

National Institutes of Health
Warren Grant Magnuson Clinical Center
OSHA Bloodborne Pathogens
Exposure Control Plan



As Required By:
29 CFR 1910.1030

INTRODUCTION:

The NIH Clinical Center strives to provide a safe work environment. Our employees are trained for their jobs. Hazard surveillance is conducted routinely to identify unsafe practices, equipment, or facilities. When identified, hazards are eliminated or measures are instituted to reduce the risk. Personal protective equipment is worn whenever it is needed. Safety equipment and supplies are inspected and maintained on a regular basis.

This Bloodborne Pathogens Exposure Control Plan has been developed in response to the Federal Occupational Safety and Health Administration's Bloodborne Pathogen Standard (29 CFR 1910.1030), the Federal Occupational Safety and Health Administration's Instruction: Enforcement of Procedures for the Occupational Exposure to Bloodborne Pathogens (directives number: CPL 2-2.44D), the Needlestick Safety and Prevention Act (HR 5178 and S 3067) and the Clinical Center's concerns for employee safety. It is vital that every employee with occupational exposure understands the safety policies and procedures described within this document. An employee only has to be accidentally exposed ONCE to pathogen-contaminated materials to become infected with the virus and, perhaps to eventually become ill with the disease. Accidental exposures may occur because employees are unaware of correct handling procedures or because they choose not to follow standard safety practices.

Clinical Center employees must understand how they are potentially exposed to infectious materials. For example, office staff may occasionally enter areas in which specimens containing bloodborne pathogens may be handled or where potentially infectious items are stored. Custodial staff may transport or package wastes containing contaminated items, or clean toilets and sinks which are potentially contaminated with infectious materials. Medical and research staff may routinely handle specimens and materials which contain bloodborne pathogens. Emergency response personnel could be called on to manage an emergency incident involving a biological hazard.

To aid employees in understanding how they may become exposed to infectious agents, the Exposure Control Plan developed by the Hospital Infections Committee contains a section entitled "Employee Exposure Determination". This section provides an overview of how exposure risks are assessed at the Clinical Center and lists the job classifications in which occupational exposures to bloodborne pathogens may occur.

The OSHA Bloodborne Pathogen Standard requires that specific issues be addressed in the Clinical Center exposure control program. These issues are as follows:

- Exposure determination (a list of job classifications in the Clinical Center that have employees who have occupational exposure to potentially infectious materials)
- The methods of compliance (the engineering controls, work practices, personal protective equipment, and housekeeping procedures used to minimize employee exposures)
- The special practices for HIV and HBV research laboratories in the Clinical Center
- The procedures for hepatitis B immunization and post-exposure evaluation and follow-up
- The communication of hazards to employees
- The record-keeping procedures required by the standard
- The procedure for the evaluation of circumstances surrounding exposure incidents

SCHEDULE OF REVIEW AND IMPLEMENTATION OF EXPOSURE CONTROL PLAN:

The specific methods instituted for each of these elements of the Clinical Center Exposure Control Plan are described in the designated sections of the plan. A schedule for program implementation is also provided in the section entitled "Schedule for Implementation." The Exposure Control Plan will be reviewed and updated annually and whenever necessary to reflect new or modified tasks or procedures which affect potential occupational exposure situations. The Clinical Center Hospital Infections Committee will be responsible for reviewing this plan.

AVAILABILITY OF THE EXPOSURE CONTROL PLAN:

The Clinical Center makes the Exposure Control Plan available to all employees at the Hospital Epidemiology Service, Bldg. 10 Rm. 10S-239 and on the HES web site at <http://www.cc.nih.gov/hes>.

I. Exposure Determination:

In March, 1992, a multi-departmental task force¹ reviewed all the current job classifications in the Clinical Center to determine those jobs with individuals who have occupational exposure to blood or other potentially infectious materials. Occupational exposure, as defined by the OSHA Bloodborne Pathogens Standard, 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.” In cases in which specific tasks of job duties were not evident, department heads and supervisors were consulted regarding the likelihood of occupational exposure with specific job classifications. The criteria for evaluating job classifications for occupational exposure are detailed in the Employee Bloodborne Pathogen Exposure Evaluation Form in Appendix A. Exposure determination was made without regard to the use of personal protective equipment. In addition, injury reporting records from the Occupational Medical Service were reviewed to determine which general categories of employees have reported occupational percutaneous injuries in the last several years.

Appendix B lists the job classifications in the Clinical Center that were determined to include at least some employees who have occupational exposure. Because it is not feasible to identify all the tasks and procedures in which occupational exposure occurs, all employees in these job classifications will be considered to be at risk for occupational exposure.

In addition to these Clinical Center employees, other non-Clinical Center federal employees traditionally considered “hospital employees” will be included in the Clinical Center Exposure Control Plan. These categories include all Clinical Center-credentialed patient care providers, and employees in Anatomic Pathology (National Cancer Institute), dental clinic (National Institute of Dental Research), and the Clinical Center Maintenance Unit (Division of Engineering Services). A listing of these job classifications is also included in Appendix B.

Other Clinical Center employees in job categories other than those above (e.g., secretarial and clerical staff working in patient care or laboratory areas)

¹ Composed of representatives from CC Administration, CC Management Support Services, CC Safety Officer, CC Hospital Epidemiology Service, and Division of Safety Occupational Medical Service

are evaluated on a case-by-case basis for occupational exposure using the Employee Bloodborne Pathogen Exposure Evaluation Form.

