

OSHA Title 29 CFR 1910.1030
Bloodborne Pathogen Standard
Exposure Control Plan

Frederick National Laboratory for Cancer Research (FNLCR)
SAIC-Frederick, Inc.

Revised 12/14/2012
Supersedes 11/01/10

Theresa D. Bell
Biological Safety Officer, EHS

Sarah L. Hooper
Manager, Occupational Health Services

APPROVED

Dr. Randall S. Morin
Director, Environment, Health and Safety

Date

BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

Table of Contents

	<u>Page No.</u>
Introduction.....	2
Purpose.....	2
Policy.....	2
Scope.....	2
Definitions	2
Responsibilities	5
Procedures	
I. Enrollment in Medical Surveillance Programs.....	9
II. Methods of Compliance.....	10
III. Special Requirements: HIV/HBV Research Laboratories and Production Facilities.....	13
IV. Communication of Hazards.....	16
V. Training and Education.....	16
VI. Hepatitis B Vaccination Program	17
VII. Accident Reporting	19
VI. Recordkeeping	20
 Attachments:	
A. Medical Surveillance Enrollment Form.....	21
B. Hepatitis B Declination Form	22

Introduction

The FNLCR is committed to the safety and health of its employees. In keeping with this philosophy, a comprehensive employee safety program has been established, an integral portion of which is this Bloodborne Pathogen Exposure Control Plan.

Purpose

The Bloodborne Pathogen Exposure Control Plan describes the policies which have been adopted by this institution regarding the prevention of the transmission of the Human Immunodeficiency Virus (HIV), the Hepatitis B Virus (HBV) and other bloodborne pathogens in the workplace. These policies, based on guidelines established by the Occupational Safety and Health Administration (OSHA) and the Maryland OSHA Code of Maryland Regulations (COMAR), are designed to eliminate employee occupational exposure to infectious agents.

Policy

Exposure to infectious agents represents a potential health hazard. It is the policy of the FNLCR that employees are entitled to information regarding the potential health hazards of any material used in their laboratories. This policy statement establishes a formal program to provide health and safety information and training in the proper handling of infectious agents in accordance with 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens. A copy of the OSHA standard can be obtained at the offices of EHS in Building 426 in accordance with the "Communications of Hazards to Employees" guideline, 29 CFR 1910.1030 (g) 2(vii). A copy of the OSHA Bloodborne Pathogen Standard can also be found at the OSHA website www.OSHA.gov

Scope

The Bloodborne Pathogen Exposure Control Plan encompasses all personnel who have occupational exposure to HIV, HBV and other bloodborne infectious diseases. The plan complements the Institutional Biosafety Committee (IBC) registration programs for human pathogens, human blood and body fluids, and recombinant DNA.

This plan applies to all personnel at the FNLCR who work with HIV, HBV, human blood, and other potentially infectious material. Additionally SAIC-Frederick employees located at offsite facilities that have an occupational exposure to blood-borne pathogens are also covered by this plan.

Definitions

- Blood: human blood, human blood components, and products made from human blood.
- Bloodborne pathogens: microorganisms that are present in human blood and can cause disease in. These pathogens include, but are not limited to, Hepatitis B Virus (HBV), Hepatitis C (HCV) and Human Immunodeficiency Virus (HIV).

- Contaminated: the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
- Contaminated sharps: means any contaminated object that can penetrate the skin (needles, scalpels, broken glass, broken capillary tubes, etc.)
- Decontamination: the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface (fomite) or item to the point where they are no longer capable of transmitting infection and the surface is rendered safe for handling, use, or disposal.
- Engineering controls: equipment or other items (e.g., sharps disposal containers, biological safety cabinets, self sheathing or retractable needles, safer medical devices and other containment enclosures that isolate the bloodborne pathogen's hazard in the workplace.
- Exposure incident: a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious material that results from the performance of an employee's duties.
- Occupational exposure: reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
- Other potentially infectious materials (OPIM):
 - i. Human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, or any body fluid that is suspect or visibly contaminated with blood and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; and
 - ii. Any unfixed tissue or organ from a human (living or dead); and
 - iii. HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV; and
 - iv. Culture medium or other solutions containing HIV, HBV or any other bloodborne pathogen; and
 - v. Blood, organs or tissues from experimental animals infected with HIV, HBV or any other bloodborne pathogen.
 - vi. Established human cell lines unless characterized to be free of bloodborne pathogens. Documentation of such verification is the responsibility of the primary investigator and must be provided to the Biological and Laboratory Safety Office, EHS.
- Parenteral: exposure to mucous membrane or non-intact skin barrier through events such as a needlestick, human bite, cut, or abrasion.

