



Indiana University Northwest
Environmental, Health & Safety

Title: (Bloodborne Pathogens) Exposure Control Plan

Applies To:
Indiana University Northwest

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Purpose

The purpose of this Exposure Control Plan is to:

- Provide a means by which to minimize or eliminate occupational exposure to bloodborne pathogens; and
- Comply with Indiana University safety and health policy and applicable OSHA standards.

Regulatory Reference

29CFR1910.1030, OSHA's Bloodborne Pathogens Standard.

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Grateful acknowledgment is made to the following Departments for providing us with their Exposure Control Plan: Research and the University Graduate School - Bloomington; Department of Environmental Health and Safety - IUPUI; Hospital Safety and Emergency Preparedness - IUPUI; and Department of Infection Control/Epidemiology-Wishard Memorial Hospital, Indianapolis; Office of Radiation, Chemical & Biological Safety-Michigan State University.

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1.0 Introduction

1.1 OSHA REGULATION

On December 6, 1991, the Occupational Safety and Health Administration (OSHA) promulgated a final rule entitled "Occupational Exposure to Bloodborne Pathogens" (see Appendix A). The purpose of this standard is to eliminate or minimize occupational exposure to the hepatitis B virus (HBV), human immunodeficiency virus (HIV), and other bloodborne pathogens. The schedule for implementation of the program elements is given in paragraph (i) (1-4) of the standard.

It has been well documented that employees with occupational exposure to blood and other potentially infectious materials containing bloodborne pathogens face a significant health risk. This risk can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, hepatitis B vaccination, warning signs or labels, and other provisions described in this plan.

1.2 DEFINITIONS

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 that 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.

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 of hepatitis B vaccination and post-exposure evaluation and follow-up sections of this program.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needless 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.

NWCME means the Northwest Center for Medical Education.

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 non-needle 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).

1.3 BLOODBORNE PATHOGENS OF CONCERN IN OCCUPATIONAL EXPOSURE

Hepatitis B virus and human immunodeficiency virus are the two bloodborne pathogens of greatest concern for occupational exposure. The elements of this exposure control plan shall also provide protection against other bloodborne diseases such as hepatitis C, syphilis, malaria, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, human T-lymphotropic virus type I, and viral hemorrhagic fever.

1.3.1 Hepatitis B Virus (HBV)

Hepatitis B virus infection is the major bloodborne occupational hazard to healthcare workers. Symptoms of the acute form of the disease may range from none, to mild flu-like symptoms, or to more severe symptoms including jaundice, extreme fatigue, anorexia, nausea, and abdominal pain. Outcomes of acute forms

of the infection may include hospitalization, weeks to months of work loss, and, in severe cases, death.

An estimated 6% to 10% of individuals infected with hepatitis B virus become chronic HBV carriers, capable of infecting other individuals. HBV carriers are at high risk of developing chronic persistent hepatitis, chronic active hepatitis, cirrhosis of the liver and primary liver cancer.

There are several ways in which the virus can be transmitted. The most efficient and common means of occupational transmission is parenteral, or the direct inoculation of infectious material by piercing through the skin barrier. In the workplace this might occur as a result of needlestick or other accidental injury with a sharp, contaminated object that is capable of penetrating the skin. Direct inoculation is also possible when preexisting lesions on hands from other injuries or from dermatitis provide a route of entry for the virus to enter the body.

A second mode of transmission is for infected blood to contact mucous membranes of the eye, nose, or mouth. Therefore, splashes of blood or serum into an individual's unprotected eyes or mouth in either clinical or laboratory settings pose a risk of infection. Hepatitis B can also be transmitted sexually, and perinatally (from infected mother to newborn infant). These modes of transfer indicate that occupational exposure to this pathogen can also have serious implications for the spouses, sexual partners, and families of infected individuals.

1.3.2 Human Immunodeficiency Virus (HIV)

HIV affects the immune system, leading to a wide range of clinical disorders, including AIDS, which usually lead to the death of the HIV patient. HIV is known to be transmitted through blood, semen, vaginal secretions and breast milk. Documented modes of transmission include:

- engaging in sexual intercourse with an infected person,
- using contaminated needles,
- having parenteral, mucous membrane or non-intact skin contact with HIV-infected blood, blood components or blood products,
- receiving transplants of HIV-infected organs or tissues,
- through blood transfusions,
- through semen used for artificial insemination, and
- perinatal transmission.

HIV is not transmitted by casual contact such as: shaking hands, talking, sharing of food, eating utensils, plates, drinking glasses, or towels, sharing the same household facilities, hugging, or casual kissing on the cheek or lips.

Occupational exposure to HIV may occur through the physical contact described above with an infected individual or with specimens from infected individuals, from parenteral exposure (accidents involving a needle, scalpel, or other sharp instrument or object which has been contaminated with blood or body fluids from HIV-infected individual), or by splashes of infected blood or other body fluids to the mucous membranes of the mouth, nose, or eyes.

1.3.3 Hepatitis C Virus (HCV)

Hepatitis C virus is transmitted from person to person in the same ways as the hepatitis B virus, though at considerably less efficiency. Though hepatitis C is more difficult to acquire than HIV or other forms of hepatitis, the disease has a greater tendency to evolve into a chronic infection than hepatitis B. This long-term infection can lead to liver cancer after many years.

HCV can produce symptoms of illness (fatigue, fever, decreased appetite, nausea and jaundice) after an average of six weeks of incubation, but up to half of the cases may have no symptoms. As neither the acute or chronic HCV infection respond reliably to any known treatment, prevention of the infection remains the most important control for this disease. Laboratory tests are available which can fairly reliably establish the presence or absence of HCV in the body.

1.3.4 Syphilis

Though usually considered to be a sexually transmitted disease, syphilis has been spread from person to person via blood exposure. The disease is caused by a bacterium that is capable of long-term residence in the body and can cause damage to blood vessels, brain and other organs if the infection is allowed to go untreated.

After a bloodborne exposure to syphilis, a sore may form at the site of the exposure that is commonly slow to heal. Four to six weeks later a flu-like illness often develops; fever, fatigue, sore throat, and a characteristic blotchy red rash are commonly seen. If the infection continues to go untreated, the disease begins to produce blood vessel and internal organ damage, often many years after the infection was acquired.

Detection of syphilis is possible through blood tests. Treatment is possible at any time in the development of the disease, but is easier in the earlier stages of the infection.

1.4 APPLICABILITY

The Bloodborne Pathogens Exposure Control Plan applies to all employees of IU-Northwest, including part-time, temporary, probationary, and employed students, who may as part of their jobs, come into contact with persons, unconditioned primate animals, or items which are infectious or potentially infectious for bloodborne pathogens.

Healthcare and laboratory employees whose work may involve the risk of exposure to blood or other potentially infectious materials may include, but are not limited to the following: physicians, surgeons, nurses, nurses aides, physician's assistants, pathologists, phlebotomists, medical technologists, medical assistants, therapists, therapy assistants, paramedics, emergency medical technicians, dentists, dental hygienists, dental assistants, dental lab technicians, laboratory and blood bank technologists, research laboratory personnel, research scientists, medical and dental teaching faculty, and animal laboratory personnel.

