National Institute of Environmental Health Sciences

Exposure Control Plan
2024

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National Institute of Environmental Health Sciences
Exposure Control Plan

Introduction

National Institute of Environmental Health Sciences (NIEHS) is committed to providing a safe and healthful work environment for its employees and to reducing or eliminating risks of injury and subsequent illness. Employees at NIEHS may be exposed to human blood or other potentially infectious materials (OPIM) and agents resulting from the performance of their duties. Thus, this Exposure Control Plan (ECP) has been developed by the Health and Safety Branch (HSB) to eliminate or minimize occupational exposure to bloodborne pathogens (BBP) in compliance with Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard 29 CFR 1910.1030 and North Carolina state law. This ECP serves as both the written plan and as a training document.

The NIEHS ECP will be reviewed and updated at least annually and whenever necessary by the NIEHS Institutional Biosafety Committee (IBC) to ensure continuing compliance, to reflect new or modified tasks and procedures which affect occupational exposure, and to reflect new or revised employee positions with occupational exposure. Review and update of the ECP shall also (A) reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and (B) document annually consideration and implementation of appropriate commercially available and effective medical devices designed to eliminate or minimize occupational exposure.

The HSB shall solicit input from applicable personnel including non-managerial employees, such as lab personnel and employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps, in the identification, evaluation, and selection of effective engineering and work practices. Updates will be made to the ECP, as needed, to reflect determined changes.

A copy of the ECP is made available to all NIEHS employees, the Assistant Secretary of Labor, and the Director, National Institute for Occupational Safety and Health, upon request, by contacting HSB at 984-287-3400 or hse@mail.nih.gov.

Exposure Determination

Job classifications in which all or some of the employees may have occupational exposure:

- Laboratory and research personnel including scientists, post-doctoral researchers, research assistants, fellows, graduate or post-baccalaureate students and volunteers, and laboratory technicians.

- Employees who provide support services to the research program including veterinarians, animal husbandry support, animal care staff, HSB personnel, Occupational Medical Service (OMS) and other healthcare professionals involved in clinical research.
- Law enforcement, medical first responders, incinerator and waste handling staff, facilities maintenance personnel, and other contract personnel.

Information regarding exposure risk to research personnel is primarily gathered via the Biological Permit or Bio Permit. Experiments and research which require a Bio Permit include those that fall under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*), human or non-human primate (NHP) blood, body fluids, tissues and primary or established cell lines, OPIM, pathogens/microorganisms, biological toxins and animal experiments involving biologicals. A Bio Permit application is submitted electronically and describes the entirety of the proposed work. Subsequent review by the NIEHS IBC or designated members allows for risk determinations and recommendation of applicable controls and practices.

If animals are used in the proposed Bio Permit, all personnel performing animal work must be listed and a copy of the current or proposed animal study proposal (ASP) must be included. Introduction of human materials into research animals requires Animal Care and Use Committee (ACUC) review and approval. The Bio Permit must first be approved by the IBC before the ASP can be approved and before performing animal work.

Principal Investigators (PIs) are ultimately responsible for providing updated information to HSB and must update their permit(s) whenever there is a change in material, method, laboratory personnel, or location. PIs are responsible for educating and training employees on the hazards of their research and ensuring that any employee on or added to a registration is offered immunization, if appropriate. Other personnel at reasonable risk for exposure to bloodborne pathogens are offered Hepatitis B vaccination and appropriate training by their employer. This includes NIEHS employees, contract staff, and medical first responders. Appropriate immunizations are offered by OMS for the work being performed. Personnel working for the janitorial contractor need to go through their employer if they desire to have Hepatitis B vaccinations.

Additionally, HSB conducts collaborative laboratory walkthroughs and routine visits of areas that work with human materials and OPIM, helping to ensure that appropriate engineering controls, administrative controls and PPE are being used and procedures described in the Bio Permit are followed.

The NIEHS Waste Manual describes waste handling procedures at the Institute. The implementation of these procedures allows a negative exposure determination to be made for the

Office of Research Facilities (ORF) Research Triangle Park Facilities Management Branch (RTPFMB), Maintenance and Operations Section staff, and the contractor staffed janitorial services.

Incidents should be reported to the employee's supervisor immediately, if available. Then reported to NIEHS OMS. After hours, the NIH Page Operator should be contacted at 301-496-1211 if assistance is needed; otherwise, report to OMS as soon as it reopens. Incidents should also be reported to HSB and will be available to select HSB staff through HealthRx if not notified directly.