- Personal protective equipment: specialized clothing or equipment worn by an employee for protection against a hazard. Examples include: labcoat, gloves, eyewear, etc.,
- Production facility: an area established to provide industrial-scale, large-volume or high concentration production of HIV or HBV.
- Regulated waste: liquid or semi-liquid blood; 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; pathological and microbiological wastes containing blood or other potentially infectious materials.
- Research laboratory: any area producing or using any amount of HIV or HBV but not in the volume found in production facilities.
- Source individual: any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients, individuals who donate or sell blood or blood components, clients of drug and alcohol treatment facilities and clients in institutions for the developmentally disabled. Source materials may include cell lines, repository cell lines, and unfixed tissues or organs.
- Special medical waste (“Regulated”): liquid or semiliquid blood or OPIM; a contaminated article that releases liquid or semiliquid blood or OPIM if compressed, or that contains dried blood or OPIM and is capable of releasing the blood or material during handling; pathological and microbiological waste containing blood or OPIM; contaminated sharps and anatomical material.
- Standard Precautions: Infection control philosophy which expands the coverage of Universal Precautions by recognizing that any body fluid may contain infectious microorganisms.
- Sterilize: the use of a physical or chemical procedure to destroy all microbial life.
- Universal Precautions: all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens
- Work practice controls: controls that reduce the likelihood of exposure by altering the manner in which a task is performed (i.e., no recapping of needles).

Responsibilities

- I. Senior management is responsible for ensuring the implementation of the Bloodborne Pathogen Exposure Control Plan. All employees, including contractor and government employees, who meet the criteria in the OSHA standard are included in its provisions.

- II. The Director, Environment, Health and Safety is responsible for general administration of this program.
- III. The Manager, Occupational Health Services is responsible for vaccination (i.e. Hepatitis B) and medical surveillance programs, including post-exposure medical evaluation and follow-up.
- IV. The Biological Safety Officer, who also serves on the Institutional Biosafety Committee (IBC), is responsible for the registration of work involving pathogens, human blood and other potentially infectious material, recombinant DNA, or transgenic animals, determining which employees need to be enrolled in medical surveillance programs and the implementation of the Bloodborne Pathogen Exposure Control Plan.
- V. EHS is responsible for:
 - 1. assisting the investigator in the design of the laboratory and the selection of laboratory practices and engineering controls that ensure a safe working environment;
 - 2. providing technical guidance to any person responsible for matters pertaining to laboratory safety;
 - 3. inspecting laboratories to assess compliance with policies for the safe conduct of work involving infectious agents;
 - 4. investigating all reported accidents which result in the exposure of personnel or the environment to infectious agents and recommending corrective action to prevent recurrence;
 - 5. supervising decontamination procedures where accidents have resulted in contamination of laboratory areas;
 - 6. developing information and to educate and promote the safe handling of infectious agents and OPIM;
 - 7. performing a job hazard assessment to determine if medical surveillance programs are needed;
 - 8. maintaining a file of reference materials available to employees on the hazards, safe handling, storage, and disposal of infectious agents;
 - 9. determining when employee exposure monitoring may be required, and conducting such monitoring as needed;
 - 10. enrolling employees in various medical surveillance programs, as a result of a job hazard assessment/medical surveillance risk assessment;
 - 11. maintenance, approving, and incorporating revisions to this policy on an annual basis, in conjunction with OHS.

VI. OHS is responsible for:

1. coordinating with EHS and individual supervisors to determine eligibility of individuals for medical monitoring programs;
2. coordinating and reviewing all new Hepatitis B, Hepatitis C, HIV production worker and HIV Surveillance enrollment applications with EHS;
3. conducting baseline, periodic, and termination medical monitoring as indicated;
4. maintaining records of medical interventions and exposure incidents as directed by 29 CFR 1910.1030;
5. conducting comprehensive vaccination programs for identified biological hazards;
6. in the event of an exposure, conducting a confidential post-exposure medical evaluation and follow-up;

VII. The Manager, Facilities Maintenance and Engineering (FME), is responsible for overseeing a program of routine testing, certification and maintenance for certain equipment including:

1. biological safety cabinets upon installation, when relocated and at least annually thereafter;
2. emergency showers and eyewash stations are to be tested semi-annually.

VIII. Laboratory and department supervisors are responsible for:

1. acquiring the knowledge and information needed to recognize and control infectious agents in the laboratory;
2. registering all work with human pathogens, human blood or other potentially infectious materials and recombinant DNA. A list of all registered laboratories is maintained by EHS to identify areas where biohazards may exist. The responsible investigator completes the registration form, identifies the agent(s), the laboratory procedures, the employees working in the laboratory, and the specific EHS policies used and enforced. Program registration is approved for three years. Updates shall be submitted to EHS whenever changes in personnel, practices, facilities or equipment are made. Registrations will be renewed every three years upon submission of a completed current registration form;
3. in conjunction with EHS, selecting and employing laboratory practices and engineering controls that prevent or limit occupational exposure to infectious agents;
4. informing those supervised employees listed on the principal investigator's registration forms, of the potential hazards associated with the use of infectious agents used in the laboratory;
5. instructing employees in safe laboratory practices and the use of protective equipment, and in the procedures for dealing with accidents involving infectious agents;