Others whose positions may include some occupational exposure tasks include workers in: law enforcement, sterilization services, janitorial/housekeeping services, laundry services, maintenance, central supply, equipment technicians,

transportation service workers, or couriers involved in delivery and transport of potentially infectious materials.

2.0 Exposure Control Plan Responsibilities

2.1 IU-NORTHWEST MANAGER OF ENVIRONMENTAL HEALTH & SAFETY

- Provide, with the assistance of the Biosafety Committee, overall administrative guidance and supervision for the Exposure Control Plan.
- Aid departments or sub-units in determining those employment positions or tasks that qualify for reasonable anticipation of exposure to bloodborne pathogens.
- Provide training to all employees who have potential occupational exposure to bloodborne pathogens.
- Aid departments or sub-units in determining appropriate personal protective equipment, work practices, engineering controls, and housekeeping schedules.
- Maintain a master file of employees trained in this program.
- Review and update the campus Exposure Control Plan annually and as new information becomes available (see Appendix L).

2.2 NORTHWEST CENTER FOR MEDICAL EDUCATION (NWCME)

- Provide the hepatitis B vaccination campus-wide to eligible employees at the expense of the employee's department.
- Evaluate employees reporting exposure incidents and provide appropriate diagnostic tests, treatment, and follow-up evaluation.
- Maintain employee records relative to the hepatitis B vaccination and post-exposure incidents and treatment.

2.3 DEPARTMENT HEADS, MANAGERS, AND SUPERVISORS

- Identify those employment positions within each department or appropriate sub-unit that fit the definition of "occupational exposure" described in Section 1.2 and specify those tasks or procedures in which occupational exposure is likely to occur.
- Customize the Exposure Control Plan for specific areas by adding appropriate information for each department or sub-unit in Appendices E, F, G, H, and I of this document.
- Enforce all elements of the Exposure Control Plan within the work setting and initiate progressive disciplinary proceedings when necessary as outlined by Human Resources Administration.
- Ensure that all existing and new employees are informed and trained in all elements of the Exposure Control Plan.
- Provide ongoing evaluation of the elements provided in Appendices E-I and update or modify them as needed to reflect current knowledge on effective infection control procedures, work practice controls, personal protective equipment and engineering controls which are likely to reduce the frequency of exposure incidents.
- Establish a program for evaluating sharps with safety devices designed to eliminate or minimize occupational exposure. This program should

include an identification process, an evaluation process, and a selection process (see Section 4.4).

2.4 EMPLOYEES

- Attend required training sessions on controlling exposure to bloodborne pathogens in the workplace.
- Comply with all elements of the Exposure Control Plan that apply to work-related tasks and procedures with potential exposure.
- Report all exposure incidents to work supervisors or other responsible individual immediately, or as soon as feasible, after they occur.

3.0 Exposure Determination

The Exposure Control Plan applies to all employees of IU-Northwest with potential occupational exposure. Each department shall list employment positions and tasks that create potential exposure (see Appendix E). Each department shall then identify their staff members who are a part of the employment positions listed or are required to complete any listed tasks. Staff members identified in this manner are a part of this Bloodborne Pathogens Program and must comply with all aspects of the Exposure Control Plan. This exposure determination shall be made without regard to the use of personal protective equipment. All employees must be notified concerning their occupational exposure status.

4.0 Procedures and Equipment for Reducing Exposure Risks

4.1 UNIVERSAL PRECAUTIONS

Universal precautions refer to approaches to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, or other bloodborne pathogens. These approaches recognize that there is no practical way to determine the health status of all patients who may be sources of bloodborne pathogens. Using this assumption when dealing with infectious materials eliminates the need for decision-making to determine the extent of actual or potential disease hazards and establishes minimum standards for contamination control that will effectively control bloodborne pathogens if they are present.

Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. In situations where differentiation between body fluid types is difficult or impossible (e.g. poor lighting, uncontrolled or emergency situations), all body fluids shall be considered potentially infectious materials.

4.2 ENGINEERING CONTROLS

Engineering controls include all measures designed to reduce the potential for contact between workers and potentially infectious materials by either removing the hazard or isolating the worker from exposure. Examples of engineering controls include puncture resistant sharps containers, plexiglass splash shields, mechanical pipettes, self-sheathing needles, biological safety cabinets, and use of disposable barrier materials to cover and prevent contamination of environmental

surfaces and equipment.

Appropriate engineering controls shall be provided by each department and should be used in preference to other control methods in order to limit occupational exposure (see Appendix F).

Engineering control mechanisms shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Each department or appropriate sub-unit shall be responsible for the evaluation and maintenance of engineering controls in their area (see Appendix F). These responsibilities shall include:

- Scheduling of inspections (Biological safety cabinets are to be certified at least annually according to the National Sanitation Foundation.).
- Written documentation of the following: inspection dates, evaluations, maintenance performed, and persons responsible.

4.3 WORK PRACTICE CONTROLS

Work practice controls are those measures that reduce the likelihood of exposure by altering the manner in which a task is performed. Specific work practices required in addition to those listed below should be specified for each department or sub-unit in Appendix G of their Exposure Control Plan. The following work practice controls shall be instituted for employees with occupational exposure to blood and other potentially infectious material.

4.3.1 Hand Washing

- Hand washing facilities that are readily accessible shall be provided for employees.
- When hand-washing facilities are not available, employees shall be provided with antiseptic towelettes or an antiseptic hand cleanser and clean cloth/paper towels. When these alternatives are used, employees shall wash their hands with soap and water as soon as feasible.
- Hands and any other exposed skin surfaces must be washed with soap and running water and mucous membranes should be flushed with water as soon as possible after contact with blood or other potentially infectious material.
- Hands must be washed as follows:
 - a) whenever there is visible contamination with blood or body fluids;
 - b) after completion of work;
 - c) after removing gloves and between glove changes;
 - d) before leaving the work area;
 - e) before eating, drinking, smoking, applying cosmetics or lip balm, changing contact lenses;
 - f) when using lavatory facilities; and
 - g) before all other activities which entail hand contact with mucous membranes, eyes or breaks in the skin.

4.3.2 Handling Contaminated Sharps

Any object that is contaminated with blood or OPIM and is capable of penetrating the skin is considered a contaminated sharp. Breakable equipment or supplies are potential sharps if they can create material capable of penetrating the skin.

Examples of sharps include needles, scalpels, broken capillary tubes, certain dental instruments, and exposed ends of dental wires. Needlesticks are an efficient means of transmitting bloodborne diseases. Because of their high potential for transmitting bloodborne pathogens to employees, contaminated sharps should be handled as follows:

- Contaminated needles and other contaminated sharps or potential sharps shall not be recapped, removed or bent unless no alternative is feasible or unless required by a specific medical procedure (e.g. procedures such as blood gas analysis, inoculation of a blood culture bottle, or administration of incremental doses of medication to a single patient).
- In situations where recapping or needle removal is required, it shall be accomplished only by means of a mechanical device or a one-handed technique.
- All contaminated sharps shall be transferred to rigid, puncture-resistant, labeled, leak-proof containers immediately or as soon as possible after use; they may not be stored or handled prior to decontamination in such a way as to require employees to reach their hands into the container to retrieve the item.