II. History and Current Practices for Universal Precautions:

A. Methods of Compliance

1. *General*

Any potential hazard associated with a job task can be minimized or eliminated by using the appropriate combination of engineering controls, work practices, and personal protective equipment. This basic tenet of safety applies to all occupational hazards, whether they are routine physical hazards, chemical hazards, or contact hazards associated with potentially infectious materials. This section of the Exposure Control Plan focuses on how the Clinical Center protects employees who may be exposed to biological hazards while performing their work tasks.

This section describes the engineering controls and personal protective equipment at the Clinical Center for employees who may come in contact with blood, blood products, or other potentially infectious materials. This section also delineates specific safe work practices which must be followed by every employee who may be exposed to infectious materials.

2. *Universal Precautions*

Universal Precautions have been implemented in the Clinical Center since 1987. Simply stated, the concept behind Universal Precautions is that all human blood and body fluids are treated as if they are known to contain hepatitis B virus (HBV), human immunodeficiency virus (HIV), or other bloodborne pathogens. Universal Precautions must be strictly adhered to by employees at the Clinical Center whenever they handle blood, body fluids, or other potentially infectious materials. By making this assumption, employees will stringently avoid all contact with potentially contaminated items by following standard safety precautions, use of proper safety controls, and wearing the appropriate personal protective equipment. Revisions to the Clinical Center Universal Precautions program were made in June, 1992, to

comply with the final OSHA Bloodborne Pathogen Standard. A summary statement of the revised booklet and the revised post-training examination are contained in Appendix C of the 'Older Versions of the Bloodborne Pathogens Exposure Control Program.' In July, 1992, annual retraining with this revised program began. In October, 1992, the Universal Precautions training video was revised to become the primary training tool. Training classes are conducted by the Hospital Epidemiology Service staff and include an opportunity for employees to ask questions. Revisions to the Clinical Center Universal Precautions program are made on an as needed basis to comply with the revision of the CC Infection Control Program Guidelines flipchart as well as other appropriate guidelines. A copy of the most recently revised Universal Precautions booklet and post-training examination and video text are contained in Appendix C. During the 2003 review of the flipchart, "Standard/Universal Precautions" was approved as the new terminology, rather than just "Universal Precautions."

3. *Engineering and Work Practice Controls*

Engineering and work practice controls are used whenever possible to eliminate or minimize employee exposures to bloodborne pathogens. Personal protective equipment will be worn when the potential for occupational exposures remain after these controls have been implemented.

Engineering controls are those devices which isolate or remove the bloodborne pathogen hazard from the work place. These engineering controls are routinely examined as part of a safety survey program. Some of the engineering controls implemented in the Clinical Center to protect employees from potential exposure situations include the following:

- handwashing facilities and antiseptic hand cleanser products
- puncture-resistant labeled containers for sharp instrument disposal

- puncture-resistant labeled containers for reprocessing instruments
- labeled containers for storage, transport, disposal, or shipping of potentially infectious specimens
- mechanical pipetting/suctioning devices
- shatterproof specimen vials
- sharps with engineered sharps injury protectionsself-sheathing needles (e.g., safety-lock syringes, needle recapping devices)
- needleless system
- biological safety cabinets

Indications and instructions for use are included as part of the annual Universal Precautions training and/or annual laboratory safety training. In addition, the Clinical Center meets the intent of The Needlestick Safety and Prevention Act (HR 5178 and S 3067) (Appendix K) on an on-going basis, through the Clinical Center Standardization Committee. Throughout the course of each year, the Standardization Committee systematically identifies and evaluates new safer medical devices as candidate products to be introduced into the Clinical Center, such as needleless systems and self-sheathing needles. Following evaluation, these devices and equipment have been and will continue to be provided to Clinical Center employees. The efficiency of these devices is monitored by the Materials Management Department, Environmental Safety Officer, Nursing Department Quality Assurance and the Clinical Center's Quality Improvement Committee via the Clinical Center Occurrence Reporting System.

Work practice controls are defined as those procedures which have been developed by the Clinical Center to reduce or eliminate employee exposures to bloodborne pathogens during the execution of their work tasks. In terms of basic safety during potential exposure situations, the policy of the Clinical Center is to eliminate all exposures. Employees must understand these procedures fully, and they must implement these practices when appropriate.

The following basic hygiene, handwashing, first aid, and exposure reporting procedures must be followed by employees who are potentially exposed to bloodborne pathogens.

- All procedures involving blood or other potentially infectious materials shall be performed in such a manner to prevent or minimize splashing, spraying, spattering, and generation of droplets of these substances.
- Mouth pipetting/ suctioning of blood or other potentially infectious materials is strictly prohibited.
- Employees must wash their hands immediately (or as soon as feasible) between patients and after removal of gloves or other personal protective equipment.
- If accidental skin contamination occurs, the area will be washed with copious amounts of soap and water.
- If the eyes or mucous membranes are accidentally contaminated, they should be flushed with water or saline for at least 15 minutes.
- If a needlestick or other percutaneous injury occurs, the wound should be washed with soap and water for 15 minutes. Some studies suggest a milking motion towards the wound to stimulate bleeding may help wash out contamination.
- All injuries must be reported immediately to the Occupational Medical Service and the employee's supervisor. For possible bloodborne pathogen exposures occurring when OMS is closed, contact the on-call OMS physician through the page operator at 301-496-1211.
- Employees who have exudative lesions or weeping dermatitis should be evaluated in OMS before reporting to work.

The following sharps handling procedures must be followed by employees who are potentially exposed to bloodborne pathogens.

- Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed by hand. Shearing or breaking of contaminated needles is prohibited. If no alternative to recapping or needle removal is feasible and such action is required by a specific medical procedure, the recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique. For example, a one-handed recapping technique involves laying the needle cap down on a flat surface, and, without touching the cap, carefully inserting the needle into the isolated cap and lifting, so the cap slides down to the hub of the needle. Only then should the employee use his/her other hand to tighten the cap on the needle hub. If recapping or needle removal is required by a specific medical procedure, the department's special recapping or needle removal procedure must be approved by the Hospital Infections Committee.
- Contaminated non-reusable sharp objects shall be placed in a puncture-resistant, leak-proof, closable container which is color coded or labeled with the biohazard symbol. Employees should not overfill these containers or reach into them. When 3/4 full, the container should be sealed and placed in a Medical Pathological Waste box.
- Reusable contaminated sharps shall be placed immediately in appropriate containers until properly reprocessed. Appropriate containers shall be: a tray or container that is puncture-resistant, color-coded or labeled with the biohazard sign, and leakproof. Contaminated reusable sharps shall not be stored or processed in a manner that requires employees to reach by hand into the containers where the sharps have been placed.

The following personal conduct policies must be followed by employees who are potentially exposed to bloodborne pathogens.

- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where a reasonable likelihood of occupational exposure to blood or other potentially infectious materials exists.
- 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.

The following containers and equipment handling procedures must be followed by employees who are potentially exposed to bloodborne pathogens.

- All potentially infectious specimens shall be placed in a sturdy, closable, biohazard-labeled container, which prevents leakage during collection, handling, or shipping. If external contamination of the primary container occurs, it shall be placed within a clean second container which prevents leakage and is biohazard-labeled or color-coded. If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which, in addition to the above characteristics, is puncture-resistant.
- Equipment that needs repair or servicing shall be decontaminated of blood or other potentially infectious materials before servicing or shipping. If complete decontamination of the equipment is not possible, a readily observable biohazard label shall be attached, indicating which portions of the equipment remain contaminated. This information must be 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.

The following labeling procedures must be followed by employees to protect other employees who are potentially exposed to bloodborne pathogens.

- Biohazard warning labels must be affixed to containers of regulated (contaminated) waste, disposable sharps containers, containers used to handle reusable contaminated sharps, and containers used to store, transport, or ship blood or other potentially infectious materials (e.g., refrigerators, freezers, shipping containers, waste containers). The label must include the universal biohazard symbol and word “Biohazard” (see below) with the label colored fluorescent orange or orange-red and lettering or symbols in a contrasting color. The label must be affixed to the container to prevent loss or unintentional removal. Medical Pathological Waste (MPW) boxes are pre-labeled.



BIOHAZARD

- Two exceptions to the labeling requirement above are:
 - 1) contaminated laundry in the Clinical Center, which is “labeled” as such by the yellow isolation laundry bag, and
 - 2) blood products that are labeled as to their contents and released for transfusion, should not be labeled biohazard.
- *Because the Clinical Center utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimen containers is not necessary if these containers are easily recognizable as holding potentially infectious agents. This exemption only applies while such containers remain within the facility. Labeling/color-coding is mandated for those containers when they leave the facility. However, it is prudent practice to label ALL containers with the contents of the container and their associated hazard.*

4. *Personal Protective Equipment*

Where potential for occupational exposure remains after institution of engineering and work practice controls, personal protective equipment shall also be used. To minimize occupational exposure, Universal Precautions employs barrier equipment such as gloves, gowns, face shields or masks, eye protection, pocket masks, etc. Barrier equipment is considered appropriate only if it does not permit blood and potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, skin, eyes, mouth, or other mucous membranes under normal conditions of use. The Clinical Center will ensure that appropriate barrier equipment is readily accessible or is issued to healthcare workers.

Personal protective equipment is provided at no cost to employees. This equipment includes but is not limited to:

- gloves
- gowns, aprons, laboratory coats, clinic jackets
- face shields
- masks
- eye protection
- surgical caps or hoods
- shoe covers or boots
- mouthpieces, resuscitation bags, and pocket masks

Indications and instructions for use, cleaning, laundering, and disposal are included as part of the annual Universal Precautions training or, in the case of resuscitation equipment, in CPR training classes. Personal protective barrier equipment is to be used in clinical situations in which blood and potentially infectious fluids are likely to contact a healthcare worker's exposed skin or mucous membranes. The type of barrier used will depend on the procedure.

Gloves

- Gloves are worn (1) to provide a protective barrier to prevent gross contamination of the hands when touching blood or other potentially infectious materials mucous membranes, non-intact, and contaminated items; (2) to reduce the likelihood that microorganisms present on the hands of personnel will be transmitted to patients during invasive or other patient-care procedures that involve touching a patient's mucous membranes and skin; (3) to reduce the likelihood that hands of personnel contaminated with microorganisms from a patient or fomite can transmit these microorganisms to another patient.
- Routinely wearing gloves is one of the most basic safety procedures used to protect employees from the hazards associated with infectious agents. Gloves shall be worn when hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin can be reasonably anticipated; when performing phlebotomies or other vascular access procedures; and when handling or touching contaminated items or surfaces. Clean gloves should be donned just before touching mucous membranes and non-intact skin.
- Gloves shall be replaced when contaminated, torn, punctured, or when their ability to function as a barrier is compromised. Disposable gloves shall not be washed or decontaminated for re-use. Gloves should be changed after direct contact with each patient, and should be removed before touching commonly used surfaces, such as door knobs, telephones, computers, and elevator buttons. Gloves should be changed between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms. Gloves must be changed between patient contacts. Disposable (single use) gloves should never be washed and re-used.