6. supervising, implementing and enforcing the safety performance of the staff to ensure that the necessary and safe laboratory practices and equipment are used;
7. arranging for immediate medical attention by OHS and reporting to EHS any accident that results in a spill or exposure incident;
8. provide OHS and EHS with the following information: a description of the exposed employee's duties as they relate to the exposure incident, documentation of the route(s) of exposure and circumstances under which the exposure occurred, and results of the source individual or material's pathogenicity testing, if available;
9. assisting representatives of EHS in investigating accidents;
10. investigating and reporting to EHS any problems pertaining to the operation and implementation of laboratory practices or equipment;
11. ensuring the proper labeling of agents when they are removed from their primary containers;
12. ensuring that eyewash stations located in the lab or outside in the hallways with emergency shower stations are tested routinely;
13. notifying EHS of persons who are working with human pathogens, human blood or other potentially infectious material, who may require enrollment into medical surveillance programs;
14. informing emergency response personnel of potential hazards within a laboratory in the event of an accident, fire or any emergency situation;
15. completing each job requisition to document any infectious agents the employee could be exposed to and the biosafety level of the laboratory.

IX. Employees are responsible for:

1. practicing universal precautions to prevent contact with blood or other potentially infectious materials;
2. understanding and complying with EHS guidelines, regulations, and procedures required for the task assigned;
3. reporting unsafe conditions to the principal investigator, immediate supervisor, or EHS;
4. reporting to the principal investigator or immediate supervisor all facts pertaining to any accident resulting in exposure of personnel or the environment to biological agents;
5. following first aid procedures in the event of an exposure incident;
6. routinely testing eyewash stations located in their area;
7. reviewing and signing the program's SOPs to document that she or he understands and will follow recommended safety practices.

Procedures

- I. Enrollment in Medical Surveillance Programs (See attachment A)
 - A. Eligibility for appropriate medical surveillance programs and immunizations will be determined by the EHS Department guided by a review of job functions and the Pathogen Registry. Employees that may have occupational exposure to blood or OPIM are included in this program. These employees may include those in the following categories:

Animal Care	Protective Services
Laboratory Research	Occupational Health
Clinical Research	Repository
Clinicians	EHS
Production Technician	Student Intern
Service Worker	
 - B. Supervisors will complete a Medical Surveillance Enrollment Form on all new hires, transferring employees and annually on all current employees. The assessment should also be completed for employees working with newly registered pathogens, tissue or DNA. The form will detail job functions, exposure to animals, biological materials, chemicals, respiratory hazards, radiation and any other potential workplace hazards. This form will be reviewed by EHS to determine if the employee needs to be enrolled in a medical surveillance program.
 - C. Enrollment in a medical surveillance program will be documented in the OHM Health Manager Database.
 - D. The following are work functions in which occupational exposure to bloodborne pathogens may occur. Employees who perform any of the following functions should be considered for enrollment in the Bloodborne Pathogen Program:
 1. direct work with pathogens such as HIV or HBV
 2. direct work with blood, human tissue lines or OPIM
 3. inoculation of research animals with live HIV, HBV, or any bloodborne pathogen
 4. necropsy of animals experimentally infected with HIV, HBV, or any human bloodborne pathogen
 5. administration of first-aid during emergency responses to accidents or injuries
 6. direct patient care.
 7. direct handling of special medical waste.

II. Methods of Compliance

A. Universal Precautions will be followed by all personnel. All body fluids, as defined by this plan, will be considered potentially infectious materials.

B. Engineering Controls

1. The facilities and equipment at the FNLCR are designed and selected in accordance with the *FNLCR EHS Operations and Compliance Manual*, the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*, current edition and the *NIH Recombinant DNA Guidelines*, current edition.
2. Biological safety cabinets serve as primary barriers and are required for all work with known or suspected infectious materials. The selection of primary and secondary barriers is based on the pathogenicity of the agent, planned laboratory manipulations, and the potential for aerosolization.
3. Whenever possible and practicable new safety technology, such as shielded needles, self-sheathing needles, retracting needles or needleless systems, will be utilized.
4. Puncture resistant, labeled or color-coded, leakproof sharps containers, available from the warehouse, must be used for the safe disposal of needles and other sharps. No recapping, bending, breaking, or further manipulation of needles is permitted.
5. Needles and other sharps must not be jammed into the containers in such a way as to overfill the containers. Fill only to the indicated line on the container or until the container is 3/4ths full, whichever is less (Ft. Detrick Regulation 385-4, Management of Medical Waste, August 1, 1996).
6. All sharps containers must be securely closed before removal or disposal. Sealed sharps containers shall be clearly labeled and discarded as medical waste.
7. If outside contamination of the primary container occurs, or if the specimen could puncture the primary container, then the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of the OSHA Bloodborne Pathogen standard.
8. EHS reviews purchase requests for certain laboratory engineering controls such as biological safety cabinets and chemical fume hoods. Monitoring of facility design and the certification of engineering controls is performed by FME in conjunction with EHS via site visits, inspections, and preventive maintenance.
9. Laboratory renovations and construction plans are reviewed by EHS to ensure appropriate design, placement of biological safety cabinets, containment, traffic patterns, etc.

