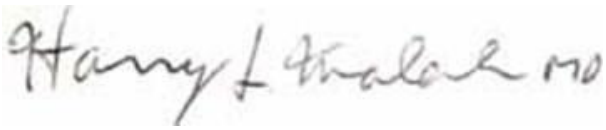
National Institutes of Health

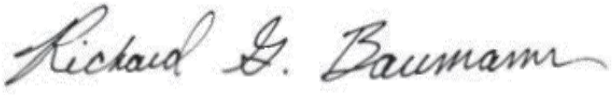
Exposure Control Program

for Non-Hospital Personnel



12/06/23

Chairperson, NIH Institutional Biosafety Committee (IBC) — date
Certification of Annual IBC Review and Approval



12/06/23

NIH Biological Safety Officer — date
Executive Secretary, NIH Institutional Biosafety Committee (IBC)
Certification of Annual IBC Review and Approval

DIVISION OF OCCUPATIONAL HEALTH AND SAFETY
(Revised December 2023)

National Institutes of Health
Exposure Control Program
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Introduction

National Institutes of Health (NIH) employees are at risk of infection and subsequent illness as a consequence of exposure to human blood or other potentially infectious body fluids and agents potentially infectious to humans. Risks also exist related to exposure to the blood, tissues, and body fluids of Old World non-human primate (NHP) species. Therefore, this Exposure Control Program (ECP) has been developed to minimize employee exposure to bloodborne pathogens, such as Hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

This ECP establishes the policy and procedures for the control of infectious diseases that may be contracted by the bloodborne route. The ECP is in compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030; https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030) and serves as both the written program, for compliance purposes, and as a training document.

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

The Division of Occupational Health and Safety (DOHS) will, in concert with appropriate focus groups including non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps, identify the availability of new technology including commercially available safer medical devices that can eliminate or reduce exposure to bloodborne pathogens in the workplace. The focus groups will aid DOHS in the identification, evaluation, and selection of effective engineering and work practice controls for non-hospital personnel.

The review and implementation of safer laboratory or medical devices will be documented in each subsequent annual review of the ECP. A copy of the ECP is made available to all NIH employees, the Assistant Secretary of Labor, and the Director, National Institute for Occupational Safety and Health, upon request, by contacting the Institute or Center (IC) Safety Specialist (301-496-2346) or DOHS (301-496-2960).

Exposure Determination

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

- Laboratory personnel, including scientists, post-doctoral researchers, research assistants, graduate students, laboratory technicians and animal care staff.
- Law enforcement, emergency response personnel as well as facilities personnel.

At the NIH, the principal method by which exposure determination information for laboratory personnel is gathered is with the registration of experiments and procedures. All principal Investigators (PIs) using either recombinant nucleic acid materials that fall under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, or potentially hazardous biological materials must register their work. This is accomplished by submitting electronic registration documents to describe the entirety of the proposed work to the NIH IBC for a subsequent review, assessment and approval. The registration of other biological agents of concern (not necessarily infectious to humans) may also be requested (or required by law) to insure best practices in animal facilities.

All PIs working with human pathogens, other potentially pathogenic materials and materials of concern; human blood, body fluids, tissues, any and all cell lines; biological toxins; and the blood, tissues, cell lines or body fluids of old-world non-human primate (NHP) species, must also submit a properly completed biological registration document to the NIH Biosafety Officer (BSO) for review by the NIH IBC. If animals are used in the research protocol, a copy of the animal study proposal (ASP) must be included. A web-based registration system exists and is accessed by following the Biological and Pathogen Registrations link at our Division of Safety web-page here https://ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/bio_chem_safety.aspx. PIs must use and submit electronic applications (and amendments when warranted), paper registrations are not accepted. The Occupational Medical Service (OMS) is notified of newly approved registrations and the personnel listed. OMS reviews the new registration document and enrolls employees in the appropriate medical surveillance program. OMS will offer immunizations appropriate for the work being performed.

Incidents with recombinant material must be reported to NIH Office of Science Policy (OSP) within 30 days for any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. Incidents involving research subject to the *NIH Guidelines* must immediately be reported to biosafety staff (in addition to reporting to OMS), and biosafety personnel will report to OSP, as required. Spills or accidents in BSL-2 laboratories resulting in an overt exposure must be reported immediately. Incidents occurring in BSL-3 or BSL-4 laboratories resulting in an overt or potential exposure must be immediately reported. Per the guidance, this reporting is a collective responsibility of the NIH, IBC, BSO, and Principal Investigator. At NIH, all incidents are reported to OSP by biosafety staff.