- Gloves should be removed promptly after use, before touching noncontaminated items and environmental surfaces (such as door knobs, telephones, computers, and elevator buttons), and before going to another patient. Hands should be washed immediately to avoid transfer of microorganisms to other patients or environments.
- Gloves are usually not necessary when administering intramuscular or subcutaneous injections as long as bleeding that could result in hand contact with blood or OPIM is not anticipated.
- Plastic film food handling gloves (“cafeteria” or “baggie” gloves) are not considered to be appropriate for use in exposure-related tasks.
- Wearing gloves does not replace the need for handwashing, because gloves may have small, inapparent defects or may be torn during use, and hands can become contaminated during removal of gloves. Failure to change gloves between patient contacts is an infection control hazard.
- Different sized sterile and non-sterile gloves (latex and latex-free), as well as 100% cotton glove liners, are available from Central Hospital Supply (CHS). In addition, specialty glove types are available from CHS. The CHS Nurse Consultant can be contacted at 301-496-3392 for questions.
- Employees who have allergies to the gloves normally provided should call the Occupational Medical Service for an appointment to be evaluated so that alternatives can be arranged. Hypoallergenic gloves, glove liners, powderless gloves, or other similar protective gear will be made available.

- Utility gloves (gloves designed for multiple use) may be decontaminated for re-use if the integrity of the glove is not compromised. Utility gloves must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration.

- OSHA permits a single exception to the requirement to wear gloves for all phlebotomy procedures: volunteer blood donation centers may apply for a special exemption to permit blood collection without gloves under certain circumstances. The Department of Transfusion Medicine may apply for a special exemption for volunteer blood donor phlebotomies provided the following policies are instituted:
 - Gloves will be made available to all employees who wish to wear them.

 - The use of gloves will not be discouraged for phlebotomy. The OSHA exemption regarding the use of gloves during phlebotomy procedures applies only to employees of volunteer donor collection centers, and does not apply to phlebotomy conducted in other settings.

 - Gloves must be worn by employees who have cuts, scratches, or other breaks in the skin.

 - Gloves will be worn by employees who deem themselves at a significantly increased risk of hand contamination (e.g., working with an uncooperative patient or donor).

 - Gloves will be worn by employees during their training in phlebotomy.

 - These policies are reviewed annually by the Hospital Infections Committee to ensure the maintenance of a safe work environment.

Face Protection

- 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 toward the eyes, nose, or mouth. Employees with acne, dermatitis, or other ailments involving the facial region should consider wearing face protection while conducting procedures where potential exposure may occur.
- During microsurgery, when it is not reasonably anticipated that there would be any splattering, a surgeon would not be required to wear eye protection while observing surgery through the microscope.

Body Protection

- Appropriate protective clothing such as gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type of clothing will depend upon the task and degree of exposure anticipated. Employees should contact their supervisors, a member of the Hospital Epidemiology Service, or the Clinical Center Safety Officer if they have any questions concerning the type of personal protective apparel appropriate for certain job tasks. Such clothing will not be worn outside of designated work areas. If a garment is penetrated by blood or other potentially infectious materials, the garment shall be removed immediately or as soon as feasible.

Other Barriers

- Surgical caps or hoods and/or shoe covers or boots shall be worn in instances in which gross contamination can reasonably be anticipated (e.g., autopsies, orthopedic surgery). Pocket masks are available in all patient care areas and other sites around the Clinical Center for emergency respiratory care.

Use of Personal Protective Equipment

- Employees will use the appropriate personal protective equipment whenever they are potentially exposed to bloodborne pathogens. According to the OSHA standard, the employee may temporarily and briefly decline to use this equipment when, in the employee's professional judgement, its use prevents the delivery of health care or poses an increased hazard to the employee or a co-worker. However, the Clinical Center does not encourage this action. When an employee makes this judgement, the circumstances shall be thoroughly investigated in order to determine whether changes can be made to prevent other, similar occurrences. In the rare instance in which an employee elects not to use appropriate personal protective equipment, the Clinical Center Environmental Safety Officer shall be contacted to initiate an investigation of the circumstances precluding barrier usage, and recommend corrective action, if indicated.

Personal Protective Equipment Storage, Cleaning, and Disposal

- All patient care and laboratory areas will have a designated location for maintaining barrier equipment. In general, yellow isolation carts in patient care areas will serve this function.
- Healthcare workers shall remove and discard personal protective equipment that is worn prior to leaving the area of use. Removed barrier equipment shall be placed in an appropriately designated area or container. Disposable gloves, gowns, faceshields, and masks should be discarded into either a patient waste receptacle or a Medical Pathological Waste box. Employees should remember to remove their gloves and wash their hands after disposal of a contaminated item.
- Reusable protective body clothing, such as lab coats or clinic jackets, should be laundered only by the Clinical

Center Housekeeping & Fabric Care Department when used intentionally as a barrier. Clothing visibly contaminated with blood or other potentially infectious materials should be handled with gloves and placed into yellow isolation laundry carts, lined with water-soluble liners.

- Personal eyewear is not recommended as barrier equipment unless the eyewear has side shields. Protective eyewear can be cleaned with soap and water; alcohol can be used for disinfection if necessary.

5. *Housekeeping Procedures*

Effective housekeeping is essential to minimize occupational hazards. Good housekeeping is so important to protect workers from the hazards associated with potentially infectious agents that this section is dedicated to describing the pertinent housekeeping procedures at this facility.