4.3.3 Other Work Practice Controls

- All procedures involving direct handling of blood or other potentially infectious material should be accomplished in a manner that minimizes splashing, spraying, spattering, or aerosol production of other potentially infectious material.
- Mouth pipetting/suction of other potentially infectious material and all other material is prohibited.
- Specimens of blood or other potentially infectious material must be placed in labeled containers that prevent leakage and are of sufficient strength to prevent expulsion during collection, handling, processing, storage, transport, or shipping. The following container requirements must be met:
 - a) These containers must be closed prior to storage, transport or shipping.
 - b) Biohazard labeling or color-coding is required on each container that leaves the university.
 - c) The specimen must be placed in a second container that meets the same provisions as above if the outside of the primary container becomes contaminated or if the specimen could puncture the primary container.
- Contaminated equipment must be decontaminated, if feasible, using approved methods prior to servicing or shipment. When such decontamination is not feasible, the equipment must be clearly labeled as a biohazard (see Section 9.0) to alert employees, as well as transportation and service personnel of the need to use universal precautions.
- Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in work areas where blood or OPIM are used or stored.
- Food or drink storage is prohibited in work areas (e.g. refrigerators, freezers, shelves, cabinets, counter tops, bench tops) where blood or OPIM are used or stored. Refrigerators or freezers used for storage of blood or specimens may not be used for storage of food or drink.

4.4 SHARPS INJURY PROTECTION PROGRAM

Supervisors of all departments who have employees with occupational exposure to bloodborne pathogens must consider and, where appropriate, use effective engineering controls, including safer medical devices, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments.

Supervisors must implement the safer medical devices that are appropriate, commercially available, and effective. An appropriate safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated.

Supervisors must establish a program for evaluating sharps with safety devices designed to eliminate or minimize occupational exposure. This program should include an identification process, an evaluation process and a selection process. The consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure must be completed on an annual basis and thoroughly documented.

Identification Process:

All sharp devices that have available products with safer engineering features shall be identified, evaluated and selected.

Evaluation Process:

1. Evaluation of the safer sharp devices must be documented on the "Safety Needle/Sharps Evaluation Form." See Appendix J.
2. Supervisors alone cannot identify, evaluate and select the safer sharps devices; supervisors must choose members of non-managerial employees who perform tasks with sharps exposure risks to be involved in this process.
3. Supervisors must determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product.
4. Supervisors will ensure that visual instructions and a demonstration of the proper use of each device is provided.
5. Supervisors will review the instructions and rating system on the evaluation form with each evaluator.
6. Supervisors should encourage each evaluator to comment on the forms. This will provide a useful decision making tool.
7. Supervisors will send (or fax) one copy of the completed evaluation forms to the EH&S office, and retain the original forms for their records.

Once the evaluation process is complete and the safer sharp device has been chosen, supervisors must implement use of the safer sharps devices as soon as possible.

If safer sharps devices are currently in use, the evaluation process must still be completed.

4.5 PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal protective equipment includes any item that the employee wears or uses on his/her person to provide barrier protection of the skin or mucous membranes from contamination by blood or other potentially infectious material. Examples include: gloves, gowns, lab coats, face shields, masks, eye protection, mouthpieces, resuscitation bags, pocket masks, and other ventilation devices.

The use of appropriate PPE is required as supplementary protection in all situations where occupational exposure remains after institution of both engineering controls and work practice controls. IU-Northwest requires the use of appropriate PPE for all employees when engaged in tasks involving contact with blood, body fluids, or any potentially infectious material for which occupational exposure is reasonably anticipated.

The only exception to this requirement shall be those rare and extraordinary occasions when, in the professional judgment of the employee, wearing of required PPE would have prevented delivery of health or public safety services or would have posed an increased hazard to the employee or coworkers. Such situations must be investigated and documented to determine whether such occurrences can be prevented.

4.5.1 Provision and Use of PPE

Each department or appropriate sub-unit shall determine appropriate types of PPE necessary to provide barrier protection for their employees (see Appendix H). Appropriate PPE shall be readily accessible to all employees for whom it is required and shall be provided in appropriate sizes.

The determination of the exact types of PPE is dependent on the procedure(s) being performed by each employee and the type and amount of exposure which is anticipated. PPE shall be judged as appropriate only if it does not permit blood or other potentially infectious materials to pass through 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 shall be used.

IU-Northwest Departments shall provide for the cleaning, laundering and/or disposal of all PPE at no cost to the employee. Only those items of clothing intended to protect the employee's person, work clothes, or street clothes against contact with blood or OPIM are considered to be PPE in this program (see Section 7.0).

4.5.2 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 and when handling or touching contaminated items or surfaces.

- **Glove Selection**

The type of gloves (e.g. sterile surgical, non-sterile examination, or utility gloves) selected should be impervious to liquids and strong enough to withstand the rigors of the task to be performed. Powder-free latex--or preferably vinyl--should be used to help avoid allergy problems. Skin

irritations/rash, especially if temporarily related to latex glove use, should be promptly evaluated at the Health Center (NWCME). Use of vinyl or latex gloves is intended to cover defects in the skin on the hands and is not intended to provide protection from puncture wounds caused by sharps.

The following guidelines are recommended by the Centers for Disease Control (Morbidity and Mortality Weekly Report, Vol. 24, 6/24/88):

- a) Sterile gloves should be used for procedures involving contact with normally sterile areas of the body.
 - b) Examination gloves should be used for procedures involving contact with mucous membranes, unless otherwise indicated, and for other patient care or diagnostic procedures that do not require the use of sterile gloves.
 - c) Surgical and examination gloves may not be re-used. Washing gloves with soap or detergents may cause enhanced penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration.
 - d) Use general-purpose utility gloves (e.g. rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, discolored, punctured, torn, or if there is other evidence of deterioration.
- o Changing Gloves
Gloves shall be changed under the following circumstances:
 - a) Between patient contacts.
 - b) If visibly contaminated with blood or body fluids (although certain repetitive tasks in laboratory settings may be completed before gloves are changed, i.e. wiping the probe on a whole blood analyzer).
 - c) When physical damage to the integrity of the glove is observed (e.g. tearing, surface defects).
 - o Contaminated disposable gloves should be discarded into a biohazard container immediately after removal.
 - o Employees with known minor skin defects (e.g. cuts, abrasions, burns, dermatitis, or exudative lesions) on arms, hands, face or neck must cover these areas with a water-resistant occlusive bandage in addition to the use of personal protective equipment.
 - o Employees with weeping or exudative lesions or dermatitis, which cannot be securely covered, shall refrain from direct patient care and handling clean or soiled patient equipment. (Indiana State Board of Health 410 IAC 1-4-8 Precautions).

4.5.3 Masks, Eye Protection, and Face Shields

These barrier devices are intended to protect the eyes, nose and mouth from coming into contact with blood or body fluid droplets. Examples are disposable facemasks, plastic or disposable face shields, protective eyeglasses with non-permeable side vents, and goggles.

Employees shall wear protective face shields or masks, and eye protection whenever splashes, spray, spatter or droplets of blood or OPIM may be generated

and eye, nose or mouth contamination can be reasonably anticipated. Plexiglass splash shields, either bench mounted or hung from the ceiling or from a ring stand, may be used in place of facial personal protective equipment. These protective devices shall be used while uncapping all blood or body fluid samples when the risk of droplet formation and spattering is present (e.g. when uncapping sample tubes).