C. Work Practice Controls

1. Emphasis is placed on safe laboratory practices and techniques to minimize the risk of exposure to pathogens in the workplace. Safetygrams and the FNLCR EHS Operations and Compliance Manual detail safe laboratory practices.

2. Handwashing facilities must be provided in all laboratories. Washing is an effective means of physical removal and dilution of infectious agents. Immediately after an exposure incident to skin or mucous membranes has occurred, employees must wash affected area with soap and water and/or flush mucous membranes with copious amounts of water.
3. Employees must wash their hands immediately after removal of gloves or other personal protective equipment.
4. The use of scalpels and glass pipettes in laboratories is strongly discouraged. Plastic tubes and pipettes or safe sharps such as knives with retractable blades are recommended
5. PIPETTING BY MOUTH IS NOT PERMITTED *
Mouth pipetting is not permitted except for work involving certain embryologic procedures using special apparatus with two in-line filters and after special permission is granted by the Biological Safety Officer.
- 6.. Eating, drinking, smoking, applying cosmetics, handling contact lenses is prohibited in laboratory work areas.
- 7.. Food and drink must not be stored in laboratory refrigerators, freezers, shelves, cabinets or on countertops/benchtops.
8. All procedures involving blood or OPIM shall be performed in a biological safety cabinet if there is potential for splashing, spraying, spattering, or generation of droplets or infectious aerosols.
9. Specimens of blood or OPIM shall be placed in containers that prevent leakage during collection, handling, processing, storage, transportation, or shipping. Relevant state and federal regulations will be followed.
10. Equipment will be decontaminated and tagged in accordance with FNLCR internal SOP "Equipment Decontamination and Safety Clearance" before repair or service by FME or an outside contractor.

D. Personal Protective Equipment (PPE):

1. PPE such as Gloves, labcoats, face shields or masks, respirators, scrubs, and safety eyewear and footwear will be provided.
2. Appropriate PPE is provided for employee use where there is occupational exposure. PPE will be considered appropriate only if it does not permit any potentially infectious material to pass through onto clothing, skin, eyes, mouth, or other mucous membranes. Minimal PPE to be worn is determined by the organisms and chemicals that are used, methods of use, and the biological containment level. Additional PPE may be required by the specific SOPs of the program.
3. The employer shall insure that appropriate PPE is in the appropriate sizes and is readily accessible at no charge to the employee.

4. If a garment has been penetrated by blood or OPIM, the garment shall be removed immediately. All PPE must be removed before leaving the work area.
5. Gloves must be worn when the employee might have skin contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, or when handling contaminated items or surfaces. Any glove must be replaced when torn, punctured, or when the ability to function as a barrier is compromised. Disposable gloves shall not be reused.
6. Masks, eye protection, and/or face shields will be worn whenever splashes, spray, spatter, or droplets of potentially infectious materials may be generated.
7. Gowns, aprons, and other protective clothing will be worn as dictated by the tasks performed and the degree of exposure anticipated.
8. Surgical caps, head protection, and shoe covers will be worn in instances when gross contamination might reasonably be anticipated.

E. Cleaning, Disinfection, and Decontamination

1. The BSL-1 and BSL-2 laboratories are maintained and cleaned routinely by custodial services. Laboratory personnel are responsible for cleaning and maintenance in BSL-3 suites. Appropriate disinfectants are determined based on the particular agent involved and the type of surfaces to be cleaned or decontaminated. Work surfaces in laboratories will be decontaminated at the beginning and end of each work day and whenever there is an overt spill. Protective coverings on work surfaces (plastic wrap, aluminum foil, or plastic-backed absorbent paper) should be changed regularly and whenever contaminated. Reusable receptacles (bins, pails, cans) will be decontaminated regularly by the laboratory staff. Red-banded cans used for the disposal of special medical waste will be decontaminated immediately upon visible contamination.
2. The safety clearance/work authorization tag system shall be used to assure proper decontamination of equipment and instrumentation before repair. EHS or other authorized personnel will sign all tags when biological materials, infectious agents, human blood or other potentially infectious materials have been used.
3. Infectious Waste Disposal - Special Medical Waste
A special medical waste program has been developed in coordination with the U.S. Army Garrison which meets all federal and state requirements. BSL-3 labs must autoclave or otherwise render non-infectious all waste before it leaves the area. Laboratory waste known to be or potentially contaminated with infectious material is special medical waste and will be decontaminated, autoclaved and/or incinerated. Special medical waste is placed in red-banded receptacles and transported by the Army to the incinerator. Puncture proof needles/sharps disposal containers are used throughout the facility. All sharps containers must be securely closed before removal or disposal. Sealed sharps containers shall be clearly labeled and discarded as medical waste.

4. Contaminated laundry (uniforms, towels, clothing) when removed in the laboratory, should be placed in appropriate containers and autoclaved before being sent for cleaning. Care will be taken in handling the unautoclaved articles (e.g., holding them away from one's clothing) so as not to cause further contamination.