Methods of Compliance

Universal precautions or the equivalent shall be observed to minimize direct contact with blood and OPIM. Universal Precautions are the premise that all human materials are considered potentially contaminated with bloodborne and other human pathogens. Employees will comply with the OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030 using the following methods:

A. Work practice controls

Work practice controls must be used to eliminate or minimize worker exposure to blood or other potentially infectious materials. Where the potential for exposure remains after implementation of these controls, engineering controls or personal protective equipment will be used in addition.

Biosafety Levels 1, 2 and 2/3

All laboratory work at NIEHS requires a minimum of lab coat, gloves and eye protection when splashes or sprays are anticipated. For each Biosafety Level (BSL), facility requirements, work practices and procedures are to be adhered to by all NIEHS employees and can be found in the CDC/NIH publication entitled Biosafety in Microbiological and Biomedical Laboratories, 6th ed.

All human blood and OPIM is to be handled at a minimum of Biosafety Level 2 (BSL-2), which equates with the concept of Universal Precautions in the clinical setting. Laboratories working with higher risk human specimens such as COVID-19 infected* respiratory samples, human immunodeficiency viruses, or other human retroviruses and/or infected cell lines at the research scale, or procedures which increase the risk of exposure though such means as aerosolization are required to use Biosafety Level 3 practices in a certified Biosafety Level 2 facility (BSL-2/3 or Enhanced BSL-2). These enhanced practices will be outlined in the Bio Permit and all work must be performed in the designated BSL-2/3 facility. Certification of these and all laboratory facilities is performed by HSB.

*Not a bloodborne pathogen, but still considered high risk necessitating enhanced Precautions

Transportation and Shipping

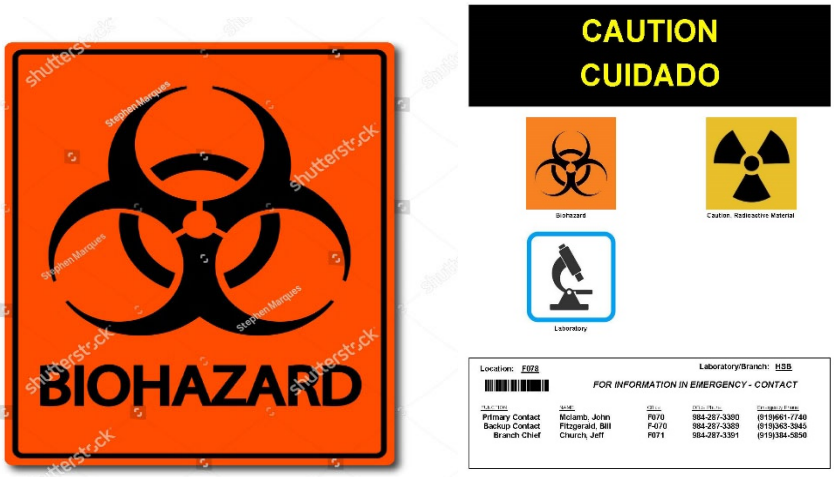
All human materials transferred or collected outside the lab must be transported in closed, durable, leakproof containers displaying the biohazard symbol. The material must be in a closed primary container, tube, bag, etc. and placed inside the transport container. Human materials must be hand carried from lab to lab in approved safety carriers and on a cart if appropriate. All shipments between NIEHS and other facilities must be packaged and transported according to applicable Federal regulations (Title 42 Code of Federal Regulations part 71 and Title 49 Code of Federal Regulations parts 172-173) or the International Air Transport Association Dangerous Goods Regulations (IATA DGR) if shipping by air. Guidance and training in the transport and shipment of biological materials can be obtained by contacting HSB (984-287-3400). Additionally, air shipments of biological materials must be coordinated with the NIEHS Mailroom (984-287-3757) and the Biosafety Specialist (see Chapter 6F)**.**

Public transportation or personal vehicles be used to transport biological materials to or from the NIEHS. Researchers must make arrangements to transport materials by government vehicle or commercial carrier only and in consultation with the Biosafety Specialist. Government vehicles are made available and can be signed out by employees for this purpose. Training for on and off campus transport of human material is encouraged and can be obtained by contacting HSB (984-287-3400).