Housekeeping policies are designed to ensure that the worksite is maintained in a clean and sanitary condition. While extraordinary attempts to disinfect or sterilize environmental surfaces such as walls or floors are rarely indicated, routine cleaning and removal of soil are required.

The following housekeeping procedures for equipment are mandatory under the OSHA Bloodborne Pathogen Standard.

Housekeeping Procedures for Equipment

- All equipment and environmental and working surfaces will be cleaned and decontaminated after contact with blood or other potentially infectious materials. Work surfaces will be washed and disinfected after completion of procedures which lead to contamination of these surfaces. The particular disinfectant used, as well as the frequency with which it is used, will depend upon the circumstances in which the housekeeping task occurs.

- For small spills of blood or other potentially infectious materials (<20 ml), the employee should put on gloves and remove visible material with paper towels or some other absorbent paper, and apply a disinfectant solution. Alternatively, a freshly mixed (no older than 24 hours) 1:10 dilution of bleach (i.e., 1 part bleach to 9 parts water) may be used. The area should remain wet with disinfectant for ten minutes.
- For large spills (>20 ml), the employee should contact Housekeeping and Fabric Care Department (301-496-2417). Prior to the arrival of housekeeping personnel, close the spill area to traffic. The employee should not cover the spill with paper towels and should not apply disinfectant or any other liquid cleaner to the spill. If desired, the employee may apply powder absorbent to spills on hard surfaces, but the employee should not apply powder absorbent, bleach or disinfectant to spills on carpets.
- Work surfaces will be cleaned at the end of the work shift when operations conducted during the shift involve potentially infectious materials. Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and surfaces must be replaced as soon as feasible when they become overtly contaminated or at the end of the work shift. All bins, pails, cans, and similar receptacles intended for reuse which may be expected to become contaminated with blood or other potentially infectious materials will be routinely inspected, cleaned, and decontaminated. These receptacles shall also be immediately decontaminated whenever they become visibly contaminated.

Contaminated work surfaces are to be cleaned with an “CC approved” disinfectant. Appropriate disinfectants include a diluted bleach solution and EPA-registered tuberculocides, sterilants, or products registered against HIV/ HBV (primarily quaternary ammonia products that EPA has approved as effective against HIV and HBV). The lists of these EPA Registered Products are available from the

National Antimicrobial Information Network at (800) 447-6349 or its web site at <http://ace.orst.edu/info/nain/lists.htm>.

Housekeeping Procedures for Sharps

- Broken glassware which may be contaminated will never be picked up directly with the hands. A brush and dustpan, tongs, forceps, or similar equipment will be used to clean up this broken glassware. Employees must wear gloves every time they clean up broken glassware. The tools used in cleanup (e.g., forceps) must be properly decontaminated or discarded after use and the broken glass placed in a sharps container. Vacuum cleaners are not appropriate for cleanup of broken glass.
- 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.

Housekeeping Procedures for Waste Materials

Waste Sharps. Contaminated sharps must be discarded immediately after use. Containers for waste sharps shall be:

- Closable;
- Puncture resistant
- Leak-proof on sides and bottom
- Labeled/color-coded according to the Federal standard and the section on labels in the document
- Easily accessible to personnel (i.e., found close to the work areas where potentially infectious materials are handled)
- Maintained upright throughout use
- Replaced routinely and not allowed to be overfilled (no more than 3/4 full is recommended)

When moving containers of contaminated sharps from the area of use, the containers will be closed immediately prior

to removal to prevent the accidental release of contents or placed in a secondary container if leakage is possible. A Medical Pathological Waste (MPW) box is the only approved secondary container at the NIH. This secondary container must be closable, constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping, and labeled/color-coded according to the Federal standard and the section designated “Label Requirements” in this document.

Containers for Other Potentially Infectious Wastes

Medical Pathological Waste (MPW) boxes are the only approved containers for packaging other potentially infectious wastes at the Clinical Center. In accordance with the Federal standard, MPW boxes are:

- Closable;
- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping;
- Labeled/color-coded according to the Federal standard and the section on labels in this document; and
- Closed prior to removal to prevent the accidental release of materials.

If outside contamination of the waste container occurs, the primary container will be placed in a secondary container. This secondary container must be closable, constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping, labeled/color-coded according to the Federal standard and the section designated “Label Requirements” in this document, and closed prior to removal to prevent the accidental release of materials.

Housekeeping Procedures for Laundered Items

Contaminated laundry will be handled as little as possible with a minimum of agitation. Contaminated laundry will be placed in a container in the area of use and shall not be sorted or rinsed in the location of use. Wet laundry which presents a potential leak problem will be placed in leak-

proof containers. Contaminated laundry from isolation rooms will be placed in water-soluble bags in yellow isolation laundry bags.

Bags of contaminated laundry from isolation rooms are color-coded yellow

Employees who have contact with contaminated laundry must wear gloves and other appropriate personal protective equipment, as deemed necessary for the safe handling of this laundry. Employees should contact their supervisors, a member of the Hospital Epidemiology Service, or the Clinical Center Environmental Safety Officer if they have any questions concerning the type of personal protective apparel appropriate for certain job tasks.

B. Special Practices for HIV and HBV Research Laboratories and Production Facilities:

Special Note: There are NO HIV/HBV production facilities in the Clinical Center; sections of the OSHA Bloodborne Pathogens Standard regarding HIV/HBV production facilities are NOT applicable to any operations conducted in the Clinical Center. This section of the Exposure Control Plan specifically addresses standard requirements for HIV/HBV research laboratories. It does NOT apply to clinical laboratories, diagnostic facilities, nor any other type of operation. Requirements in this section are covered by the "NIH Exposure Control Plan for Non-Hospital Personnel" developed by the NIH Division of Safety, Occupational Safety and Health Branch.

