

13. Unreimbursed costs of the drugs, initial and follow-up laboratory tests for the exposed individual and for the source person (if not already performed), initial and follow-up visits, counseling and record-keeping shall be borne by the Schools and Student Health Services in the case of students; and by the University's Workers' Compensation Program in the case of University-employed faculty, non-faculty staff and housestaff.

## V. EXHIBIT

Sample Consent Form/Declination of Treatment Form

By Direction of the President:

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Vice President for Academic Affairs

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EXHIBIT

SAMPLE CONSENT FORM/DECLINATION OF TREATMENT FORM

POSTEXPOSURE PROPHYLAXIS FOR PREVENTION OF HIV INFECTION

AFTER POTENTIAL OCCUPATIONAL/EDUCATIONAL EXPOSURE TO HIV

I may have been exposed to human immunodeficiency virus (HIV), the virus which causes AIDS, in my workplace or educational site. My health-care provider has offered me treatment with drugs which might reduce my risk of infection. These drugs are currently indicated for treatment of established HIV infection and for the prevention of transmission of HIV from infected pregnant women to their infants, and are recommended by the Centers for Disease Control and Prevention following exposure to HIV to reduce the occurrence of infection. These drugs are not approved by the Food and Drug Administration for preventing infection after exposure.

IF I DECIDE TO BE TREATED WITH POSTEXPOSURE PROPHYLAXIS, THE FOLLOWING WILL OCCUR:

1. Approximately four tablespoons of my blood will be drawn and tested for routine studies including complete blood count, platelet count, blood chemistry, liver function tests and kidney function tests, as well as for human immunodeficiency virus (HIV) and hepatitis B and C infections.
2. A urine sample to evaluate my kidney function will be obtained.
3. A urine sample to determine if I am pregnant may be obtained (appropriate women only).
4. I will be given an initial supply of drug(s) or the first one to three days' supply of drug(s) and a prescription for an initial supply plus instructions for taking it. A prescription for an additional supply of drug(s) may be provided at my next visit.
5. I will be required to return to my health-care provider every other week for six weeks, and at three months, six months and twelve months after my exposure. Blood and urine tests will be repeated at some visits.
6. If I experience adverse reactions or develop abnormal laboratory tests, the drug(s) dose may be lowered, the dosing interval changed or the drug(s) discontinued by my health-care provider.

## BENEFITS OF TREATMENT:

The risk of infection from my exposure is not known with certainty. However, should HIV infection occur, the eventual outcome probably will be fatal. Postexposure prophylaxis may prevent infection after exposure to HIV.

The benefit of zidovudine in preventing infection after exposure is indicated by studies in exposed health-care personnel and in infected pregnant women who can transmit the infection to their infants. However postexposure prophylaxis does not offer complete protection against HIV infection in exposed health-care personnel. The benefit of other anti-HIV drugs in preventing infection after exposure has not been similarly studied.

The duration of treatment likely to prevent infection is not known. My health-care provider recommends taking the drug(s) for four weeks.

## RISKS:

If I take zidovudine or other anti-HIV drugs, I might develop symptoms including headache, muscle pain, abdominal pain, weakness, tiredness, loss of appetite, trouble sleeping, fever, nausea, vomiting, dizziness and diarrhea. Although unlikely, I might also develop anemia, low white blood count, low platelet count, hepatitis (liver inflammation), pancreatitis, nervous system inflammation (meningitis/encephalitis), muscle inflammation, kidney stones, hyperglycemia/diabetes or other serious adverse effects. The risk of kidney stones may be lessened by drinking at least 48 oz. (1.5 liters) of fluid per 24-hour period. These adverse effects are expected to, but may not, disappear after treatment is stopped. These adverse effects could be, but usually are not, life-threatening.

Although considered unlikely, delayed effects of these drugs could include cancer (carcinogenesis) or mutations in my genetic material (mutagenesis). These drugs might have harmful effects on unborn fetuses and on nursing infants.

Drawing blood may be painful and may cause a bruise, or rarely an infection.