PIs are ultimately responsible for providing updated information to DOHS and must update their electronic registration(s) whenever there is a significant change in procedure that may affect risk, or any change in laboratory, personnel, or location. Annual reviews of each registration are required each year after their approval, or since the last amendment made to that registration. PIs are responsible for educating employees on the hazards of their research and ensuring that any employee added to a registration after initial approval is offered immunization, if appropriate. DOHS staff conduct laboratory surveys and walk-through visits of registered labs and spaces to ensure appropriate equipment is being used and procedures are being followed.

Law enforcement officers may risk exposure to blood during the conduct of their duties. For example, at a crime scene or during the processing of suspects, law enforcement officers may encounter blood-contaminated hypodermic needles, weapons, or be called upon to render emergency aid. Fire and emergency response personnel provide emergency medical services and may encounter exposures common to those experienced by paramedics and emergency medical technicians. Job duties may be performed in laboratories during emergencies or in the pre-hospital setting under uncontrolled conditions. Therefore, NIH law enforcement and fire personnel are covered under the ECP for bloodborne pathogens, are offered hepatitis B immunization, and will receive appropriate training.

Methods of Compliance

Universal precautions or the equivalent (see below) shall be observed to prevent contact with blood or other potentially infectious materials (OPIM). When differentiation between body fluid types is not possible, all body fluids shall be considered potentially infectious materials.

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 shall also be used.

Food and drink are strictly prohibited in any laboratory or animal care setting. They may not be brought into or walked through a laboratory, an animal care setting, or in any area where blood materials or OPIM are stored; nor should they be consumed in a laboratory, animal care setting, or area that stores blood or OPIM. As such, open food shall not be transported in any elevator that is used for the transportation of biological materials or OPIM. Similarly, smoking, applying cosmetics and handling contact lenses are prohibited in areas where there is the potential for exposure to bloodborne pathogens.

The NIH will provide hand washing facilities that are readily accessible to all employees. When provision of hand washing facilities are not feasible, NIH shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible. When handling blood or OPIM, hands must be washed after removal of gloves or other personal protective equipment, once work with the biological material or OPIM is completed, and before leaving the laboratory or animal care setting. Supervisors are responsible for ensuring that employees wash their hands and other skin that may encounter blood or OPIM with soap and water, and flush mucous membranes with water immediately after contact with biological materials or OPIM occurs.

Transportation and Shipping of Infectious Materials

All potentially infectious materials transported between NIH Bethesda campus and outlying buildings must be packaged and transported according to applicable Federal regulations (42 CFR 71, 72 and 49 CFR 173.386-172.388). Guidance in complying with regulations pertaining to the shipment of biological materials can be obtained by contacting your IC Safety Specialist at 301-496-2346. Shipping activities must be performed in accordance with NIH Policy Manual #26101-42-F, “Shipping Policies and Procedures”, and be performed by trained individuals only.

All potentially infectious materials transported between buildings on the NIH Bethesda campus

must be placed in labeled, sealed, leak-proof, and unbreakable primary and secondary containers. Blood or OPIM must be stored in a container that will not leak. The container must also prevent leakage during collection, handling, processing, transport, and shipping when applicable. An amount of absorptive material adequate to contain a spill must be placed between the primary and secondary containers. The following rules for transportation of biological or OPIM between laboratories applies when these materials are brought outside of the laboratory and through any building, elevator, and between laboratories and buildings on and off campus. Each building where transportation of blood or OPIM occurs between floors, whether it is from the loading dock to a laboratory or from lab to lab, there must be at least one elevator dedicated to transport of hazardous materials. The elevator shall be marked in a manner so that personnel and visitors do not bring open consumables into the elevator designated for hazardous uses. Emergency stairwells must not be used for transportation of biological materials or OPIM.

International shipments of biological materials must be coordinated 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

Any container used to store blood or OPIM must have a biohazard warning 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. Blood or OPIM must be labeled with a material that cannot be easily removed or lost. Examples of containers that need to be labeled include but are not limited to the following: fridges, freezers, sharps-safe boxes, medical pathological waste (MPW) boxes, equipment contaminated with blood or OPIM, transportation and shipping vessels.