International shipments of biological materials must be coordinated with the Biosafety Specialist and through the Quarantine Permit Service Office (QPSO) (301-496-2960) so that the correct import permits and export licenses can be issued (NIH Policy Manual 1340-1).

Labeling

Equipment such as freezers, refrigerators, centrifuges, incubators or containers used to store, manipulate or transport (i.e., lab to lab) human materials or OPIM must have a biohazard warning label affixed. Additionally, cages containing infected animals or those exposed to human materials must also have the biohazard label affixed. Biohazard warning labels must have an orange red or fluorescent orange label, the word “BIOHAZARD” and the biohazard symbol must be printed on the label in a highly contrasting color such as black. The type of label may be a sticker, bag, or fixed container. All (human) medical waste transferred to the incinerators will be placed in red bags imprinted with the biohazard warning symbol. Non-human infectious waste must be disposed of in orange biohazard bags imprinted with the biohazard warning symbol. Waste bags can be obtained through the NIEHS Supply Catalog. Door Placard where biological materials are used will also display the biohazard symbol.



Decontamination and Spill Clean-up

All work surfaces and equipment that come into contact with blood or OPIM must be disinfected upon completion of work with an appropriate disinfectant. Appropriate disinfectants must be EPA registered as effective against BBP including Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV). Additionally, work surfaces and equipment must be disinfected after any overt spill, splash, or spray. Work surfaces should be covered with plastic-backed absorbent toweling to facilitate clean-up and reduce production of aerosols as a result of the spill.

Spills within work areas are to be cleaned up by properly trained laboratory personnel. Janitorial staff *are not authorized* to clean up spills of human research materials. Spills of blood or OPIM are to be cleaned up using the following procedures:

1. Alert persons in the immediate area that a spill has occurred. If outside the laboratory (public corridor) contact the Security Base using VOIP at 911 or with cell phone at 919-541-2800.
2. Wearing the appropriate protective equipment (e.g., gloves, lab coat, eye/face protection, etc.), cover the spill with absorbent toweling or other material.
3. Carefully, pour a freshly prepared 1:10 dilution of household bleach (or other EPA registered disinfectant prepared to manufacturer's specifications) around the edges of the spill working toward the center. Allow thirty minutes contact time.
4. Using paper towels or other suitable absorbent material, wipe up the spill working from the edges of the spill to the center.
5. Be careful to avoid cuts with broken glass. Broken contaminated glassware must not be picked up with bare hands (use tongs, dustpan and brush). Any broken glass should be carefully discarded into an approved broken glass container.
6. Clean the spill area again with fresh disinfectant.

7. Place all used materials into two red bags, secure with tape or twist tie and contact HSB for disposal.
8. In the event of an unusual or particularly large spill, contact the Health and Safety Branch for assistance.

Regulated Medical Waste

Regulated medical waste is a designation for wastes that may contain pathogenic microorganisms including but not limited to BBP and was previously termed "pathogenic" or Medical Pathogenic Waste (MPW).

According to the North Carolina Medical Waste Rules regulated medical waste includes:

1. Liquid or semi-liquid human blood, human blood components and products made from human blood.
2. Liquid volumes of human body fluids including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid >20 ml in volume.
3. Contaminated items that would release blood or body fluids in a liquid state when compressed, such as soaked surgical sponges.
4. "Sharps", including needles, syringes with attached needles, slides, and cover slips, capillary tubes, Pasteur pipets, or scalpel blades.
5. "Pathological Waste" includes human tissues, organs, and body parts; and the carcasses and body parts of all animals that were known to have been exposed to pathogens that are potentially dangerous to humans during research, were used in the production of biologicals or in vivo testing of pharmaceuticals, or that died of a known or suspected disease transmissible to humans.
6. "Microbiological Waste" including cultures and stocks of infectious agents. At NIEHS this also includes recombinant DNA/transgenic organisms.

Regulated medical waste requires special packaging, labeling, and must be decontaminated prior to disposal. All personnel must manage these types of waste in order to minimize potential personnel exposures and to assure environmentally sound disposal of medical waste. PIs and supervisors will ensure that all medical waste generators within their branch or laboratory comply with this policy. Specific waste handling practices will vary depending on the individual type of medical waste being generated, and consequently, general guidelines for a variety of different work areas are described in the NIEHS Waste Manual.