Employees shall remove masks, eye protection, and face shields when leaving the work area. All disposable masks and shields shall be discarded in an infectious waste container when visibly contaminated or penetrated by blood or OPIM. Reusable eyewear and shields that are visibly contaminated should be washed with soap and water using gloved hands.

4.5.4 Protective Body Clothing

Protective body clothing, such as gowns, lab coats, lab jackets, or aprons, shall be provided when needed to cover and protect work clothing and exposed skin from contamination with potentially infectious blood or body fluids. Use of protective clothing may be required during patient treatment, when handling contaminated materials, or during decontamination procedures.

Protective gowns or laboratory coats may be made of cloth or of disposable impervious material depending on the degree and type of contamination that is anticipated. Protective clothing items should be long-sleeved and kept buttoned or fastened at all times to maximize protection of exposed skin and work clothes.

All protective clothing items shall be removed before leaving the laboratory or work area; contaminated or soiled gowns or coats may not be worn in public areas. Public areas include, but are not limited to, employee break rooms, lounges, eating areas, storage areas, and rest rooms. Protective clothing shall be changed immediately, or as soon as possible, after becoming visibly contaminated with blood or body fluids.

Contaminated gowns or coats shall be laundered or disposed of according to IU-Northwest Campus policy for infectious waste or contaminated linen (see Section 7.0). Disposable gowns shall be discarded in biohazard containers or bags. Protective clothing may not be taken home to be washed or discarded.

4.5.5 Cardiopulmonary Resuscitation Masks

Employees whose tasks include participation in cardiopulmonary resuscitation (CPR) shall use a one-way mask when performing mouth-to-mouth resuscitation. Masks shall be provided and made readily available wherever the need for CPR may be reasonably expected to occur. (Source: Indiana Department of Health 410 IAC 1-4-8)

4.6 HOUSEKEEPING

All work areas shall be maintained in a clean and sanitary condition. To ensure this, each department or sub-unit shall establish and implement a written schedule for specific cleaning and methods of decontamination for affected work areas (see Appendix I). Frequency and methods of decontamination should be based on the

location within the facility, the type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the work area. These schedules and instructions must be responsive to the following elements:

- All equipment and working surfaces must be cleaned, then decontaminated after contact with blood or OPIM.
- Contaminated work surfaces must be decontaminated with an appropriate disinfectant at the following times:
 - a) after completion of procedures;
 - b) immediately, or as soon as possible, after surfaces are overtly contaminated or after any spill of blood or OPIM; and
 - c) at the end of the work shift if the surface may have become contaminated since the last cleaning.
- Solutions that are acceptable disinfectants include, but are not limited to the following:
 - a) Sodium hypochlorite, five-tenths percent (0.5%) concentration, by volume (common household bleach should be diluted 1 part bleach to 9 parts water). The solution shall be dated and **SHALL NOT BE USED IF IT IS MORE THAN TWENTY-FOUR (24) HOURS OLD.**
 - b) Other chemical agents, which have an Environmental Protection Agency (EPA) registration number and that meet hospital level disinfection standards.
 - c) Only chemical agents that have an EPA registration number and a TB kill claim as required by CDC may be used in patient areas of the NWCME.
 - d) **REMINDER:** Isopropyl alcohol (rubbing alcohol) is no longer considered to be an acceptable disinfectant by the Indiana State Board of Health and therefore is not an acceptable disinfectant at Indiana University Northwest.
- The use of protective barrier coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper is useful in covering work surfaces or for covering equipment or items which may be difficult to clean and decontaminate effectively. When such barrier coverings are used, they must be removed and replaced as soon as they become overtly contaminated or at the end of the shift if they have become contaminated during the shift.
- All bins, pails, cans, or other receptacles which are re-used and which may become contaminated must be inspected and decontaminated on a regularly scheduled basis. These receptacles should also be cleaned and decontaminated immediately or as soon as possible once visible contamination is detected.
- Broken glassware that might be potentially contaminated should never be picked up with unprotected hands. Mechanical means such as a brush and dustpan, tongs, or forceps should be used. These items should then be disposed with contaminated sharps.
- Reusable sharps that are contaminated should not be stored or processed in such a way that employees are required to reach by hand into containers where these sharps have been placed.

4.7 CONTAINING AND HANDLING REGULATED WASTE

4.7.1 Contaminated Sharps Containers

- All contaminated sharps and potential sharps must be discarded immediately after use, or as soon as possible into containers which meet the following requirements:
 - a) closable and not able to be opened except by use of tools,
 - b) puncture-resistant,
 - c) leak-proof on bottom and sides to prevent leakage of contaminated liquids, and
 - d) labeled using the universal biohazard symbol and the word "biohazard" and/or color-coded in accordance with 29CFR1910.1030.
- Sharps containers must be easily accessible for use, maintained in an upright position during use, and replaced routinely so that they are not overfilled.
- When moving containers of contaminated sharps, the containers must be closed so that their contents do not spill or protrude.
- If leakage of the primary container is possible, it must be placed into a second container that is closable, labeled, and shall safely contain all contents without leaking.
- Reusable containers should not be opened, emptied, or cleaned manually or in any manner that would expose employees to the risk of injury.

4.7.2 Other Regulated Waste Containers

- Regulated waste shall be placed in containers that are closable and labeled using the universal biohazard symbol and the word "biohazard."
- Containers must be constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping. Containers must be closed prior to being handled, stored, or transported.
- If outside contamination of a regulated waste container occurs, it must be placed in a second container that meets the requirements stated above.

4.8 WASTE TREATMENT AND DISPOSAL

Infectious waste generated on campus may be autoclaved on site or collected in a biohazard container and transported for treatment. If waste is autoclaved, the container must be labeled as "treated" prior to disposal with general refuse. If an autoclave is unavailable for treatment on site, the department must handle collection and transportation and arrangements made for incineration.

5.0 HIV/HBV Research Laboratories

5.1 LABORATORY INCLUSION AND EXCLUSION

Any research laboratories or production facilities which are involved in the culture, production, concentration, experimentation, or manipulation of HIV or HBV must comply with the following OSHA special regulations affecting its activities in addition to the other requirements set forth in this plan. These regulations do not apply to clinical or diagnostic labs that are engaged solely in the analysis of blood, tissues, or organs.

5.2 SAFETY REQUIREMENTS FOR BOTH HIV AND HBV RESEARCH

AND PRODUCTION FACILITIES

5.2.1 Standard Microbiological Practices

These facilities shall comply with standard microbiological practices as set forth by the CDC for Biosafety Level 2 (BL2). All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving that is known to destroy bloodborne pathogens.

5.2.2 Special Practices

The following special practices shall also be instituted.

- Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.
- Contaminated materials that leave the site must be placed in durable, leak-proof, labeled containers that are closed before leaving the work area.
- Access to the work area shall be limited to authorized persons. Written entry and exit procedures and policies shall be established and implemented.
- Warning signs containing the universal biohazard symbol shall be posted on all access doors whenever potentially infectious materials or infected animals are present in the work area or containment module.
- All activities involving OPIM shall be conducted in biological safety cabinets or other physical-containment devices. No work with these OPIM shall be conducted on the open bench.
- Appropriate PPE must be used in the work area and animal rooms. PPE may not be worn outside the work area and must be decontaminated before being laundered.
- Gloves are required when handling infected animals or making hand contact with OPIM.
- Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters (or filters of equivalent or superior efficiency). Filters shall be checked routinely and maintained or replaced as needed.
- 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 (those in which the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Needles and syringes shall be handled with extreme caution at all times. Needles may not be bent, sheared, replaced in the sheath or guard, or removed from the syringe after use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.
- All spills shall be contained immediately and cleaned up by appropriate professional staff or by others who have been properly trained and equipped to work with concentrated potentially infectious materials.
- All spills or accidents that result in an exposure incident shall be reported immediately to the laboratory director or other responsible person.
- A biosafety manual shall be prepared or adopted and reviewed and updated at least annually. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures and shall

be required to follow them.