Decontamination and Spill Clean-Up

Basic decontamination procedures need to be followed in every laboratory that handles, stores, or processes blood or OPIM. Basic decontamination procedures are outlined below in this section. Supervisors are responsible for ensuring that the laboratory or animal care area is maintained, clean and sanitary. Supervisors and PIs must have a written cleaning schedule and a written method of decontamination for every procedure that involves blood or OPIM. All equipment that is used to process or store blood or OPIM must be cleaned and decontaminated after contact with blood or OPIM. Absorbent bench papers must be replaced frequently and when contaminated with blood or OPIM. Whenever a spill of blood or OPIM occurs, clean the spill immediately and decontaminate the affected area. If you or others in the area were exposed to aerosols created by the blood or OPIM, seek medical attention immediately. To choose an appropriate decontaminant for your laboratory or animal care area, refer to Biosafety in Microbiological and Biomedical Laboratories, 6th edition, produced by the CDC and NIH and consult your assigned IC safety specialist. Information on chemical safety can be found in the current edition of the NIH Chemical Hygiene Plan.

All work surfaces where blood, body fluids, infectious agents and materials are handled must be disinfected after each use with an appropriate disinfectant. Additionally, work surfaces must be disinfected after any spill. Work surfaces should be covered with plastic-backed absorbent toweling (plastic facing down) to facilitate clean up and reduce production of aerosols that may result from a spill while work is being performed. Spills within work areas are to be cleaned by laboratory or research personnel. Custodial staff are not authorized to clean spills of potentially infectious material. Spills of potentially infectious material are to be cleaned using the following method:

- Notify persons in the immediate area that a spill has occurred.
- Wearing the appropriate protective equipment (e.g., gloves, lab coat, goggles, etc.), cover the spill with absorbent disposable toweling.
- Carefully, pour a freshly prepared 1 in 10 dilution of undiluted household bleach- 5.25% sodium hypochlorite (or other suitable disinfectant prepared to manufacturer's specifications) around the edges of the spill working toward the center.
- Allow disinfectant to sit for an appropriate contact time (20 minutes for 0.5% bleach).
- Using paper towels, wipe up the spill, working from the outside edges toward the center. Avoid the potential for cuts with broken glass or other sharps by using tongs, a dust pan or other device for pickup and carefully discard into an approved sharps container prior to wiping up spill.
- Repeat process with fresh disinfectant.
- Place all used materials into an autoclave bag for decontamination, or MPW box for disposal.

In the event of an unusual or large spill, contact the NIH Fire Department (911) for clean-up. In the event of a spill of infectious material in a public access area (e.g., hallway, elevator, etc.), keep all persons away from the spill area and call 911 for clean up.

Blood or OPIM must be disposed of in containers that are closable, labeled as biohazard, and/or color-coded in red or orange to indicate that they contain blood or OPIM. Refer to the NIH Waste Disposal Guide, current edition, for specific NIH requirements and to comply with local and federal waste disposal guidelines.

Infectious Waste Disposal

All employees shall comply with the guidance given in the NIH Waste Disposal Guide. Additional copies of this document are available from NIH Division of Environmental Protection/Waste Management Services (DEP).

Equipment Repair and Transfer

All equipment that may have been exposed to hazardous materials (i.e., known hazardous chemical, radiological, or biological substances) must be appropriately decontaminated and certified by the user as being clear of hazards, using NIH Form 2683 before transfer, service, or repair is done (these forms are available at the NIH Self-Service stores and in the NIH Stock Catalogue, also online). This includes 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 Instruction and Information (I&I) Memorandum DL 91-3.

Biosafety Levels 1, 2 and 3

Certification of Biosafety Level 2 and 3 laboratory facilities is performed by DOHS.

All specimens of human blood, tissue, or body fluids are to be handled utilizing BSL- 2 practices and procedures comparable to the concept of Universal Precautions in the clinical setting. Laboratories working with human immunodeficiency viruses (HIV), complex human retroviruses, simian immunodeficiency virus (SIV), at the research scale, BSL-3 practices and procedures must be utilized in a certified Biosafety Level 2 facility.

A laboratory-specific biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Laboratory personnel must sign-off on review of the manual annually and be advised of potential hazards. Personnel are required to read instructions on practices and procedures and are required to follow them. The NIH requires that all BSL-2 and above laboratories have a laboratory-specific biosafety manual, of course having a safety manual is a best practice for all laboratories, regardless of BSL level.