Equipment Repair and Transfer

All equipment which may have been exposed to hazardous materials including human materials (i.e., known hazardous chemical, radiological, or biological material) must be appropriately decontaminated prior to transfer, servicing, or repair. Included are all scientific/medical equipment and any office furniture/equipment or supplies that have been

used in clinical areas, laboratories, or other potentially hazardous locations. Guidance for the decontamination of such equipment is provided by in the document *Preparing Property for Safe Movement* (see Chapter 5D).

Food and Drink

Storage or consumption of food and drink is strictly prohibited in any laboratory or animal care setting where blood or other potentially infectious materials (OPIM) are used or stored. Food or drink may be transported through a space (e.g., laboratory, elevator, etc.) so long as it remains tightly covered or closed. Similarly, smoking, applying cosmetics and handling contact lenses are prohibited in these same areas.

Hand washing

Hand washing facilities that are readily accessible to all employees will be provided. When provision of hand washing facilities is not feasible, an appropriate antiseptic hand cleanser (alcohol-based gel, lotion or liquid) will be provided. If antiseptic hand cleansers are used, hands must still be washed with soap and running water after completion of work, or before leaving the laboratory or animal care setting. Supervisors are responsible for ensuring that employees wash their hands as appropriate.

B. Engineering Controls

Engineering controls are those that eliminate, isolate, or remove the BBP hazard from the workplace. Appropriate biocontainment levels for work with human materials, which specify necessary engineering controls, are reviewed and approved by the Biosafety Specialist and the IBC.

Primary Barriers

Class II biological safety cabinets (BSC) or other equivalent physical containment devices are the preferred engineering control for procedures that have a high potential for generating aerosols, splashes, or sprays. These procedures may include centrifuging, grinding, vortexing, blending, sonication, pipetting or opening containers of infectious materials whose internal pressures may be different from ambient pressures. For work at BSL-2 with BSL-3 practices (BSL-2/3), all manipulations of human materials must be conducted inside a BSC. Intranasal inoculations or other animal procedures which have the potential for producing splashes and aerosols, must be performed in a BSC. If a BSC is not available or appropriate, prior approval may be obtained from HSB for procedures to be performed on the open bench with appropriate personal protective equipment (PPE). Use of surgical masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields will be described in the Bio Permit (see Safety Manual Chapter 5F3d on Biosafety Cabinets

Sharps and Sharps Containers
Sharps include but are not limited to syringes with attached needles, sutures, scalpels, razor blades, capillary tubes, slides and cover slips, lancets, auto injectors, connection needles and sets, exposed ends of dental wires, and objects that can penetrate the skin.

Sharps must never be bent, recapped, or removed from the area of immediate use. Shearing or breaking of contaminated needles is prohibited. If it can be demonstrated that no alternative is feasible, or such action is required by a specific procedure, a needle may be bent, recapped, or removed through the use of a mechanical device or a one-handed technique. Where BSL-2/3 practices are used, sharps must be minimized to the extent possible. **Consideration must be given to the use of sharps with an engineered safety device if available and feasible for the procedure.** These sharps have built-in safety features like retractable needles or sheaths that cover the needle or scalpel. HSB maintains information on these devices and may be contacted for further information.

Sharps containers must be made available at all work areas where sharps are used. Sharps must be disposed of immediately or as soon as possible after use in puncture resistant sharps containers. Sharps containers should always be within arm's reach or inside containment devices when feasible (e.g., inside the biosafety cabinet). Sharps are to be disposed in accordance with the guidelines found in the NIEHS Waste Manual. Puncture resistant sharps containers are available through the NIEHS Stock Catalog.

Vacuum Lines
Vacuum lines are to be protected with liquid disinfectant traps and in-line High Efficiency Particulate Air (HEPA) filters before going into either the building vacuum system or a vacuum pump (see Chapter 5J - Vacuum Equipment)

Safety Eyewash & Handwashing Sinks
Eyewash safety equipment must be available and unobstructed in laboratories working with human materials. Mucous membranes should be flushed immediately with water if exposure occurs followed by medical evaluation at the Occupational Medical Services. Handwashing sinks will be available, and hands should be washed after gloves and other PPE are removed. If a sink is not immediately accessible, antiseptic hand cleanser will be available and should be used prior to leaving the area only as an interim measure until hands can be washed at the nearest sink.