5.2.3 Safety Equipment

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices (e.g. special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, 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. Biological safety cabinets shall be certified when installed or when moved, and at least annually.

Each laboratory shall contain: readily available facilities for hand washing, an eye wash station, and an autoclave for decontamination of regulated waste.

5.3 SAFETY REQUIREMENTS FOR HIV AND HBV PRODUCTION FACILITIES

The following criteria shall apply to all HIV/HBV Production Facilities:

- Work areas shall be separated from areas 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.
- Surfaces of doors, walls, floors and ceilings in the work area shall be water resistant and easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.
- Each work area shall contain a sink for washing hands and a readily available eye wash station. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.
- Access doors to the work area or containment module shall be self-closing.
- An autoclave for decontamination of regulated waste shall be available within, or as near as possible, to the work area.
- A ducted exhaust-air ventilation system shall be provided which creates directional airflow that draws air into the work area through the entry area. 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.

5.4 TRAINING REQUIREMENTS

Employees in HIV/HBV Laboratories and Production Facilities are required to meet the following training criteria in addition to the training requirements of Section 9.3:

- Demonstrated proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility must be established before employees are allowed to work with HIV or HBV.
- Employees must have had prior experience in handling human pathogens

- or tissue cultures before working with HIV or HBV.
- Employees who have had no prior experience handling human pathogens shall be provided with a training program. Initial work experience shall not include handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. Employees shall not be allowed to participate in work activities involving infectious agents until after proficiency with such agents have been demonstrated.

6.0 Hepatitis B Vaccination/Screening

The hepatitis B vaccine shall be made available to all employees of IU-Northwest campus who are identified as having potential occupational exposure to bloodborne pathogens. HBV vaccinations shall be provided by the NWCME. Each employee's department will pay the vaccination expense.

Vaccinations shall be available to all existing employees of IU-Northwest campus with occupational exposure after receiving training regarding the risk of exposure to bloodborne pathogens and within 10 working days of initial assignment to jobs with occupational exposure. Vaccination is not indicated for employees who have already had the HBV series, who have had antibody testing documenting immunity to HBV, or who have medical contraindications to the vaccine. Pre-screening is not a prerequisite for receiving the vaccination.

Any employee who initially declines the recommended vaccination shall be required to read and sign the declination form provided by the NWCME (see Appendix B). Employees who decline the vaccination initially may elect to accept it at a later date if still employed in a position with occupational exposure.

7.0 Procedures for Spill Cleanup and Contaminated Clothing Handling

7.1 SPILL CLEANUP

The following steps shall be taken in cleaning up small (specimen-size, less than 100 ml or 4 oz.) spills of human blood or potentially infectious materials:

- Vinyl or rubber gloves shall be worn during spill cleanup.
- Sprinkle dry chlorine sanitizing compound on the spill to completely cover the spilled material. If dry chlorine compound is unavailable, place paper towels on the spill and pour only enough 10% bleach solution onto paper towels to cover them.
- Remove the residue and/or soaked paper towels with additional clean paper towels. Dispose of all residue and paper towels in an infectious waste container.
- Apply a final application of 10% bleach solution or hospital-approved tuberculocidal disinfectant to the spill area and clean up with paper towels.
- Remove gloves and wash hands.

7.2 CONTAMINATED CLOTHING HANDLING

Protective clothing is provided by the employer and is to be worn when it can be reasonably anticipated that contact might be made with human blood, body fluids,

or other potentially contaminated materials during performance of normal job duties. Therefore, contamination of personal clothing/uniforms should not occur.

In the unlikely event such contamination does occur, and since contaminated apparel cannot be taken home to be laundered, the employer will provide laundering of contaminated personal apparel. Staff should follow the following procedure.

- Remove clothing as soon as feasible after contamination and before leaving the area/location where contamination occurred. Contaminated clothing may not be worn in public areas which includes, but is not limited to, staff break rooms, lounges, eating areas, storage areas, and rest rooms.
- Apparel should be removed with a minimum of handling and minimum of agitation and placed in a properly labeled plastic bag that is to be closed while in the area/location in which the contamination occurred. Apparel should not be rinsed prior to being placed in bags.
- Clean skin that may have been contaminated with soap and water.
- Change into clean dry clothing.
- Contact your department's laundry cleaning vendor for a pickup as soon as possible.

8.0 Exposure Evaluation and Follow-up

8.1 MEDICAL EXAMINATION AFTER EXPOSURE

Exposure incidents are defined as any specific occupational incident involving eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials. Employees are required to report all exposure incidents to their work supervisor. Following a report of an exposure incident, the NWCME (or local emergency room physician) shall provide a confidential medical evaluation and follow-up to the employee.

Exposure incidents must be documented by the supervisor on an Occupational Injury-Illness Report form available in each department. This completed form shall be provided to the physician at the time of medical evaluation and shall include the following information:

- the route(s) of exposure,
- the circumstances under which the exposure incident occurred, and
- identification and documentation of the source individual if possible; whenever possible, and with consent of the individual, the source should be tested to determine HIV and HBV status unless it is already known. The results of these tests shall be disclosed to the exposed employee but may not be otherwise disclosed to preserve the confidentiality of the source individual.

8.2 COLLECTION AND TESTING OF BLOOD FOR HIV/HBV STATUS

The testing of the exposed employee's blood shall be done as soon as feasible after obtaining consent. If the employee consents to baseline blood testing, but not to HIV testing, the samples must be stored and preserved for 90 days. If within that time the employee consents to further testing, it shall be done as soon as possible.

8.3 POST-EXPOSURE PROPHYLAXIS AND FOLLOW-UP

The Northwest Center for Medical Education (or local emergency room physician) shall provide counseling to employees as part of the post-exposure treatment as well as medical evaluation of all reported illnesses following the exposure incident. When post-exposure prophylaxis is medically indicated, the Exposure Control Plan protocols for post-exposure prophylaxis to HBV or HIV shall be followed (see Appendix C).

A written evaluation of the exposure incident shall be provided to the employee within 15 days of the completion of evaluation (see Appendix D). The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

- That the employee has been informed of the results of the evaluation, and
- 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.

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

9.0 Biohazard Communication

9.1 LABELS

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material. Labeling also applies to other outer containers used to store, transport or ship blood or other potentially infectious materials. Labels are also required for equipment to be serviced or transported that has parts that are unable to be decontaminated. These labels must identify which portions of the equipment remain contaminated.

These labels must meet the following criteria:

- Include the biohazard legend depicted to the right.