1. *Definitions of HIV/HBV Research Laboratories and Production Facilities*

According to the Bloodborne Pathogens Standard, HIV/HBV research facilities are those laboratories using laboratory-scale amounts of HIV/HBV-containing materials. The standard defines HIV/HBV production facilities as those which engage in industrial-scale, large-volume, or high-concentration production of HIV/HBV-containing materials.

2. *Special Practices and Requirements*

Because of the high concentration and/or large volume of the potentially infectious materials handled at research laboratories and production facilities, special safety procedures must be developed for the protection of employees. There are additional requirements for employee training, biosafety manuals, facilities, and authorization processes for entry into HIV/HBV work areas. A description of these safety programs are contained in the “NIH Exposure Control Plan for Non-Hospital Personnel” developed by the NIH Division of Safety, Occupational Safety and Health Branch. The NIH Division of Safety, Occupational Safety and Health Branch is responsible for implementing the sections of the OSHA Bloodborne Pathogens Standard pertaining to HIV/HBV research laboratories.

3. *Required Hazard Warning Sign*

HIV/HBV research laboratories in the Clinical Center are identified by hazard warning signs posted on all access doors. Such signs are described in the section in this document designated “Sign Requirements.” An example is included in Appendix F.

C. Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up

1. *Hepatitis B Vaccination*

Hepatitis B Vaccine Program. Hepatitis B immunization is an important part of the Exposure Control Program of the Clinical Center. Hepatitis B vaccine has been offered free of charge to NIH employees since 1983. The hepatitis B vaccine is available to all employees who have occupational exposures to potentially infectious materials. The vaccination series is provided at no cost to the employee and is provided under the supervision of a licensed physician through the Occupational Medical Service (OMS).

Although not required by the OSHA standard, new recommendations were issued by the U.S. Public Health Service in December 1997² regarding postvaccination testing for adequate antibody response. OMS offers testing for antibody to hepatitis B surface antigen (anti-HBs) one to two months after completion of the 3-dose vaccination series, to employees who have contact with patients or blood and are at ongoing risk for injuries with sharp instruments or needlesticks. Persons who do not respond to the primary vaccine series are offered a second 3-dose vaccine series or are offered evaluation to determine if they are HBsAg-positive. Revaccinated persons are offered retesting at the completion of the second vaccine series. Non-responders are medically evaluated.

Booster doses of hepatitis B vaccine are not considered necessary, and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not offered.

In accordance with the requirements of the OSHA standard, the hepatitis B vaccine is made available to employees at the time of pre-placement evaluations at OMS, after appropriate information on hepatitis B virus is reviewed during Universal Precaution training sessions, and at any future time employees who have occupational exposures request the vaccine. Employees may obtain the vaccine by calling OMS at 301-496-4411 and scheduling an appointment. Further details regarding the hepatitis B vaccine program are included in Appendix D.

Exemptions to the Hepatitis B Vaccine Program. Employees who have already completed the hepatitis B vaccine series are exempt from further hepatitis B vaccine requirements. Employees for whom antibody testing has revealed an

² Centers for Disease Control and Prevention. Immunization of Health-Care Workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR* 1997;46(No. RR-18): 22-23.

immunity to hepatitis B virus or for whom the vaccine is contraindicated for medical reasons are also exempt. Anti-HBs testing is offered through OMS during the employee pre-placement evaluation.

Employees Who Decline Hepatitis B Vaccine. Employees who have occupational risk may decline the hepatitis B vaccine. As required by the OSHA standard, when an employee covered by the OSHA standard elects not to participate in the hepatitis B vaccine program, the employee declining treatment must sign the following statement:

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

As indicated by the previous statement, employees who decline hepatitis B virus vaccine may receive the vaccine series at a later date. The vaccine will be provided at no cost to the employee at that time.

2. *Post-Exposure Evaluation and Follow-Up*

Post-exposure immunization and medical evaluation following an exposure incident are essential to an effective Exposure Control Program. In keeping with the Clinical Center's concerns for employee safety, the post-exposure

evaluation and follow-up program available at the NIH through the OMS exceeds the guidelines required under the OSHA Bloodborne Pathogens Standard. The employee post-exposure evaluation program has been continually modified over the years as new laboratory diagnostic tests for bloodborne pathogens have become available.

OMS has been provided a copy of the OSHA Bloodborne Pathogens Standard and this Exposure Control Plan to facilitate employee hepatitis B immunization and post-exposure management.

Post-exposure immunization and medical evaluation are available to all employees who have had an exposure incident. These procedures are provided at no cost to the employee by or under the supervision of a licensed physician through the OMS at a reasonable time and place. All necessary laboratory tests are conducted by an accredited laboratory.

Availability of Evaluations and Their Results. Confidential medical evaluation and follow-up are available to all employees who report exposure incidents. These include the following elements:

- Documentation of the routes of exposure and circumstances by which the exposure occurred.
- Identification and documentation of the source individual, unless such identification is not possible.
 - The source individual's blood is tested as soon as feasible after consent is obtained in order to obtain the person's status for human immunodeficiency virus (HIV), hepatitis B virus (HBV), human T-cell leukemia virus type 1 (HTLV-I), hepatitis C virus (HCV) and elevated liver enzymes for non-A, non-B, non-C hepatitis. The consent document is included in Appendix E.
 - When the source individual's consent is not obtainable after all reasonable attempts have been

made to obtain informed consent, Clinical Center HIV Testing Policy permits testing to be performed. Regardless of the outcome of the test, the source individual should be informed of the results of the test in accordance with Clinical Center policy.