Safety Devices for Centrifuges
For low-speed centrifugation of human materials, safety centrifuge cups or a biocontainment lid may be used. If used, the cups are to be loaded and unloaded only within a BSC. High speed centrifugation must be performed using a safety rotor which is loaded and unloaded

within a BSC. For BSL-2 with BSL-3 practices work that involves human materials, safety cups or sealed rotors must be used.

C. Administrative Controls

Employees must be notified of the presence of biohazardous materials in any workspace or laboratory, and specifically where blood or OPIM is stored or manipulated. These areas will have placards showing the biohazard symbol. Note that work areas are *only* posted upon approval of the Bio Permit and successful completion of a laboratory survey. A copy of the NIEHS Universal Precautions poster is available to all laboratories that work with human materials and can be obtained from HSB. A copy of this plan is accessible electronically at all times on the NIEHS Junction (or downloaded PDF) by any employee and serves as a means of employee notification.

Training and Education

Training for employees, in compliance with the OSHA Bloodborne Pathogen Standard, is provided monthly and required annually for all laboratory and research support employees. Principal Investigators and supervisors are responsible for assuring that all employees, under their direction potentially exposed to a bloodborne pathogen, complete training prior to handling human materials and receive refresher training on an annual basis thereafter. Training schedules as well as refresher courses and safety shorts are available on the HSB training website. Principal Investigators and Supervisors are additionally responsible for job-specific safety training and must document that employees selected for jobs involving manipulation of infectious human materials have been adequately trained to perform these tasks.

1. Contractor incinerator staff management is responsible for job-specific training of personnel and must document that employees have been adequately trained to perform the tasks. If properly packaged, biohazardous waste exposure to staff should be minimal.
2. Security staff management is responsible for ensuring that their employees have basic first aid training to perform job-specific tasks.
3. Medical First Responders personnel receive training consistent with the information provided in the HHS publication entitled Guidelines for Prevention of Human Immunodeficient Virus and Hepatitis B Virus to Health Care and Public Safety Workers. These guidelines were developed in response to Public law 1000-607, the Health Omnibus Programs Extension Act of 1988, portions of which are specific for personnel working in the emergency response arenas. Training is provided on an annual basis.

D. Personal Protective Equipment (PPE)

A variety of PPE is readily available, in a variety of sizes, to all NIEHS employees through the NIEHS Self Service Stores, the NIEHS Stock Catalog, or from the Health and Safety Branch. If

required PPE is not currently available through the NIEHS store or supply catalog, it is to be ordered from the appropriate source subject to approval by HSB at no cost to the employee. An employee's personal preference is not adequate justification for ordering personal protective equipment.

Gloves

Gloves must be worn by all employees directly handling human materials. Gloves may be chosen by the employee based on individual need and resistance/protection to other hazardous materials involved. Nitrile gloves are the recommended type for all work with blood and OPIM. Gloves are to be changed routinely followed by rigorous adherence to hand washing practices. Employees must inspect gloves routinely and replace them whenever they are visibly soiled, torn, or punctured. If gloves are suspected of being contaminated (i.e., splattered with blood or OPIM) they must be discarded immediately and are NOT to be worn outside of the laboratory area. All gloves are to be discarded into the regulated medical wastes stream. For BSL2/3 work, double gloves must be worn when handling infectious material, potentially contaminated equipment, and work surfaces. Hands must be washed with soap and water after removal of PPE and prior to exiting the laboratory. Latex gloves are not recommended at NIEHS. Personnel wishing to use latex gloves may contact HSB (984-287-3400) for alternative glove material recommendations.

Other Protective Garments

Disposable laboratory coats, gowns, aprons, or Tyvek suits, whichever is most appropriate for the application, are to be worn by all personnel manipulating or otherwise handling blood or OPIM. As with gloves, if these garments are suspected of being contaminated, they are NOT to be worn outside of the laboratory area. Disposable protective polypropylene coated closed front gowns (which meet American Society for Testing and Materials F1670 and F1671 test criteria for blood and virus penetration resistance) and disposable Tyvek coveralls appropriate for animal work are available through the warehouse distribution system and are required for BSL2/3 work. Disposable protective garments must not be reused. These items are to be discarded in the regulated medical waste stream as described in the NIEHS Waste Manual.