- Have a fluorescent orange or orange-red colored background with lettering or symbols in a contrasting color.
- Be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

The following are exceptions to the labeling requirements:

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

9.2 SIGNS

Signs which are fluorescent orange or orange-red, with lettering or symbols in a contrasting color, and bearing the biohazard legend (see Section 9.1) shall be posted at the entrance to work areas for HIV and HBV research laboratories and production facilities. Also posted at the entrance to HIV and HBV research

laboratories, the following shall be prominently displayed:

- 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.

9.3 INFORMATION AND TRAINING

All employees with occupational exposure to bloodborne pathogens shall participate in a training program that shall be provided during working hours and at no cost to the employee. Training shall be provided to all existing IU-Northwest campus employees as part of the initial implementation of this plan and at least annually thereafter. New employees shall participate in a training program at the time of initial assignment to tasks where occupational exposure may take place. Additional training shall be provided when changes occur which affect the employee's occupational exposure. These include the modification of tasks or procedures or the institution of new tasks or procedures.

The training program shall be designed so that content and vocabulary are appropriate for the educational level, literacy, and language of employees. Training shall be conducted by an individual who is knowledgeable in the subject matter covered in the content of the training program. The content of the training program shall contain at a minimum the following elements:

- A copy of the standard and 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 IU-Northwest Exposure Control Plan and the means by which employees can access 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 practices 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 and vaccination shall be offered free of charge.
- Information on the appropriate actions to take and persons to contact regarding a personal exposure 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 the employer is required to provide for the employee following an exposure incident.
- An explanation of the signs and labels required by the Exposure Control

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

10.0 Recordkeeping

Appropriate records shall be kept for all employees with occupational exposure documenting HBV vaccination, exposure incidents, and training relative to occupational exposure to bloodborne pathogens.

10.1 MEDICAL RECORDS

The NWCME shall establish and maintain records for employees with occupational exposure for the duration of employment and 30 years after termination of employment.

10.1.1 Contents

All medical records of employees with occupational exposure to bloodborne pathogens shall include the following elements:

- the employee's name and social security number;
- hepatitis B vaccination status;
- copies of results of all exams, tests, and follow-up related to reported exposure incidents; and
- written medical opinion of post-exposure incidents.

10.1.2 Confidentiality

- All employee medical records shall be kept confidential.
- Medical records shall not be disclosed or reported without the employee's written consent to any person within or outside the workplace except as required by this plan or by law.

10.2 TRAINING RECORDS

The Manager of Environmental Health & Safety and each affected department shall maintain records of employees trained in this program.

All training records shall be kept for three (3) years from the date of training, and shall include the following information:

- dates of training sessions;
- names, and job titles of employees attending each session;
- contents or summary of training sessions; and
- name(s) and qualifications of trainer(s)

10.3 AVAILABILITY OF RECORDS

All employee medical and training records shall be provided upon request for examination and copying to the subject employee, to employee representatives (with written consent of subject employee), to the Director or Assistant Secretary of OSHA in accordance with 29 CFR 1910.20 or to the Indiana State Department of Health in accordance with 410 IAC 1-3-23.

Appendix A
Occupational Safety and Health Standards

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1030
Title: Bloodborne Pathogens
Appendix: A
Source: www.osha.gov
[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]

Occupational Safety & Health Administration
200 Constitution Avenue, NW
Washington, DC 20210

A copy of the latest OSHA Bloodborne Pathogens Standard is available online at www.osha.gov.
You may also request a copy of the text from the IUN Environmental Health & Safety office.

Manager of Environmental Health & Safety
Tamarack Hall
Indiana University Northwest
(219) 981-4230

Appendix B

Sample Consent/Declination Form

Northwest Center For Medical Education
3400 Broadway
Gary, Indiana 46408
(219) 980-6550

Consent/Declination Hepatitis B Vaccination

I, _____, authorize Dr. P.G. Iatridis or other authorized person at the Northwest Center Medical Services Corporation, to give the hepatitis B vaccine for the purpose of immunization against hepatitis B infection. I have been informed and I understand the benefits as well as the side effects of the vaccine, and to the best of my knowledge, I have no known allergies to yeast.

SIGNATURE

SS#

DATE

WITNESS

DATE

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

NAME

SS#

WITNESS

DATE

Appendix C

PROTOCOL FOR NEEDLESTICKS OR OTHER CONTAMINATED INJURIES

PROCEDURE

1. Make site bleed.
2. Wash the area thoroughly.
3. Notify supervisor/department head of the accident.
4. If puncture from needle or instrument associated with known patient who has:
 - A. **No history of hepatitis or syphilis:** Tetanus booster indicated if not current. The supervisor should fill out the Indiana University Occupational Injury-Illness Report and forward a copy to the NWCME. The employee should go to the NWCME (or local emergency room) during facility hours with a copy of the report.
 - B. **History or possibility of hepatitis:** Bring the incident report to the NWCME (or local emergency room) for consideration of prophylaxis with Immune Serum Globulin (ISG) or Hepatitis B Immune Globulin (HBIG) and for hepatitis B vaccine. The incident report should contain pertinent information. The NWCME (or local emergency room physician) will assist in collection of this information.
 - C. **History or possibility of syphilis:** If the patient has a positive VDRL, with or without primary or secondary syphilis, the supervisor should follow 4.A by filling out the incident report and having the exposed employee report to the NWCME (or local emergency room) for baseline VDRL. After 90 days, a VDRL will be repeated on the exposed employee.
 - D. **History or possibility of (+) HIV:** If the patient has a positive HIV or is in a high risk group, the supervisor should follow 4.A by filling out the incident report and having the exposed employee report within 30-60 minutes to the NWCME (or local emergency room physician) for evaluation. If the incident occurs after NWCME hours and it is a known exposure to HIV infection, the employee is to report to the emergency room of the local hospital within 30-60 minutes.
5. If the puncture wound is not associated with known patient (i.e., item found in linen or trash):
 - A. Do as in 4.A.
 - B. ISG 3cc is given and hepatitis B vaccine series initiated.
6. If questions arise concerning the proper procedure to follow, the NWCME (219-980-6551) or the IU Health Center (317-855-2850) should be consulted.
7. If the patient is known to be HBsAg positive:
 - A. It will be determined if the exposed employee has started and/or completed the hepatitis B vaccine series. If yes, see 10 below:
 - B. If the exposed employee has not been vaccinated, serum will be drawn and tested for HBsAg and HBsAb and they should receive prophylaxis with hepatitis B Immune Globulin (HBIG) and started on hepatitis B vaccine. This should be instituted within 24-48 hours.
 - C. If it is determined that the exposed person is HBsAb negative, the hepatitis B vaccine will be given again in one month and six months according to the standard recommendations.
 - D. If the exposed person is HBsAb positive, no further injections of HBIG will be needed.

8. If the source's hepatitis status is not known, the exposed employee will have serum drawn and tested for HBsAg and HBsAb and receive prophylaxis with ISG until results of the patient's hepatitis screening is available.
9. If the patient is HBsAg negative and HBsAb positive and has clinical evidence of active hepatitis, a GI or Infectious Disease consultation should be considered, if needed, to determine the risk of transmissibility. The risk of transmission of hepatitis virus to the fetus in the case of pregnancy will be explained.
10. Persons who have been immunized with hepatitis B vaccine must still report an exposure and be seen by the NWCME (or local emergency room physician). If an exposed employee has received one dose of the HB vaccine, HBsAb will be drawn and prophylaxis with HBIG will be given.