## TREATMENT OPTIONS:

Treatment with these drugs is voluntary. My health-care provider has discussed with me the alternative of declining postexposure prophylaxis. If I decide to stop taking these drug(s), I should notify my health-care provider within 24 hours. Whether I elect to receive these drugs, decline them, or start but then discontinue them, neither my employment, studies nor other treatment and follow up of my exposure will be affected. Declining treatment will not affect benefits to which I am otherwise entitled as a result of my exposure.

## PREGNANCY: (non-pregnant women)

To the best of my knowledge, I am not currently pregnant. A pregnancy test will be performed if I decide to be treated with postexposure prophylaxis. I agree to attempt to avoid pregnancy and refrain from breast-feeding while I am taking these drug(s) and for four weeks afterward. My

health-care provider has offered to provide me with information regarding birth control and has answered my questions about birth control. I will immediately contact my health-care provider if pregnancy is suspected.

PREGNANCY: (pregnant women)

I am pregnant and have discussed the potential benefits and potential risks of postexposure prophylaxis to me and my fetus with my health-care provider.

BREASTFEEDING: (women)

I am currently breastfeeding and have been counseled about the risk for HIV transmission through breast milk and about the passage of postexposure prophylaxis drugs into breast milk.

SEXUAL RELATIONS:

I have been counseled that I and my partner should use a condom during sexual relations or practice sexual abstinence while I am taking these drug(s) and during the entire 12-month follow-up period in order to prevent pregnancy and/or to prevent transmitting the HIV virus to my sexual partner.

CONSENT/DECLINATION:

I have read this Consent Form, have been given a copy, and have been given the opportunity to ask questions relevant to this treatment. This treatment has been fully explained to me, including the risks involved, potential complications, possible adverse effects and potential benefits. I understand that this use of these drugs has not been approved by the Food and Drug Administration, but has been recommended in situations such as mine by the Centers for Disease Control and Prevention.

I agree to treatment with postexposure prophylaxis for prevention of HIV infection as outlined above and to adhere to the therapy, follow-up schedule and instructions. I will contact the responsible health-care provider or counselor if I experience any acute illness or adverse drug effects, especially, but not limited to, back or abdominal pain, pain on urination or blood in my urine, increased thirst or frequent urination, or have questions related to the treatment.

MY SIGNATURE BELOW INDICATES MY WILLINGNESS TO TAKE ANTI-HIV DRUGS AS POSTEXPOSURE PROPHYLAXIS:

\_\_\_\_\_  
Participant's Signature Date

\_\_\_\_\_  
Participant's Name Printed

\_\_\_\_\_  
Supervising Clinician's Signature Date

\_\_\_\_\_  
Supervising Clinician's Name Printed

\_\_\_\_\_  
Witness's Signature Date

\_\_\_\_\_  
Witness's Name Printed

I HAVE READ THIS CONSENT FORM AND HAVE BEEN GIVEN THE OPPORTUNITY TO ASK QUESTIONS RELEVANT TO THIS TREATMENT. I DECLINE TREATMENT WITH ANTI-HIV DRUGS AND POSTEXPOSURE PROPHYLAXIS.

\_\_\_\_\_  
Participant's Signature Date

\_\_\_\_\_  
Participant's Name Printed

\_\_\_\_\_  
Supervising Clinician's Signature Date

\_\_\_\_\_  
Supervising Clinician's Name Printed

\_\_\_\_\_  
Witness's Signature Date

\_\_\_\_\_  
Witness's Name Printed

**APPENDIX E**  
**Biological Safety and Bloodborne Pathogens References**

AIHA Laboratory Health and Safety Committee Biosafety Website:

<http://www2.umdnj.edu/eohssweb/aiha/technical/biosafety.htm>

Updated U.S. Public Health Service, Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis, MMWR, June 29, 2001

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

Centers for Disease Control/National Institutes of Health (CDC/NIH). 1999. Biosafety in Microbiological and Biomedical Laboratories, 4th ed.

<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings, 1999

<http://www.cdc.gov/niosh/2000-108.html>

Centers for Disease Control/National Institutes of Health (CDC/NIH). 1995. Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.

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Fleming, D et. al., eds. 1994 Laboratory Safety, Principles and Practices, 2nd ed. AMS Press, Washington, DC.

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