III. Special Requirements for HIV/HBV Research Laboratories and Production Facilities

- A. This applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. This does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.
- B. According to 29 CFR 1910.1030(e), all HIV and HBV research laboratories and production facilities shall follow these additional requirements:
 1. The work practice controls, personal protective equipment, decontamination procedures and special medical waste handling as described in this policy.
 2. Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.
 3. Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before removal from the work area.
 4. Access to the work area shall be limited to authorized persons. Authorized persons shall comply with entry/exit procedures, understand the potential biohazard and meet any specific entry requirements.
 5. A biohazard warning sign shall be posted on all access doors whenever work with bloodborne pathogens, OPIM or infected animals are in progress.
 6. All activities involving bloodborne pathogens, and/or OPIM shall be conducted in biological safety cabinets or other physical containment devices within the containment area. No work with these materials shall be conducted on an open bench.
 7. Appropriate protective clothing shall be used in the work area and animal rooms. All protective clothing must be removed prior to leaving the laboratory and hands shall be washed immediately upon removal of gloves.
 8. Avoid skin contact with blood and OPIM. Gloves shall be worn when handling infected animals, bloodborne pathogens and OPIM.
 9. Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters that are hydrophobic on the inlet side. Filters shall be checked routinely and replaced as necessary.

10. Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Whenever possible and practicable new safety technology, such as shielded needles, self-sheathing needles, retracting needles or needleless systems, will be utilized. Needles shall not be bent, sheared, resheathed or removed from the syringe following use. The needle/syringe unit shall be placed promptly in an approved sharps container and decontaminated before disposal.
 11. Spills shall be appropriately contained and cleaned up by personnel trained and equipped to work with bloodborne pathogens and OPIM.
 12. A spill or accident resulting in an exposure incident shall be reported immediately to OHS, the laboratory supervisor or the Principal Investigator.
 13. A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, required to read instructions on practices and procedures and shall be required to follow them.
 14. Containment equipment (such as certified biological safety cabinets, respirators, centrifuge safety cups, special protective clothing, and containment caging for animals) shall be used for all activities with bloodborne pathogens and OPIM that pose a threat of exposure to droplets, splashes, spills or aerosols.
 15. Biological safety cabinets shall be certified when installed, whenever they are moved, and at least annually.
- C. HIV and HBV research laboratories are required by 29 CFR 1910.1030(e)(3) to follow these additional requirements:
1. Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.
 2. An autoclave for decontamination of regulated waste shall be available.
- D. HIV and HBV production facilities as outlined in 29 CFR 1910.1030(e)(4), shall also:
1. Work area shall be separated from areas that are open to unrestricted traffic flow within the building with a self-closing, double-door airlock or change room.
 2. Work surfaces, doors, ceilings, floors, and walls shall be water-resistant for easy cleaning. Penetrations in these surfaces shall be easily sealable for easy decontamination.
 3. Each laboratory shall contain a facility for hand washing and an eye wash facility that is readily available within the work area. The sink shall be elbow, foot or automatically operated and shall be located near the door of the work area.
 4. All regulated waste shall either be incinerated or decontaminated by an autoclave. An autoclave shall be available within or as near as possible to the work area.

5. A ducted air ventilation system shall be provided. This system shall create 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. Proper directional airflow shall be verified.
6. Access doors to the work area shall be self-closing.

E. Additional Initial Training:

1. Employees working in HIV and HBV research laboratories and production facilities must demonstrate proficiency in standard microbiological practices and safe techniques before working with HIV or HBV. It is the responsibility of the manager, program director, and supervisor to provide training on safe handling techniques and practices. Only after proficiency has been demonstrated may the employee participate in work activities involving infectious agents.
2. Each employee working in an HIV and HBV research laboratory or production facility must submit to EHS, through their supervisor, an Additional Initial Training Form to indicate their experience and/or proficiency in handling pathogenic materials. The form can be obtained from EHS.
3. Employees with Lesions or Impaired Skin Integrity:
 - a. The following statement addresses the findings of the IBC HIV Subcommittee regarding the Morbidity and Mortality Weekly Report (Vol. 36, No. 2S Supplement, August 21, 1987) "Prevention of HIV Transmission in Health Care Settings".
 - b. Since it is understood that health care workers also wear gloves under conditions where contact with blood or body fluids is anticipated, it is clear that lesions on the hand automatically prevent an individual from handling materials or equipment which contain or may contain infectious virus. The reason for this is to protect even against the low probability occurrence of defective gloves or the inadvertent penetration of the gloves by virus-containing fluids. In contrast to the health care workers, there should be no circumstance in the laboratory where direct contact with infectious material is anticipated. Under BSL-3 conditions, automatic prohibition from working in a BSL-3 laboratory should be limited to lesions of the hands, face, or neck. For employees with lesions or impaired skin integrity, the judgment on whether a worker may work (or return to work) is the responsibility of OHS. To decide if the lesion will prevent an individual from handling material or equipment which contain or may contain an infectious virus, this requires an expert medical opinion and is not a matter for the affected individual or their supervisor to decide independently. The judgment must be made with safety as the overriding factor.