IF THE SOURCE PATIENT HAS AIDS OR OTHER EVIDENCE OF HIV INFECTION, DECLINES TESTING, OR HAS A POSITIVE TEST, THE EMPLOYEE SHOULD BE EVALUATED CLINICALLY AND SEROLOGICALLY FOR EVIDENCE OF HIV INFECTION AS SOON AS POSSIBLE AFTER THE EXPOSURE, AND, IF SERONEGATIVE, RETESTED AFTER 6 WEEKS AND ON A PERIODIC BASIS THEREAFTER (e.g. 3, 6, AND 12 MONTHS) FOLLOWING EXPOSURE, TO DETERMINE IF TRANSMISSION HAS OCCURRED. The employee will be informed of HIV prophylactic therapy as a treatment option. If the employee desires prophylactic treatment, this will be administered in consultation with the NWCME. During the initial follow-up evaluation, exposed employees should receive counseling about the risk for infection and to help them follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV. If the source patient is seronegative and has no other evidence of HIV infection, no further follow-up of the employee is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the patient was infected.

Since HIV-positive patients are also often in high-risk groups for syphilis and hepatitis B, it would seem prudent to follow existing recommendations for hepatitis B and possibly syphilis prophylaxis. The recommended post-exposure prophylaxis for acute percutaneous exposure to hepatitis B virus is found in the Indiana University Health Center Policy for control of hepatitis and through communication with the I.U. Health Center (317-855-2850).

HIV POST-EXPOSURE TREATMENT INFORMATION

Following a potential non-sexual exposure to the human immunodeficiency virus (HIV), a limited amount of scientific evidence suggest that the prompt use of anti-HIV medication(s) can slow or actually prevent the development of HIV infection in humans. After reading the following information, discuss these points and your situation with your healthcare provider before proceeding with treatment. Make sure all of your questions have been answered to your satisfaction.

Current (June, 1996) U.S. Public Health Service recommendations for HIV post-exposure drug treatment include the use of one, two or three drugs. Zidovudine, lamivudine and indinavir (or equivalent medications) may be used singly or in combination for post-exposure treatment, depending upon the likelihood of a person actually having been exposed to HIV and other factors. You have the right to decline any or all of the recommended drugs at any time, before or after treatment begins.

The best scientific evidence currently available suggests that post-exposure treatment for possible HIV infection is best started within one to two hours after exposure, and continued for four weeks. If you are unsure that you wish to commit to a four week course of treatment, you might consider at least starting the medications now so that you have a bit more time to consider your options. At this time, it is unknown just how long starting treatment can be delayed yet still offer some benefit. Beginning the treatment beyond one to two hours after exposure may slow but not prevent the establishment of HIV infection in the body.

Possible side effects of the medications noted above are as follows:

- Zidovudine: Gastrointestinal symptoms, headache, fatigue
- Indinavir: Gastrointestinal symptoms, abnormalities of liver function, kidney stones
- Lamivudine: Gastrointestinal symptoms, inflammation of the pancreas

With indinavir and lamivudine, the listed side effects have been observed only with HIV-infected persons, and may not apply to persons without active HIV infection. Further, there is no information regarding the long-term or delayed effects of treatment with any of these drugs in HIV-free individuals. During the latter 2/3 of pregnancy, limited trials of treatment with zidovudine suggest that this drug is not associated with serious or harmful effects in mothers or infants. The possible effect of any of these medications when given during the first three months of pregnancy is unknown. Potential side effects of lamivudine and indinavir when given at any time during pregnancy are unknown.

Before treatment is begun and at regular intervals afterwards, blood tests and clinic visits will be used to monitor for possible medication side-effects and the presence or absence of HIV infection. Your healthcare provider will discuss the tests and schedule with you today.

If it is likely that you were exposed to the human immunodeficiency virus, your healthcare provider will discuss with you the steps you can take to prevent the potential spread of HIV infection from yourself to other persons.

Remember that if your possible HIV exposure occurred at work and as a result of your usual work duties, today's and subsequent evaluations, clinic visits, medication(s) and laboratory testing will be supplied to you at no cost.

Appendix D

Physician's Evaluation Of Bloodborne Injury

Employee's Name _____ Date _____ Date of Injury _____

Employee's SSN _____

Description of Injury/Exposure:

EMPLOYEE:

History of Hepatitis B: Yes _____ No _____; History of +HIV: Yes _____ No _____
Previous Hepatitis B vaccination: Yes _____ No _____ 1 dose _____ 2 dose _____ 3 dose _____
Date completed _____ Booster (date) _____
HB AB/AG date _____ Results _____ HIV-AB date _____ Results _____
Anti-HCV date _____ Results _____
Liver function tests: Normal _____ Abnormal _____ Not Indicated _____ RPR _____

SOURCE PATIENT:

History of Hepatitis B: Yes _____ No _____; History of +HIV: Yes _____ No _____
Previous Hepatitis B vaccination: Yes _____ No _____ 1 dose _____ 2 dose _____ 3 dose _____
Date completed _____ Booster (date) _____
HB AB/AG date _____ Results _____ HIV-AB date _____ Results _____
Anti-HCV date _____ Results _____
Liver function tests: Normal _____ Abnormal _____ Not Indicated _____ RPR _____

RECOMMENDATIONS (After review of above data):

- _____ 1. No treatment because evaluation suggests you were very unlikely to be exposed to any disease.
- _____ 2. No treatment because you already have adequate immunity to Hepatitis B.
- _____ 3. H-BIG: _____ 1 dose _____ 2 dose at 28 days.
- _____ 4. Hepatitis B vaccine series (0-1-6 months) started _____
Reason(s) for Hepatitis B vaccine: _____
- _____ 5. Hepatitis B vaccine booster; Date: _____
- _____ 6. Recommended HIV follow-up: baseline, 6 weeks, 3-6-12 months
- _____ 7. HIV counseling: Yes _____ No _____
- _____ 8. AZT treatment: AZT 200 mg q4h X 2 weeks
Then AZT 100 mg q4h X 4 weeks

With baseline CBC, Chem-12, creatine kinase-
all repeated every 2 weeks

Started Date _____ Time _____

Physician _____ Date _____

NOTE: Under Indiana Code 16-1-9-5-7, it is unlawful for any person to disclose medical information involving a communicable disease without a release. Therefore, when consent is sought from a source individual, the source individual must be informed that the result will be released only to the exposed employee and the healthcare professional evaluating the employee after exposure. Positive HIV must be reported to ISBH.

If you did not give consent for HIV testing at that time your blood will be preserved for 90 days.