Eye/Face Protection

Surgical masks in combination with eye protection (i.e., goggles or glasses with solid side shields) or chin length face shields, must be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated, and eye, nose, or mouth contamination can be reasonably anticipated.

Respiratory Protection

Respiratory protection may be indicated for some work with human materials.

Supervisors *are not* authorized to select or recommend the use of respiratory protection, regardless of the type. Surgical face masks, used for mucous membrane protection, are not considered respirators and are not to be used in situations where respiratory protection is required. All respirator users must be enrolled in the NIEHS Respiratory Protection Program. Contact Health and Safety Branch office (984-287-3400) for prior approval and if respiratory protection is required.

Clothing

In a laboratory or animal care setting, an individual entering the area must cover themselves as much as possible with street clothing as a first line of defense against biological exposure. Shorts, skirts, leg coverings that fall above the ankle, and open toed shoes are prohibited.

Laundry

Reusable laboratory clothing (lab coats) must be cleaned by an HSB approved commercial laundry facility. Soiled lab coats should not be reused and must be placed in bins for cleaning once removed. Protective clothing, especially used, should not be worn outside the laboratory or taken home for any reason.

E. Hepatitis B Virus and HBV Vaccination

Occupationally acquired HBV

Hepatitis B is a leading occupationally acquired illness among health care workers. Hepatitis B virus (HBV), is one of several viruses which attacks the liver, producing swelling, tenderness, and sometimes permanent liver damage. HBV is spread primarily through contact with blood and body fluids that contain blood. The virus enters the body through open wounds, or breaks in the skin, needle sticks or other punctures, or splashes of blood and/or body fluids to the mucous membranes. The virus may also be transmitted via blood transfusion, sexual contact, ear piercing, tattooing, and acupuncture if appropriate precautions are not taken.

Symptoms of HBV

The most frequent symptoms of HBV infection include fatigue, mild fever, muscle or joint pain, nausea, vomiting, loss of appetite, and abdominal pain. Many symptoms suggest a flu-like illness but tend to last longer and jaundice may occur in up to 25% of cases. However, 50% of infected individuals have no symptoms.

Risk of HBV Infection

The risk of HBV infection in NIEHS employees is considered to be *high* if their jobs entail frequent contact with blood and body fluids. NIEHS employees can protect themselves from occupationally acquired HBV infection by practicing Biosafety Level 2 practices and

procedures (Universal Precautions) and by becoming vaccinated against HBV to provide long term immunity in the event of future exposures. Employees must be alert to situations where they or their co-workers may be exposed to blood and OPIM.

Hepatitis B (HBV) Vaccination

A recombinant HBV vaccine is available and free of charge to all NIEHS employees and applicable personnel who may come into contact with blood and OPIM during the performance of their research and work duties. Employees engaged in off-site research are also eligible to receive the vaccine.

The HBV Vaccine:

- The recombinant HBV vaccine does not contain any human blood products
- Both safe and effective
- Series of 2-4 injections
- Clinical studies have shown that over 90% of healthy adults vaccinated become immune to the Hepatitis B virus.
- The HBV vaccine may also be used prophylactically in combination with Hepatitis B immune globulin (HBIG) and is 90% effective in preventing Hepatitis B following a documented exposure. Side effects of the vaccine are minimal. The most common complaint (20%) is a sore arm lasting one or two days. A few individuals have reported headache, fatigue, weakness, or rarely, a low-grade fever.

To receive the vaccine and for more information on HBV, contact NIEHS Occupational Medical Services (984-287-4178). If an employee initially declines to receive the vaccination by signing a declination form, this does not prevent them from receiving the vaccination in the future. Employees are strongly encouraged to become vaccinated.

Medical Monitoring and Post-Exposure Evaluation and Follow-up

Post-exposure evaluation and follow up must be provided for NIEHS employees through Occupational Medical Services. Employee occupational medical services and counseling are provided free of charge. Emergency care will be provided to visitors and contract personnel who sustain a potential exposure. These individuals will be referred to their private or company physician for follow up. As the Clinical Research Unit (CRU) does not regularly test donors, employees receiving donor samples may never be informed if their sample is infectious. The determination that a donor sample from the CRU is infectious is not, by itself, grounds warranting testing of NIEHS personnel. The CRU does not have a standard operating procedure for testing NIEHS employees. Occupational Medical Services will only test personnel that have or suspected to have sustained an actual exposure.