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

Results of the source individual's testing is made available to the exposed employee. The employee is also counseled of the importance of maintaining the privacy and confidentiality of the source individual's records.

Obtaining Post-Exposure Evaluations. OMS procedures for evaluating exposure incidents are included in Appendix E. Post-exposure measures designed to prevent the spread of the disease or development of disease symptoms are made available to the employee, when medically indicated. This program follows the recommendations of the U.S. Public Health Service and includes counseling and evaluation of reported illnesses.

Collecting and Testing of Employees Blood Samples. If an employee blood sample is not already available at OMS, a sample of the employee's blood is collected after the employee's consent is obtained. The employee's blood sample will be tested according to OMS procedures included in Appendix E. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample is preserved for at least 90 days. If the employee elects to have the baseline sample tested within this 90 day period, such testing will be done as soon as possible after the decision has been made.

Healthcare Professional's Written Opinion. OMS will complete their evaluation and will provide, at the employee's request, a written opinion as soon as possible, usually within 2 work days but no later than 15 days following completion of the evaluation. In terms of hepatitis B virus evaluations,

OMS's written opinion for hepatitis B vaccine will be limited to whether hepatitis B vaccine is indicated for the employee, or if the employee has already received the vaccine. Written opinions concerning other results of post-exposure evaluations are limited to the following information, in accordance with the OSHA regulation:

- An indication that the employee has been informed of the results of the evaluation.
- An indication that the employee has been told about potential medical conditions resulting from exposure to blood or other potentially infectious materials which may require further evaluation or treatment.

All other findings or diagnoses not specified in the above paragraphs will remain confidential and cannot be included in the written report.

Medical records are maintained in accordance with the requirements specified in the Recordkeeping section of this Exposure Control Plan.

D. Communication of Hazards to Employees

Communication of the hazards associated with blood, blood products, or other potentially infectious materials is extremely important. The Clinical Center provides such hazard information to employees through the use of labels and signs. The Clinical Center also provides information and training programs which review the hazards associated with bloodborne pathogens and how to prevent exposure.

1. *Label Requirements*

Warning labels will be affixed to all containers of regulated waste, as well as refrigerators, and freezers containing blood or other potentially infectious materials. Labels must also be affixed to containers used to store, transport, or ship blood or other potentially infectious material. Labels must include the universal biohazard symbol and be fluorescent orange or orange-red, with lettering or symbols in a contrasting color. The following figure is the universal biohazard symbol



BIOHAZARD

Labels are also required for equipment which has been contaminated with potentially infectious materials. Labels will be affixed as close as feasible to the container or equipment by string, wire, adhesive, or other method that prevents their loss or unintentional removal. Labels required for contaminated equipment must also state which portions of the equipment may remain contaminated. Labels can be obtained from Central Hospital Supply.

Materials Exempt From Label Requirements. Containers of blood or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempt from

these label requirements (i.e. the bag does not require the biohazard symbol).

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

Regulated waste that has been decontaminated need not be labeled.

2. *Sign Requirements*

HIV/HBV research and production facilities are required to post signs at the entrance to work areas in which potentially infectious materials are handled. These signs will have the universal biohazard symbol, include the name of the infectious agent, special requirements for entering the area, and the name and telephone number of the laboratory director or other responsible person. These signs must be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color. A sample sign is included in Appendix F. These signs are available from the Occupational Safety and Health Branch, Bldg. 13, Rm. 3K04 (496-2346).

3. *Information and Training*

Universal Precautions Training. The Clinical Center provides all potentially exposed employees with appropriate training, in accordance with the Federal regulation and the Clinical Center's concerns for employee health and safety. Such training is provided:

- At the time of initial assignment to tasks where occupational exposure may occur.
- Within 90 days after the effective date of the standard.
- Refresher training is provided annually. Additional refresher training may also be provided to employees on the recommendation of the Clinical Center Safety Officer and supervisors.

Additional training will be provided when changes in equipment, tasks, or procedures create new potential exposure situations. This additional training will be provided to employees on the recommendation of the supervisor or the Clinical Center Safety Officer, and may be limited to addressing the new exposures created.

Clinical Center training includes the following elements:

- An accessible copy of the regulatory text of the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, and an explanation of its contents.
- A general explanation of the epidemiology and symptoms of bloodborne diseases.
- An explanation of the modes of transmission of bloodborne pathogens.
- An explanation of the Clinical Center Bloodborne Pathogens Exposure Control Plan and the means by which employees can obtain a copy of the written plan.
- An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.
- An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practice controls, and personal protective equipment.
- Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment.
- An explanation of the basis for selection of personal protective equipment.
- Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine is provided free of charge.
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.

- 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.
- Information on the post-exposure evaluation and follow-up that are provided an employee following an exposure incident.
- An explanation of the signs and labels and/or color coding used to convey biohazard information.
- An opportunity for interactive questions and answers with the person conducting the training session.

The person conducting the training is knowledgeable in the subject matter covered by the elements contained in the training program. The Clinical Center training program was developed by and is administered by the Hospital Epidemiology Service staff. The standard training consists of a videotape and additional verbal and written material, and is followed by a written test. Alternative training options are available for physicians. Physicians may independently read the Universal Precautions booklet (Appendix C) and either complete the written test or complete the same test available in the Medical Information System (MIS). Nurses may complete their training requirement through the de' MEDICI System tutorial. In all training formats, employees are encouraged to contact the Hospital Epidemiology Service if they have any questions.