IV. Communication of Hazards

A. Warning Labels

Warning labels with the fluorescent orange-red biohazard symbol with contrasting lettering or symbols shall be affixed to containers of regulated waste: to refrigerators and freezers which contain human pathogens, human blood or other potentially infectious material; and other containers used to store, transport or ship human pathogens, human blood or OPIM.

1. Required labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
2. Individual containers of blood or OPIM that are placed in a labeled container for storage, transport, shipment, or disposal are exempt from the labeling requirement.
3. Regulated waste that has been decontaminated does not need to be labeled or color-coded.
4. Red bags or red containers may be substituted for labels.
5. Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

B. Signs

The biosafety containment level is determined by the biological agent, its concentration, and the laboratory manipulations planned. A biohazard sign with the fluorescent orange-red biohazard symbol indicating the containment level, the responsible investigator, the supervisor, their phone numbers, and the required PPE must be posted at the entrance to work areas.

V. Training and Education

- A. All employees working in areas of potential occupational exposure must complete bloodborne pathogen training sponsored by EHS. Training shall be provided at the time of initial assignment and annually thereafter. Documentation of attendance shall be maintained by the EHS.
- B. Training shall include: information on prevention of exposure, the epidemiology and symptoms of bloodborne diseases; the modes of transmission of bloodborne pathogens; methods for exposure determination; use and limitations of engineering controls; work practices; PPE; information on the types, use, selection, removal, handling, decontamination, and disposal of PPE; appropriate use of biohazard signs; and information on the availability, efficacy, safety, and information on the Hepatitis B vaccine.
- C. Training shall also include information on the appropriate action to take and persons to contact in an emergency (e.g., a spill) involving blood or other potentially infectious materials. Emergency first-aid, methods of reporting the incident, and medical follow-ups shall be stressed. Information on post-exposure evaluation and follow-up, which the employer is required to provide, is included.

- D. The employee's supervisor, manager, and/or program director are responsible for reviewing with the employee all specific intra- departmental safety policies and procedures as well as expectations of compliance. This information must be reviewed and updated annually. Individual programs are responsible for maintaining documentation of this requirement. Additional training must be provided when tasks or procedures are modified or instituted thereby affecting the occupational exposure of the employee.

VI. Hepatitis B Vaccination Program

A. Introduction

Infection by Hepatitis B virus (HBV) is the most frequent occupational risk among health care workers. The significant factors for nosocomial infection are the intensity of exposure to human blood and the duration of that exposure. The Centers for Disease Control and Prevention (MMWR 55:RR-16, December 8, 2006) recommends that health care workers who may potentially have contact with human blood or blood products be vaccinated against HBV. Immunization should take place as early in their careers as possible. OSHA regulations require employers to identify employees who may have occupational exposure and to offer them the hepatitis B vaccine within ten working days of their initial assignment.

1. The Hepatitis B vaccination shall be made available after the employee has received the training and within 10 working days of initial assignment and to all employees who have occupational exposure unless the employee has previously received the Hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccination is contraindicated for medical reasons.
2. If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

B. Eligibility

1. Any workers who have reasonably anticipated contact with blood or OPIM during performance of their jobs are considered to have occupational exposure and to be at risk of being infected. The standard requires employers to offer the vaccination series to all workers who have occupational exposure. The vaccine and vaccination must be offered at no cost to the worker and at a reasonable time and place.
2. HBV infection in pregnant women may result in severe disease for the mother and a markedly increased risk of chronic infection for the fetus. Unvaccinated pregnant women with possible occupational exposure should be strongly encouraged to begin the vaccination series.

C. Enrollment

Supervisors must complete a medical surveillance enrollment form (MSEF) at the time of hire, transfer, reassignment, when new pathogens, tissue or DNA are registered. (see attached form) The MSEF should also be completed if at any time an employee's work functions changes to include possible exposure to blood, blood products or potentially infectious materials. EHS will

review job functions, the risk assessments, and appropriate pathogen registries to determine if the employee should be enrolled in the Bloodborne Pathogen Program. If the employee is enrolled in the Bloodborne Pathogen Program, they will receive the required training and will be offered the Hepatitis B vaccine within 10 working days of initial assignment.

D. Declination/Exemption

1. Employees who elect not to receive Hepatitis B vaccination will be required to sign a declination form indicating their understanding of the associated risks. *See attached form.*
2. If the employee initially declines the Hepatitis B vaccination, but at a later date decides to accept the vaccination, the Hep B vaccine will be made available.
3. The only employees who are exempt from this requirement are those who provide acceptable documentation of completion of a properly administered 3-vaccine immunization series and subsequent immune antibody titer. The employee is required to sign an exemption form (see attached).