Macacine herpesvirus 1 (also known as B virus, Monkey B virus, or CHV-1) can represent a significant hazard to those who handle the blood, tissues, or body fluids of Old World NHP species. Safety standards, as defined in NIH Manual Chapter 3044-2, for working with NHP must be followed and require enhanced PPE that meets or exceeds the guidance established by the NIH Animal Research Advisory Committee (ARAC). This guidance is procedure-specific and a summary of these requirements can be found in the appendix of Manual Chapter 3044-2. Biosafety Level 2 practices and facilities are recommended for all activities involving the use or manipulation of tissues, blood, or body fluids from Old World nonhuman primates. Laboratories outside of an ACUC-approved NHP animal research facility using or manipulating these tissues must register with DOHS using a pathogen registration document (https://oms.ors.nih.gov) and consult a safety specialist for obtaining a special kit (BSSE kit) to address potential exposures. Enrollment in the Animal Exposure Program (AEP) is required for personnel who have direct contact with a variety of animals (including NHP), their viable tissues, body fluids, wastes or living quarters. Enrollment in "Working Safely with HIV and Other Bloodborne Pathogens" training given through DOHS is required for personnel who handle the tissues, blood, or body fluids of old-world nonhuman primates. The risks presented by handling tissues and fluids from other species should be evaluated by OMS and DOHS on a case-by-case basis.

Large-scale work with HIV or the other human retroviruses must be performed in a BSL-3 facility using Biosafety Level 3 practices and procedures. These requirements may extend to other human bloodborne pathogens. (see HIV work details on p.11) Certain laboratory procedures or other factors may require that these organisms be handled at a higher biological safety level than described above. The NIH IBC will conduct situational risk assessments on a case-by-case basis in order to determine the appropriate biological safety practices and procedures.

These practices, procedures, and facility requirements are described in the CDC/NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories, 6th ed.*, and are to be adhered to by all NIH employees working with potentially infectious material. The document is available online at: https://www.ors.od.nih.gov/sr/dohs/safety/Pages/publications.aspx Fire, emergency response, and law enforcement personnel are required to follow procedures specific for their job

categories, as outlined in *Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers*. Copies of this document are available from the NIH Biosafety Officer (301-496-2960).

B. Engineering Controls

Engineering controls must be used to eliminate or minimize worker exposure to blood or other potentially infectious materials. At the NIH these engineering controls include but are not limited to biological safety cabinets, mechanical pipetting devices, sharps disposal containers, self-sheathing needles, sharps with engineered sharps injury protections, and needleless systems.

Primary Barriers- Class II biological safety cabinets or other physical containment devices are to be used when procedures with a high potential for creating potentially infectious splashes or aerosols are conducted. Such procedures may include centrifuging, grinding, vortexing, blending, sonic disruption, transferring liquids, homogenizing, withdrawing liquids under pressure, and opening containers of infectious materials having internal pressures different from ambient pressures.

Intranasal inoculations and animal necropsies at ABSL-2 or lower (excluding ABSL-3 and ABSL-4 approved work) may be allowed to be performed on an open bench if it is determined by the NIH Biosafety Officer that conducting the procedure in a biological safety cabinet would place the employee at a significantly increased risk of percutaneous exposure to a bloodborne pathogen. In these cases, strict adherence to mucous membrane protective practices is required, which includes face masks and goggles or face shields with eye protection, as well as using appropriate gloves and protective garments.

Annual Inspections of Primary Barrier Equipment and Local Exhaust Ventilation – Annual inspection and certification of all biological safety cabinets (BSC), chemical fume hoods and other local exhaust ventilation equipment is performed by DOHS. Service calls or questions should be directed to the Technical Assistance Branch (301-496-3353), the IC Safety Specialist (301-496-2346), or online to the Primary Barrier Program.

Mechanical Pipetting Devices - Mechanical pipetting devices are to be used for all pipetting activities. Mouth pipetting is strictly prohibited. Automatic pipetting devices are readily available in the NIH Self Service Stores or through the NIH stock catalog.

Needle Handling - Sharps must be disposed of immediately or as soon as possible after use in a sharps-safe container approved for biohazardous materials and has a biohazard symbol affixed. Dispose of sharps in a sharps-safe container that is located in the immediate area. Contaminated 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 as specified in a laboratory-specific SOP. The SOP needs to include written justification for recapping or removing needles and needs to be approved by DOHS before procedures begin.

Needleless Systems - Needleless systems are devices that do not use needles for: 1) the collection of bodily fluids or withdrawal of body fluids after 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.

Plasticware- Substitution of plastic materials for glass should be considered whenever possible as it can help to greatly reduce sharps related injuries and exposure to blood and OPIM.