Additional Training for Employees in HIV/HBV Research Laboratories. Employees in HIV or HBV research laboratories receive additional training as described in the "NIH Exposure Control Plan for Non-Hospital Personnel" developed by the NIH Division of Safety, Occupational Safety and Health Branch (OSHB). Briefly, these employees receive the following initial training from the OSHB, in addition to the above training requirements:

- The OSHB assures that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the laboratory before being allowed to work with HIV or HBV.

- The OSHB assures that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.
- The OSHB assists supervisors to provide training to employees who have no prior experience in handling human pathogens. Initial work activities do not include the handling of infectious agents. A progression of work activities is assigned as techniques are learned and proficiency is developed. Supervisors assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

E. Recordkeeping

1. *Medical Recordkeeping*

OMS maintains accurate medical records (in accordance with: 29 CFR 1910.20; OSHA Instruction. Directives Number: CPL 2-2.44D [AppendixJ]; The Needlestick Safety and Prevention Act (HR 5178 ans S 3067) [Appendix K.....]) for employees with occupational exposure. These records include:

- The name and social security number of the employee.
- A record of the employee's hepatitis B vaccine status, including the dates of all hepatitis B vaccine administrations and any medical records related to the employee's ability to receive such vaccine.
- A record of all results of examinations, medical testing, and follow-up procedures.
- A record of the healthcare professional's written opinion, where applicable.
- A record of any exposure information supplied to the healthcare professional by an employee.

These medical records are kept confidential and are not disclosed without the employee's written consent to any person within or outside the work place (except as may be required by law). The OMS identifies these records as needing to be retained for the duration of an employee's employment plus 30 years thereafter; these are maintained with NIH records at the Federal Records Center (National Archives and Records Administration, National Personnel Records Center).

2. *Training Records*

Training records are maintained by the Hospital Epidemiology Service and include the following information:

- The dates of the training sessions;
- The contents or a summary of the training session;
- The names and qualifications of persons conducting the training; and
- The names and job titles of all persons attending the training sessions.

These training records are maintained for 3 years from the date on which the training occurred.

3. *Administrative Records*

The Clinical Center is responsible for ensuring that employees with occupational exposure are identified, receive training initially and on an annual basis, are offered the hepatitis B vaccine, and, if indicated, receive the vaccine or sign a declination statement. Although not specifically required by the Federal standard, to centralize the tracking of compliance with the standard the Hospital Epidemiology Service will maintain a computerized database of Clinical Center employees covered by the Federal standard. The purpose of the database is to ensure that employees with occupational exposure have been identified, have received initial and annual training, and have complied with the hepatitis B

vaccine requirements of the Federal standard. A schematic of this administrative tracking mechanism is presented in Appendix G.

4. *Exposure Investigation Records*

Data on all reported occupational injuries and exposures to blood or other potentially infectious materials are collected by OMS. A standardized form is used and data are entered into a computerized database (see Appendix E). Summaries of these data (without identifiers) are presented to the Clinical Center Safety Committee and the Hospital Infections Committee.

5. *Availability of Records*

As required by the Federal standard, the Clinical Center will ensure that all records required to be maintained by the Federal standard will be made available upon request to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, for examination and copying.

Employee training records required by the Federal standard will be provided upon request for examination and copying to employees, to employee representatives, to the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, and to the Assistant Secretary of Labor for Occupational Safety and Health, in accordance with 29 CFR 1910.20.

Employee medical records required by the Federal standard will be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, and to the Assistant Secretary of Labor for Occupational Safety and Health, in accordance with 29 CFR 1910.20.

6. *Transfer of Records*

The Clinical Center will comply with the requirements involving transfer of records as required by the Federal standard. If the Clinical Center ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the Clinical Center will notify the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, 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.

F. Schedule of Implementation

The schedule for the Clinical Center's implementation of the applicable elements of the OSHA Bloodborne Pathogens Standard is included in Appendix H.

III. Procedure for Evaluation of Circumstances of Exposure Incidents

Exposure incident investigation is a necessary and effective technique for preventing future occurrences. When an exposure incident occurs it is vital that supervisors and employees take the opportunity to determine the causes of an incident and to determine how to eliminate them. This section of the Exposure Control Plan describes the incident investigation policies for the Clinical Center.

A. Exposure Incident Reporting, Evaluation and Follow-Up

- All exposure incidents must be reported to the OMS. OMS procedures for evaluating exposure incidents are included in Appendix E. These include documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred. All exposures involving HIV and all exposures in which a safety problem is identified are immediately reported to the Clinical Center Safety Officer for further investigation and follow-up. The form used by the CC Safety Officer for evaluating HIV exposures is also included in Appendix E. The Clinical Center Safety Officer receives a monthly report of all occupational injuries/exposures, and a quarterly report (without identifiers) is presented to the Clinical Center Safety Committee and the Hospital Infections Committee.
- For sharps injuries OMS procedures for evaluating exposure incidents include: the type and brand of device involved in the incident, the department or work area where the exposure incident occurred, and an explanation of how the incident occurred.
- Any hazards or problems identified through employee complaints, routine inspections, or exposure incident investigations are reported to the area supervisor and the Clinical Center Safety Officer. The Safety Officer will investigate the circumstances of the hazard or problem and ensure that corrective action is taken and documented.