E. Administration of the vaccination series

1. The vaccination series consists of three intramuscular injections administered into the deltoid muscle. The first dose is administered at the time of enrollment in the program. The second and third doses are usually administered one and six months after the first dose.
2. If an accelerated schedule is needed, the minimum interval between the first two doses is 4 weeks and the minimum interval between the second and third doses is 8 weeks. However, the first and third doses should be separated by no less than 16 weeks. A booster is given at 12 months to complete the accelerated series.
3. Doses given at less than these minimum intervals should not be counted as part of the vaccination series. It is not necessary to restart the series or add doses because of an extended interval between the doses.

F. Serologic monitoring

1. For employees who provide documentation of a previously completed and properly administered hepatitis B immunization series, an initial serologic screen for hepatitis B surface antibody may be performed. If a protective titer is indicated in an employee who previously completed the vaccination series, the employee will not need to receive the vaccination series. An exemption form is signed. (See Attachment B).
2. Participants completing the Hep B series will be serologically screened for hepatitis B surface antibody 4-8 weeks after administration of the 3rd dose of vaccine. If the employee fails to develop a protective antibody titer, the vaccination series will be repeated one time. Employees who fail to develop a protective antibody titer following two complete vaccination series will be counseled regarding their risk in the event of an exposure and referred to their primary care physician for further serologic and evaluation.

VII. Accident Reporting, Post Exposure Evaluation and Follow-up

A. Potential Exposure incident at FNLCR at Ft. Detrick or offsite facilities in Frederick (Government and SAIC-Frederick Employees):

1. Immediately following a potential biological, chemical, or radiological exposure the employee is to perform immediate first aid at the worksite, notify the supervisor and report to OHS. OHS staff immediately notifies EHS staff of every potential exposure incident.
2. OHS staff are on-call 24 hours a day for post exposure response. During posted office hours of Monday through Friday 8:15 AM – 5:00 PM the employee is to report in person at OHS, Building 426, on the FNLCR Campus, x1096. After hours, the employee must contact Protective Services, x1091 for the on-call OHS health care provider who will meet the employee at OHS if indicated.
3. The OHS health care provider will perform a medical evaluation which includes a detailed history obtained from interviews with the employee supervisor, EHS personnel, and may consult with the following: Medical Consultant, Infectious Disease Physician.
4. The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.
5. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be banked for at least 90 days. If, within the 90 days of exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.
6. Identification of source shall be documented, unless identification is not feasible. The source's blood shall be tested as soon as feasible after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and results documented.
7. Post exposure prophylaxis, if indicated, will be provided to the employee within 2 hours of the incident. Selection of the appropriate post exposure prophylaxis will be based on the most current CDC or ID consultant guidelines established for OHS practice. (See Post Exposure Protocol)
8. Results of the source individual's testing shall be made available to the exposed employee and the employee shall be informed of applicable laws and regulations concerning disclosure of identity and infectious status of source individual.
9. Post exposure baseline and follow-up testing of the source and the employee will be provided as indicated and described in the following attachment on an individual basis. Detailed risk counseling is provided by the OHS clinician and referral to the Employee Assistance Program is provided. OHS records and maintains the OSHA Sharps log for those exposure incidents meeting recordability criteria

B. Potential exposure of SAIC-Frederick employees at offsite facilities not located in Frederick:

Response to potential exposure incidents that occur at off-site facilities outside of the immediate Frederick Area will be performed by the nearest available medical center. Off-site facilities include those located in Gaithersburg, Shady Grove, Rockville, and nearby areas. Incidents occurring in laboratories located between Bethesda and Frederick should report to Shady Grove Hospital or Suburban Hospital for post exposure assessment and treatment. Telephonic notification is made to OHS at the FNLCR as soon as possible.

C. Potential exposure of SAIC-Frederick employees occurring on the NIH campus :

Exposures shall be immediately reported to Occupational Medical Services (OMS) in Building 10. The staff of OMS will make a determination as to disposition. Telephonic notification is made to OHS at the FNLCR as soon as possible.

VIII. Recordkeeping

A. Medical Records

1. An electronic medical record will be maintained by OHS of all individuals with occupational exposure. The medical record will be kept for the duration of employment plus thirty (30) years.
2. The employee will be provided a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.
3. OHS follows Maryland State Law with regards to reporting test results of communicable diseases. This information must be kept strictly confidential. No information will be disclosed or reported without the written consent of the employee, except where required by law.

B. Training Records

Records will be maintained for three (3) years from the date of the training. The records will include an outline or summary of the information presented and the dates of the training sessions. Records will also include the names and lab of all persons attending the training sessions. Those attending a live session will sign an attendance sheet. Training is also available online through the FNLCR training portal.

C. Sharps Injury Log

If an exposure involving a needlestick occurs, OHS will maintain a sharps injury log. That log will be maintained in a manner that protects the privacy of the employee. The log will contain information regarding the type and brand of device involved in the incident, the location of the incident, and description of the incident.

EHS Medical Surveillance Enrollment Form

SUPERVISORS: Please complete this form for all employees and submit to EHS.

Please print when completing this form

Employee Name: _____ Employee#: _____

New Hire (Start Date _____) Annual Update Job Transfer

Job Title: _____ Assigned Bldg/Rm: _____

Supervisor: _____ Supervisor: _____ Date: _____
Printed Name Signature

Job Hazard Assessment

(Call EHS at 301-846-1451 for guidance to complete this form).