Sharps Containers - Puncture resistant sharps containers are to be used at all work sites where needles and syringes, Pasteur pipettes, scalpel blades, razor blades, and other sharps are used. These containers must be closable, labeled as described above in the labeling section and must be leakproof on the bottom and on the sides. During use, the container must remain upright. When no more than three-quarters filled, the containers are to be appropriately sealed and placed in a Medical Pathological Waste (MPW) box for disposal by incineration. Puncture resistant sharps containers are available from the NIH Self Service Stores and through the NIH stock catalog.

Safety Devices for Centrifuges - For low speed centrifugation of infectious materials, safety centrifuge cups are recommended. If used, the cups are to be loaded and unloaded within a BSC. High-speed centrifugation of infectious materials should be performed using a safety rotor that is loaded and unloaded within a BSC. Use of plastic is always recommended over glass for centrifugation.

Vacuum Traps and Filters- Vacuum traps and filters serve as the first barrier of protection against transfer of biological materials into building vacuum systems. Whenever a bench-line vacuum is in use in a laboratory a trap must be installed before the vacuum inlet that has an in-line filter installed between the trap and the vacuum inlet. If the in-line filter becomes wet or damaged, it must be replaced. Traps should contain appropriate disinfectant that is replaced at necessary intervals.

Devices with Engineered Sharps Injury Protections – A non-needle sharp or a needle device with engineered sharps injury protection may utilize non-needle technology or incorporate built-in safety features or mechanisms that effectively reduce the risk of exposure incidents. These devices may be used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids. Blades and cutting devices that are retractable or use extendable edge covers for safety are preferred.

C. Personal Protective Equipment

A wide selection of personnel protective equipment (PPE) in a variety of sizes is available to all NIH employees through the NIH Self Service Stores or through the NIH stock catalog. The items stocked by the NIH for use by its employees are routinely reviewed by DOHS personnel to ensure that the items stocked meet the needs of the user community. New items are added as specific safety needs are identified. All personnel are encouraged to discuss their needs for PPE with the Safety Specialist assigned to their IC. The Specialist may be reached by calling 301-496-2346. If equipment is required that is not currently available through the NIH stores or stock catalog,

it is to be ordered from the appropriate source at no cost to the employee. However, personal preference alone is not justification for special ordering of PPE.

PPE must prevent blood or OPIM from reaching work clothes, street clothes, undergarments, skin, eyes, mouth, and mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. It is the supervisor's responsibility to ensure employees are utilizing PPE effectively and properly, and in agreement with NIH policy. If the employee refuses to wear PPE to protect themselves from blood or OPIM, their supervisor must ensure that they do not work with blood or OPIM. Supervisors are responsible for providing the laundering, repairing, and replacing of PPE when needed. Laundry that is contaminated with blood or OPIM must be labeled and handled as a biohazard. The laundering facility where contaminated laundry is sent must handle laundry with universal precautions, therefore, NIH ICs must ensure that contaminated laundry is handled appropriately by laundering facilities. If contaminated items cannot be laundered, they must be disposed of as hazardous waste. All forms of PPE must be removed before leaving the laboratory or animal facility and may not be worn in any public area or outside of any building. Once PPE is removed it must be placed in a designated area for storage, laundering, or disposal. Minimum PPE and attire requirements have been established as policy as described in the NIH Manual Chapter 1340 (App. 1). Contact your IC Safety Specialist at 301-496-2346 if you have any further concerns regarding laundering of PPE.

Clothing - In any laboratory or animal care setting, the first line of defense against biological exposures is the clothing worn by the individual entering the area. Therefore, in order to provide the best protection an individual must cover themselves as much as possible with street clothing. Shorts, capris, short skirts, and any leg covering that falls above the ankle are prohibited in laboratory settings. Tights and nylons do not serve as a substitute for appropriate leg covering. Open toe shoes or any shoe that does not cover the top and sides of an individual's foot are not permitted in the laboratory or animal care setting. Minimum clothing requirements have been established as standard laboratory safety policy as described in the NIH Manual Chapter 1340 (App. 1).

Gloves - Gloves are to be worn by all employees when directly handling potentially infectious material or when in contact with contaminated surfaces. Based on individual need, the employee may choose vinyl examination, surgical latex, or nitrile gloves. Gloves are to be changed routinely and rigorous hand washing policies established in laboratory areas. Employees must inspect gloves routinely and replace them whenever they are contaminated, visibly soiled, torn, or punctured. Disposable, single use gloves shall not be washed or decontaminated for re-use. All gloves are to be discarded into the MPW stream. Hands are to be washed when gloves are changed or removed on completion of work.