Appendix F
ENGINEERING CONTROLS

DEPARTMENT: _____

Check all that apply:

- _____ Puncture resistant sharps container
- _____ Isolation of hazard
- _____ Isolation of worker from hazard
- _____ Resuscitation bags
- _____ Biological safety cabinets
- _____ Use of disposable barrier materials to cover and prevent the contamination of surfaces
- _____ Plexiglass splash shields
- _____ Self-sheathing or retractable needles
- _____ Mechanical pipettes
- _____ Other (please list)

DEPARTMENT HEAD/SUPERVISOR

DATE

Appendix G

WORK PRACTICE CONTROLS

DEPARTMENT: _____

Check all that apply:

- Adhere to universal precautions
- Wash hands immediately after removing gloves
- Wash hands whenever visibly contaminated with blood or OPIM
- Wash hands before eating, drinking, applying cosmetics, contact lenses and leaving lab

Other work practices employed:

The following are prohibited:

- Eating/Drinking in affected areas
- Applying cosmetics/lip balm in affected areas
- Mouth pipetting
- Storage of food/drink in locations where blood and OPIM are kept
- Shearing and breaking of needles
- Recapping, removing or bending needles

Other work practices prohibited:

DEPARTMENT HEAD/SUPERVISOR

DATE

Appendix H

PERSONAL PROTECTIVE EQUIPMENT

DEPARTMENT: _____

- 1. Gloves a) sterile, b) non-sterile examination, c) utility
- 2. Face shields
- 3. Goggles
- 4. Masks
- 5. Gowns
- 6. Lab Coats

Other PPE (please list)

- 7.
- 8.
- 9.
- 10.

JOB CLASSIFICATION	PPE (NUMBERS LISTED ABOVE)

DEPARTMENT HEAD/SUPERVISOR

DATE

Appendix I

HOUSEKEEPING/DECONTAMINATION SCHEDULE

DATE	ITEM LAUNDERED	REMARKS

DATE	ITEM DECON.	REMARKS

DEPARTMENT HEAD/SUPERVISOR

DATE

Appendix J

Safety Needle/Sharps Evaluation Form

Evaluator's Name:
Department:
Supervisor's Name:
Name of Device:
Name of Manufacturer:
Applications of Device:
Number of Times Used:

Job Title:
Date:
Telephone #:

Please circle the most appropriate answer for each question. A rating of one (1) indicates the highest level of agreement with the statement, five (5) the lowest. Not applicable (NA) may be used if the question does not apply to this product.

Please explain all problems with the device in the comments section.

- | | Agree..... | Disagree |
|--|------------|----------|
| 1. The safety feature can be activated using a one-handed technique. | 1 2 3 4 5 | NA |
| 2. The user's hands remain behind the needle/sharp until activation of the safety mechanism is complete. | 1 2 3 4 5 | NA |
| 3. The safety feature does not interfere with normal use of this product. | 1 2 3 4 5 | NA |
| 4. Use of this product requires you to use the safety feature. | 1 2 3 4 5 | NA |
| 5. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated. | 1 2 3 4 5 | NA |
| 6. The device is easy to handle while wearing gloves. | 1 2 3 4 5 | NA |
| 7. The device is easy to handle when wet. | 1 2 3 4 5 | NA |
| 8. The device does not require more time to use than a non-safety device. | 1 2 3 4 5 | NA |
| 9. The safety feature operates reliably. | 1 2 3 4 5 | NA |
| 10. The exposed sharp is blunted or covered after use and prior to disposal. | 1 2 3 4 5 | NA |
| 11. The safety feature works well with a wide variety of hand sizes and with a left-handed person as easily as with a right-handed person. | 1 2 3 4 5 | NA |
| 12. Use of this product does not increase the number of sticks to the patient. | 1 2 3 4 5 | NA |
| 13. Sterilization (if applicable) of this device is as easy as a standard device. | 1 2 3 4 5 | NA |
| 14. The product does not require extensive training to be operated correctly. | 1 2 3 4 5 | NA |
| 15. The device can be used without causing more patient discomfort than a conventional device. | 1 2 3 4 5 | NA |

Would you recommend using this device?

Yes No

Comments:

Send one copy of this evaluation form to EH&S, Tamarack Hall, F02 or fax to EH&S at 219-980-6506. Retain the original form for your records.

Appendix K
Sharps Injury Log

**CONFIDENTIAL
OSHA RECORD**

Please complete a log for each employee exposure incident involving a sharp.

Name of Injured: SSN:
Name of Supervisor: Telephone:
Date of Birth: Male Female
Department: Building and area of injury:
Date of Injury: Time of Injury:

Fill in the square corresponding to the most appropriate answer.

Procedure:

- | | |
|--|---|
| <input type="checkbox"/> Draw venous blood | <input type="checkbox"/> Draw arterial blood |
| <input type="checkbox"/> Injection, through skin | <input type="checkbox"/> Cutting |
| <input type="checkbox"/> Suturing | <input type="checkbox"/> Unknown/Not applicable |
| <input type="checkbox"/> Other (please specify): | |

Exposure incident occurred:

- | | |
|--|--|
| <input type="checkbox"/> During the use of sharp | <input type="checkbox"/> Between steps of a multi-step procedure |
| <input type="checkbox"/> After use and before disposal of sharp | <input type="checkbox"/> While putting sharp into disposal container |
| <input type="checkbox"/> Disassembling | |
| <input type="checkbox"/> Sharp left, inappropriate place (table, chair, bed, etc.) | |
| <input type="checkbox"/> Other (please specify): | |

Body part(s) involved (check all that apply):

- | | | |
|--|------------------------------------|-------------------------------|
| <input type="checkbox"/> Finger | <input type="checkbox"/> Face/head | <input type="checkbox"/> Hand |
| <input type="checkbox"/> Torso | <input type="checkbox"/> Arm | <input type="checkbox"/> Leg |
| <input type="checkbox"/> Other (please specify): | | |

Identify sharp involved (if known):

Type:

Brand:

Model:

e.g. 18g needle/ABC Medical/"no stick" syringe

Engineered Sharps Injury Protection:

Did the device being used have engineered sharps injury protection?

- Yes No Don't Know

Was the protective mechanism activated?

- Yes-fully Yes-partially No

Did the exposure incident occur

- before, during, or after activation?

Exposed employee: If sharp had no engineered sharps injury protection, do you have an opinion that such a mechanism could have prevented the injury? Yes No

Explain:

Exposed employee: Do you have an opinion that any other engineering administrative or work practice control could have prevented the injury? Yes No

Explain:

Appendix L

RECORD OF ECP REVIEW/CHANGES

5/1992 8/1994	ECP plan established The addition of the Universal Precautions sign that is to be posted at all hand washing locations (App. G)	Feeney Williams
7/1995 7/1995	Corrected App. H Replaced old copy of the Fed. Register with new cleaner copy that could be read.	Manteuffel Manteuffel
7/1996	4.5 Housekeeping (bullet 3), sodium Hypochlorite...dilution.	Manteuffel
7/1997	Replaced Appendix A, C, & D with newly revised information.	Manteuffel
7/1998	Added 1.3.3 and 1.3.4 Added text to 4.4.2 Glove Selection re: allergies Changed 4.5 (b) to exclude Isopropyl alcohol as acceptable (not effective on bacteria) Changed text in Appendix C Re: HIV treatment options	Manteuffel Manteuffel
8/1999 8/2000	No Changes Changed title of Env'1 Compliance Manager to Manager of Environmental Health & Safety	Manteuffel Manteuffel
8/2000	Sections regarding post-exposure evaluation and follow-up changed to include local emergency room as alternate when physician not available at NWCME.	Manteuffel
8/2001 8/2002	No Changes Changed format, added definitions, added responsibilities in Section 2.3, new Section 4.4, new appendices J and K (to include requirements of 2001 OSHA update [Needlestick Safety & Prevention Act]).	Manteuffel Manteuffel
8/2003	No Changes	Manteuffel