JOB CATEGORY (Department or function)

- Administrative Functions Only (not in a lab) Administrative functions in non-office setting
- FME Service Staff FME Laboratory Staff Protective Services EHS/OHS Driver
- Health Care Staff Direct contact w/ Animals Non-Human Primate Handler Warehouse/Mailroom
- Other _____

BIOLOGICAL HAZARDS

IBC REGISTRATION #(S) : _____

HUMAN MATERIALS:

- Blood Body fluids
- Tissues Cell Lines (human)

NON-HUMAN PRIMATE MATERIAL:

- Blood Tissues Other _____

INFECTIOUS MATERIALS:

- | | | |
|--|---|------------------------------------|
| <input type="checkbox"/> Adenovirus | <input type="checkbox"/> Adenovirus + HIV | <input type="checkbox"/> Influenza |
| <input type="checkbox"/> HIV-1 | <input type="checkbox"/> Herpes Simplex | <input type="checkbox"/> Rabies |
| <input type="checkbox"/> HIV-2 | <input type="checkbox"/> Lentivirus | <input type="checkbox"/> Vaccinia |
| <input type="checkbox"/> HTLV-1 | <input type="checkbox"/> Polio | <input type="checkbox"/> Varicella |
| <input type="checkbox"/> HTLV-2 | <input type="checkbox"/> SIV | <input type="checkbox"/> XMRV |
| <input type="checkbox"/> Tuberculosis | <input type="checkbox"/> Toxoplasma gondii | <input type="checkbox"/> H1N1 |
| <input type="checkbox"/> Other-specify _____ | <input type="checkbox"/> Retrovirus Production Worker | |

TOXINS: Diphtheria Pertussis Other-specify _____

VIRAL VECTORS (adeno, lenti, retro)

CHEMICAL/GENERAL SAFETY HAZARDS

- NOISE EXPOSURE** > 85dBa for 8 hrs
- FORKLIFT OPERATOR**
- RESPIRATOR** Required – specify _____

RADIATION HAZARDS

- CLASS IIIB OR IV LASERS**
- X-RAY MACHINES, ELECTRON MICROSCOPES, IRRADIATORS** – specify _____
- RADIOACTIVE MATERIALS** – specify isotopes _____

ATTACHMENT B

FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH OCCUPATIONAL HEALTH SERVICES CONSENT FORM FOR HEPATITIS B VACCINATION AND RELEASE OF INFORMATION

HEPATITIS B VACCINATION

I have read the attached information sheet and understand the risks and benefits of receiving the Hepatitis B vaccine. Additionally, I have had the opportunity to discuss and ask questions about the Hepatitis B vaccine with a member of the Occupational Health Services (OHS) staff.

As with any drug, there is a slight chance of allergic or more serious reactions with a vaccine. However, to date, there has been no serious side effects reported that have been attributed to administration of the recombinant Hepatitis B vaccine. Several relatively minor side effects have been reported to occur within 72 hours following vaccination. Soreness at the site of vaccination has been the most common adverse reaction and occurs in about one of every seven vaccinated individuals.

I understand that Hepatitis B vaccination consists of a series of three (3) injections: the first injection; a second injection one month after the first; and a third injection six months after the first. I understand that I may have limited or no protection from Hepatitis B virus until the vaccination series is completed.

CONSENT

_____ I consent to receive the Hepatitis B series.

RELEASE OF INFORMATION

I UNDERSTAND THAT THE Frederick National Laboratory for Cancer Research (FNLCR) is required to comply with the Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens; Final Rule (29 CFR Part 1910:1030). To facilitate compliance with this rule, OHS may inform a responsible representative of my employer of my current status in the Hepatitis B Vaccine Program. Specifically, the OHS may disclose whether I have "initiated" the vaccine series. "Initiated" is defined as receiving at least one dose of the vaccine series. The OHS may also disclose the date I received the first dose of the vaccine, and personal identifiers consisting of: my name, and my date of birth.

I understand that OHS will protect all other aspects of my medical records, in accordance with their usual policies and procedures, and that only the above information will be released without my further written consent. I have had an opportunity to ask questions of a representative of OHS and understand that requirements to release information as specified above.

EXEMPTION

I am exempt from receiving the Hepatitis B vaccine at this time for the following reasons:

- _____ I have completed the vaccine series elsewhere
- _____ I have previously been infected with Hepatitis B virus.
- _____ Vaccination is contraindicated for medical reasons.
- _____ It is most unlikely that I will have any exposure to human blood or other potentially infectious material while performing my job.

DECLINATION

_____ I do not wish to receive the Hepatitis B vaccine at this time.

I understand that I may be at risk of acquiring Hepatitis B virus infection due to potential occupational exposure to human blood or other potentially infectious materials.

I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline the Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a potentially life-threatening disease.

If in the future I continue to have occupational exposure to human blood or 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.

Name: _____

Date: _____

Signature: _____

Badge Number: _____