Other Protective Garments - Laboratory coats, gowns, aprons, or suits, whichever is most appropriate for the particular application, are to be worn by all personnel manipulating or otherwise handling infectious or potentially infectious materials. Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can be reasonably be anticipated: necropsies, dissections, or tissue removal within an animal facility. These garments are not to be worn outside of the laboratory area. After disposable protective garments are used, discard them in the MPW stream as described in the NIH Waste Disposal Guide. Cloth

laboratory coats are not to be taken home by the employee for laundering.

Masks, Eye Protection, and Face Shields – Masks in combination with eye protection (such as 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.

Respirators - Respirators must not be used in the laboratory without prior approval of DOHS. Supervisors are not authorized to select or recommend the use of respiratory protection, regardless of the type. Call your IC Safety Specialist (301-496-2346) if you feel respiratory protection is required. 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 NIH Respiratory Protection Program. Each IC will supply and maintain the recommended respiratory protective device.

HIV and HBV Research Laboratories and Production Facilities

HIV and HBV Specific Procedures

Waste must be autoclaved or decontaminated before transportation. Only needle-locking syringes or disposable syringes and needles may be used. All syringes and needles must be placed into a sharp-safe container and autoclaved before disposal in an MPW box.

Vacuum lines must have a liquid disinfectant trap and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency. The laboratory in which vacuum lines are used must develop a standard operating procedure and schedule for inspecting and maintaining the vacuum line on a regular basis.

Engineering Controls - In HIV and HBV research production facilities, a clothes change room must be included in the design.

The NIH may have laboratories engaged in the culture, concentration, experimentation and manipulation of HIV and HBV. Such laboratories must follow the same pathogen registration procedure described above. At NIH, a laboratory is considered a production facility when greater than 10 (ten) liters of HIV are produced. Most HIV and HBV may be handled at BSL 2/3 but certain high titer HIVs, SIVs, SHIVs, and HTLVs must be handled in a BSL-3 facility using BSL-3 practices and containment equipment. The determination for the handling of these materials may only be made by the IBC and is not up to the discretion of the PI, branch chief or other individual outside of the IBC.

The IBC will conduct a risk assessment based on the organism involved and the methodology used. The laboratory will be required to follow the appropriate level of biological containment practices and procedures as determined by the NIH Biological Safety Officer or the NIH IBC.

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

Occupationally acquired HBV - Hepatitis B is the leading occupationally acquired illness

among health care workers, affecting approximately 15,000 workers annually. HBV, formerly known as "serum hepatitis," is one of several viruses that attack the liver producing swelling, tenderness, and liver damage. HBV is spread primarily through contact with blood and body fluids that contain blood.

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, and 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 for NIH employees is considered to be high if their jobs entail frequent contact with human blood and body fluids. NIH employees can protect themselves from occupationally acquired HBV infection by practicing Biosafety Level 2 practices (equivalent to Universal precautions in a clinical setting) and by becoming immunized against HBV.

HBV Vaccine - A recombinant HBV vaccine is available, free of charge, to all NIH employees who may come in contact with blood and body fluids during the performance of their duties. To receive the vaccine, call the OMS at 301-496-4411. It is strongly recommended that eligible employees accept the vaccine. Any unvaccinated personnel should discuss and reach alternate accommodation with their supervisor to avoid potential risks of exposure.

The recombinant HBV vaccine does not contain any human blood products; it is both safe and effective. Clinical studies have shown that over 90% of healthy adults administered the vaccine-developed antibody 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. Eligible employees who decline to accept the vaccination must sign the following statement:

"I understand that due to my occupational exposure to blood or other potentially infectious material 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."

Further information on hepatitis B and HBV vaccine can be given by OMS (301-496-4411).

Hepatitis C Virus (HCV)

Occupationally acquired HCV - HCV is a leading cause of chronic liver disease and is the leading reason for liver transplant in the United States. Although the potential for HCV

transmission associated with percutaneous injury is low, varying between 3 and 10% depending on the study, the risk of infection appears to correlate with the severity of the wound. It is estimated that greater than 85% of people who acquire an HCV infection will become chronically infected, and greater than 70% of HCV-infected people will have chronically elevated levels of liver enzymes. About 5% to 10% of infections will not be detected unless polymerase chain reaction is used to detect HCV RNA. Cirrhosis and primary hepatocellular carcinoma may result from chronic HCV.

Symptoms of HCV - HCV infection has two phases. The first, experienced by 75% of infected people, is a flu-like illness that includes headache, loss of appetite, nausea and vomiting, and fatigue. Eventually, 20-30% of infected people will progress to the second phase of HCV infection, which includes the development of overt signs and symptoms such as jaundice, clay-colored stools**,** and dark brown urine.

Risk of HCV Infection - Employees who must routinely handle human blood and body fluids are considered to be at risk for HCV infection. The risk of occupationally acquired infection may be reduced through the use of Biosafety Level 2 practices and procedures (equivalent to Universal Precautions in a clinical setting) and appropriate mucous membrane and eye protection.

HCV Vaccine - There is currently no vaccine available to prevent infection with HCV, and immune globulin is not recommended for post-exposure prophylaxis however medications may be available for treatment in cases of potential exposure. It is therefore very important to use PPE, and to be especially careful when handling sharps. It is also very important to report any potential exposures to OMS (301-496-4411) immediately.

Exposure Reporting Responsibilities – The ultimate responsibility for reporting exposures, spills, and other biological hazards rests with the Principle Investigators, supervisors, and the NIH employees. Such exposures and hazards need to be reported to supervisors, principle investigators, DOHS, and OMS. The following areas serve as examples:

- The ultimate responsibility for reporting exposure to a potentially infectious material rests with the NIH employee who has been exposed.
- Notifying employees of the presence of potentially infectious materials in any workplace is the responsibility of the Principle Investigator or supervisor in charge of the work area.
- Notifying emergency services, DOHS, and OMS of spills is the responsibility of all NIH employees.
- Notification of exposures, spills, and other hazards must be done immediately upon becoming aware of the situation.

Other Potentially Infectious Materials (OPIM)

Many pathogens at the NIH are infectious through bloodborne transmission. Refer to the BMBL, 6th Edition, for basic guidelines for material specific precautions to take against and minimize the chance of exposure. Ensure that all potentially infectious materials are registered with the IBC. Any research work with human blood and body fluids or OPIM must be registered with the NIH IBC as described in the Exposure Determination section of the Exposure Control Plan. OSHA

Describes OPIM as:

(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 or cells from experimental animals infected with HIV, HBV or other bloodbourne pathogens

Regarding cell lines, because it is not possible to test every cell line for every possible virus or ever make the claim any particular cell line is pathogen free, we require all human cell lines be afforded the same level of biosafety consideration as a line known to carry HIV. We require registration for research work with all human cell lines, particularly any lines being used in animal models. Additionally, individuals should not utilize their own cells to generate induced pluripotent stem cells (iPSC) or work with such as generated from their own cells due to the risk of auto-inoculation of potentially cancerous cells. If you are not sure if a material needs to be registered, contact your IC Safety Specialist at 301-496-2346 for help in determining correct precautions to take and to determine whether registration with the NIH IBC is required. The Biosafety Officer (BSO) can also address immediate concerns.

Surveillance Programs

The objective of our Occupational Medical Service is to provide updated epidemiological and safety information on avoidance of potential worksite exposures to biological materials or OPIM and to instruct personnel on what to do in the event of an overt exposure.

Animal Exposure Program - The Animal Exposure Program (AEP) is a mandatory program designed to monitor and support the health of personnel who have direct contact with a variety of animals, their viable tissues, body fluids, wastes or living quarters. NIH employees are eligible for AEP if they participate in at least one of the following activities: 1) direct care of animals or housing; 2) direct contact with animals (live or dead), their tissues, body fluids, or wastes; or, 3) work with a zoonotic disease agent. **All employees must report bites and scratches promptly to OMS.** Further information on the AEP may be obtained by calling OMS (301-496-4411).

Emergency Steps to Take in the Event of a Potential Exposure - If an employee sustains a potential exposure to HIV or other bloodborne pathogen, immediate first aid should be initiated before leaving the worksite. Contaminated skin should be thoroughly washed for fifteen minutes using soap and copious amounts of water. Contaminated eyes and mucous membranes should be irrigated for 15 minutes using normal saline or water. The employee must notify their supervisor, if he or she is immediately available, and report to OMS (Building 10, Room 6C306) within one hour of the exposure. If emergency transport is needed, call 911 (on campus). When OMS is closed, contact the Clinical Center Operator (301-496-1211) to notify an OMS physician. A poster entitled *3 Emergency Steps to Take in the Event of a Potential Bloodborne Pathogen Exposure* ('1-2-3 poster') is to be placed prominently in all work areas where there is a potential for exposure to human blood, body fluids, human retroviruses, or other potentially infectious material. Copies of this poster may be obtained by contacting your IC Safety Specialist (301-496-2346) or online (1-2-3 Poster).

Post-Exposure Evaluation and Follow-up - Post-exposure evaluation and follow-up for NIH employees is provided by OMS. Employee counseling is provided free of charge by the OMS.

Emergency Care - 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 physicians for follow-up.

Post-Exposure Incident Review - In the event an employee sustains a potential exposure to HIV or other bloodborne pathogen, the IC Safety and Health Specialist as well as the employee's supervisor will review the incident. As part of the incident review, a sharps injury log will be maintained for the recording of percutaneous injuries and mucous membrane exposures. The information in the sharps injury log shall be recorded and maintained in such a manner as to protect the confidentiality of the injured employee. The log contains information on the type and brand of device involved in the incident; the IC and work area where the incident occurred; and an explanation of how the incident occurred. The log will be maintained by DOHS and used to gather information that may aid in the implementation of safer technologies.

All work-related needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material (as defined by 29 CFR 1910.1030) will be entered in the OSHA 300 Log as an injury using the OSHA 301 Injury and Illness Incident Report. All required records are kept for a minimum of five (5) years following the end of the calendar year that the records cover.

Related to working with animals: Waste and Anesthetic Gas (WAG) Surveillance Program- DOHS has established a Waste and Anesthetic Gas (WAG) Surveillance Program to:

1. Identify and quantify occupational exposure levels (through surveys and site assessments) to the anesthetic gases used at the NIH
2. Provide information and recommendations for engineering controls and work practices that are effective in minimizing exposures to anesthetic gases

For more information on the WAG program, contact the Technical Assistance Branch in DOHS at (301) 496-3353.

Communication of Hazards to Employees

Employees must be notified of the presence of potentially infectious materials in any workspace. Laboratories and other work areas handling human blood and body fluids, any human pathogens, or unfixed Old World NHP blood and tissues must be posted with an NIH-approved biohazard sign. Work areas are posted by DOHS personnel upon completion of a survey and certification of the area at the appropriate biosafety level. Any special requirements (e.g., immunizations, personnel protective equipment) required for entry to a workspace will be designated on the biohazard sign affixed to the entry door.

All infectious waste transferred to incinerators is placed in a MPW box ("burn box") imprinted with the international biohazard warning symbol. For BSL-3 practices all waste must be chemically deactivated, chemically decontaminated, or autoclaved before being placed in a MPW box.

All containers used to transport infectious materials between laboratories or buildings will be labeled with stickers carrying the international biohazard-warning symbol. Any item used to store human or old-world NHP tissues, blood, or OPIM such as refrigerators, freezers, and incubators must have a biohazard label affixed in a highly visible area. These stickers are available in the Self- Service Store.

Training and Education

Training for employees, in compliance with the OSHA Bloodborne Pathogen Standard, is provided on a monthly basis for all employees. PIs and supervisors are responsible for assuring that all employees under their direction who may be potentially exposed to a bloodborne pathogen attend one of these sessions prior to handling infectious materials and receive refresher training on an annual basis. Consult the DOHS website (https://www.safetytraining.nih.gov/) or call the DOHS office (301-496-2960) for current course schedules. PIs and supervisors are responsible for job-specific safety training and must document that employees selected for jobs involving manipulation of infectious materials have been adequately trained to perform these tasks.

Fire, emergency response personnel, and NIH law enforcement officers receive training consistent with the information provided in the HHS publication entitled *Guidelines for Prevention of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers*. These guidelines were developed in response to P.L. 1000-607 *The Health Omnibus Programs Extension Act of 1988*, portions of which are specific for personnel working in the emergency response or law enforcement arenas. Training is provided upon employment and updated annually as required.

Bloodborne Pathogen and other DOHS safety training courses available: For details contact DOHS at 301-496-2960.

Working Safely with HIV and Other Bloodborne Pathogens Laboratory Safety
at the National Institutes of Health
Bloodborne Pathogen Training for NIH Fire and Emergency Response Personnel Bloodborne Pathogen Training for NIH Law Enforcement Officers
Bloodborne Pathogen Refresher Training for Laboratory Personnel Biosafety
Level 3 Training Lecture
Biosafety Level 3 Training Hands-On Shipping
Biological Materials